HEPATITIS B VACCINE: HELPING OR HURTING PUBLIC HEALTH?

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

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HEPATITIS B VACCINE: HELPING OR HURTING PUBLIC HEALTH?

TUESDAY, MAY 18, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY,
AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2247, Rayburn House Office Building, Hon. John L. Mica (chairman of the subcommittee) presiding.

Present: Representatives Mica, Towns, Tierney, and Waxman.

Staff present: Sharon Pinkerton, deputy staff director; Amy Davenport, clerk; Cherri Branson, minority counsel; and Jean Gosa, minority staff assistant.

Mr. MICA. Good morning, I would like to call this meeting of the Subcommittee on Criminal Justice, Drug Policy, and Human Resources to order.

This morning, the topic of hearing is "Hepatitis B Vaccine: Helping or Hurting Public Health?" I will begin this morning's proceeding by reading my opening statement, then I will yield to the minority for their opening comments and other Members who may join us. Finally we will proceed to our four panels this morning, and I am sure into this afternoon.

Public health, including vaccine safety, is critically important to our subcommittee. Today we are exercising our oversight responsibility for the Department of Health and Human Services, and we are committed to ensuring that our national immunization policies and programs are functioning properly.

The Centers for Disease Control and Prevention, the CDC, and the Food and Drug Administration are Federal agencies primarily responsible for immunization policy and safety. They will be sharing their expertise with us later in this hearing.

There is no doubt that immunizations have greatly improved public health in our country. Small pox has been eradicated, and cases of polio, tetanus, and diphtheria are today very rare. These are great victories for our public health system.

Unfortunately, however, the history of immunization shows that sometimes vaccinations do injure a child or an individual rather than inoculating them. That is why Congress created the Vaccine Injury Compensation Program in 1986 to compensate those who have been harmed by a vaccine.

My colleague, the ranking member of our full committee, the gentleman from California, Mr. Waxman, who I hope will be join-

ing us shortly, and my brother Dan Mica, who was then a Member of Congress from Florida, worked to successfully enact that law.

Oversight of that law and program, I believe, is a very important congressional responsibility. This is the first oversight hearing on that law held in 10 years. The purpose of which is not only to protect vaccine manufacturers, but also to compensate individuals injured from inoculation by a vaccine. I do have some concerns whether the compensation fund is working in the way Congress intended, and we will discuss that today and possibly hold additional hearings.

The Department of Health and Human Services has issued new rules making it harder to receive compensation, so that while there is over $1 billion in the fund, only a fraction of that was awarded last year. The vaccine experience in the early 1980's also demonstrates that when a pattern of injuries from a vaccine emerges, the vaccine can be made safer.

The crisis in public confidence in diphtheria, tetanus, and pertussis, DPT as it is commonly known, led to creating the compensation law and also resulted in the creation of a safer vaccine. Today what is termed the ''whole cell vaccine'' that caused the controversy is coming off the market, and has been replaced by a safer vaccine called ''acellular vaccine.''

Today, we have convened individuals from a variety of government, academic, professional, and citizens groups in an effort to provide a structured opportunity for Members of this subcommittee to ask questions about the Federal Government's hepatitis B vaccine policy and its impact on our public health.

I want to make very clear at the outset that the purpose of this hearing is not to scare parents away from immunizing their children. That should not be the result of today's hearing. The purpose of this hearing is to examine the effectiveness of the 1986 law, also to learn more about how our Federal agencies are administering immunization policy and monitoring and analyzing the safety of the hepatitis B vaccine, and finally to review evidence of adverse reactions to the vaccine.

The hepatitis B virus is certainly a very serious disease. We will hear today from witnesses who have experienced the terrible effects of this disease. In 1996, the CDC reported 10,637 new cases of hepatitis B, 279 cases which affected individuals below the age of 14. The CDC estimates that 4,000 to 5,000 people each year die from hepatitis B-related liver disease.

To combat this disease, the CDC issued guidelines in 1991 recommending that every infant receive the hepatitis B vaccine. In 1995 the CDC recommended the routine vaccination of teenagers. The FDA first licensed a plasma-derived hepatitis B vaccine in 1981. In 1986, the FDA licensed the first recombinant hepatitis B vaccine, meaning the vaccine is the first genetically engineered one.

Based on CDC recommendations, 42 States mandate that children be vaccinated before entering kindergarten; 20 million children a year now receive some type of required vaccine. Almost 90 percent of all children in this country are now immunized.

When a parent takes their child in for a vaccine, they are supposed to be given an information sheet outlining the risks and benefits of the vaccine. While almost all of the States mandating child-

hood vaccinations allow exemptions, the information sheet does not tell parents that these exemptions exist.

Recent news reports have questioned the safety of the hepatitis B vaccine, and have also suggested an association between the vaccine and multiple sclerosis and other autoimmune disorders.

I would like to point out a report I have seen from New Hampshire. The 48 reported adverse reactions to the vaccine in children aged 1 to 10 in recent years were 16 times greater than the cases of the disease. There were only three cases of the disease.

It was reported that there were four times as many child deaths, 11, as there were cases of the disease. If this is true, I find the information quite shocking.

We will hear more about these statistics later in the hearing from some of the researchers that were involved in analyzing this particular series of cases.

Is it possible that the preventive measure for the disease is riskier than the disease itself? We must ask ourselves that question. But our job today is not to prove whether or not this vaccine causes illnesses or death. Instead, we have created a forum for asking questions about what scientific evidence does exist and whether further studies should be completed.

Specifically, I would like this hearing today to examine some of the following issues. First, what is being done to study the adverse reactions reported in the Vaccine Adverse Event Reporting System?

Second, do the benefits of administering the vaccine to infants outweigh the risks?

Third, what process does the CDC employ to make a recommendation for a vaccine? What role do pharmaceutical companies play in that process, and do conflicts of interest exist?

Fourth, what disclosure is required before the vaccine is given, and is that disclosure adequate?

With this outline in mind, I would like to now recognize the ranking member of our full committee. As I mentioned before, he was one of the individuals very much involved in passage of the 1986 law. I know he worked with my brother Dan on this matter, and was very instrumental in reviewing this whole matter of vaccinations, adverse reactions, and compensation. So I am delighted that he has joined us, and I would like to recognize our ranking member, the gentleman from California, Mr. Waxman, for a statement.

Mr. WAXMAN. Thank you very much, Mr. Chairman. I appreciate your recognizing me to make this opening statement and I want to thank you for the accommodations that you have made in adding additional witnesses to this hearing.

This hearing today touches on an extremely important public health issue. Vaccination is an essential weapon against infectious disease, and I think it is important that we pay attention to how well we are succeeding in our fight against infectious disease.

While childhood diseases continue to spread death, disability, and misery through other parts of the world, the United States has made tremendous progress against polio, diphtheria, whooping cough, and other diseases.

Without vaccination, our population would be vulnerable to devastating outbreaks of these diseases. We cannot be complacent

about our success. Unlike our parents and grandparents, we are not terrorized every year by the threat of polio and whooping cough epidemics.

Perhaps that makes it easier to doubt the value of vaccines and to focus on their potential risk, but if children are discouraged and parents frightened from the vaccines and do not take these important vaccines, we will quickly become vulnerable again to infectious diseases.

No one doubts that there are adverse reactions to some vaccines. They happen. Children and adults suffer disease or disability as a result. That is why I sponsored the National Childhood Vaccine Injury Act of 1986 which established the compensation program. This program relies upon the best available science and medicine to provide an alternative to litigation for individuals who suffered the specific vaccine-related injuries.

Today, we must continue to rely upon what science tells us about the benefit and risks of vaccines. We know that hepatitis B kills 4,000 to 5,000 people in the United States every year. We know that at least 25,000 children are infected with hepatitis B each year, and we know hepatitis B is a silent killer that waits decades before destroying livers and ending lives.

Everything we know about the hepatitis B vaccine indicates that its benefits far outweigh its risks. That being said, we must naturally remain vigilant and continue epidemiological research into potential side effects of the vaccine.

Today, we are going to hear compelling stories from both sides of the controversy over hepatitis B vaccines. We will hear from families who have suffered adverse reactions to the vaccines or health problems they believe are linked to the vaccine. We will hear from the families of those who have experienced hepatitis B, the social stigma surrounding it, and the fears engendered by this highly infectious disease, and I am sympathetic to all of our witnesses and look forward to their testimony.

Mr. Chairman, I wish to submit for the record, along with this statement, letters and statements supporting hepatitis B vaccine from leading medical and patient organizations, including the World Health Organization, the American Medical Association, the American Academy of Pediatrics, the American Liver Foundation, Hepatitis Foundation, and the National Multiple Sclerosis Society.

I think it is important to have in our record what these public health groups say about this vaccine and their support of the efforts to continue the vaccination program.

I am pleased that we have Congressman Moakley, who will tell us from his own experience about the hepatitis disease; and I welcome all of the other witnesses and look forward to their testimony.

Mr. MICA. I thank the gentleman. Without objection, the items that he mentioned will be made part of the record.

[The prepared statement of Hon. Henry A. Waxman and the information referred to follow:]

Statement of Congressman Henry A. Waxman
Government Reform Subcommittee on Criminal
Justice, Drug Policy & Human Resources
Hearing on "Hepatitis B Vaccine:
Is The Vaccine Helping or Hurting Public Health?"

Tuesday, May 18, 1999
2247 Rayburn HOB

Mr. Chairman, today's hearing touches upon an extremely important public health issue. Vaccination is an essential weapon against infectious disease, and I am pleased this hearing calls attention to it. I also want to thank you for your consideration in agreeing to the appearance of many of our witnesses today. You have been very generous and very fair, and I appreciate it.

While childhood diseases continue to spread death, disability and misery through other parts of the world, the United States has made tremendous progress against polio, diphtheria, whooping cough and other diseases. Without vaccination, our population would be vulnerable to devastating outbreaks of these diseases.

We cannot become complacent about our success. Unlike our parents and grandparents, we aren't terrorized every year by the threat of polio and whooping cough epidemics. Perhaps that makes it easier to doubt the value of vaccines and to focus on their potential risks. But if children are discouraged and parents frightened about vaccines, we will quickly become vulnerable again to infectious disease.

No one doubts that there are adverse reactions to vaccines. They happen, and children and adults suffer disease or disability as a result. That is why I sponsored the National Childhood Vaccine Injury Act of 1986, which established the National Vaccine Injury Compensation Program. This program relies upon the best available science and medicine to provide an alternative to litigation for individuals who suffered specific vaccine-related injuries.

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Today we will hear many compelling stories from both sides of the controversy over hepatitis B vaccines. We will hear from families who have suffered either adverse reactions to the vaccine or health problems they believe are linked to the vaccine. We will also hear from the families of those who have experienced hepatitis B, the social stigma surrounding it, and the fears engendered by this highly infectious disease. I am sympathetic to all of our witnesses and look forward to their testimony.

In conclusion, Mr. Chairman, I wish to submit for the record statements and letters supporting hepatitis B vaccination from leading medical and patient organizations, including the World Health Organization, American Medical Association, American Academy of Pediatrics, American Liver Foundation, Hepatitis Foundation and National Multiple Sclerosis Society.

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Contact: Carrie Schum, 202-973-3645
Lisa Grossman, 212-598-3694

FOR IMMEDIATE RELEASE

HEPATITIS B VACCINE USE SUPPORTED
Vaccine Safe and Prevents Potentially Deadly Infection

Washington, D.C., May 18: A coalition of groups dedicated to the protection of the health of children and families today voiced their support for use of the hepatitis B vaccine. Their statement was made in response to a Congressional hearing held today by the House of Representatives Subcommittee on Criminal Justice, Drug Policy, and Human Resources, a subcommittee of the Committee on Government Reform.

The groups include the Vaccine Initiative (a project of the Infectious Diseases Society of America and the Pediatric Infectious Diseases Society), PKIDs (Parents of Kids with Infectious Diseases), the American Liver Foundation, the Hepatitis Foundation International (HFI), the Albert B. Sabin Vaccine Institute, and the Immunization Action Coalition (IAC). A statement endorsed by the groups appears below.

"Because of the risks of serious, even fatal, liver disease caused by hepatitis B infection, and the proven safety record of the vaccine, we continue to support the use of the hepatitis B vaccine for infants, children and adults. One out of 20 Americans will become infected with hepatitis B during their lifetime. Before the vaccine was widely used, over 300,000 infections occurred each year and about 5,000 people died from

hepatitis B complications. Children who become infected before the age of six have a much higher chance of developing chronic liver diseases – including liver cancer – than those who get hepatitis B later in life. Most people who die from hepatitis B in their 30s and 40s were infected as children."

"The hepatitis B vaccine is extremely safe and is our best protection against this disease. More than 500 million doses of the vaccine have been given worldwide. The World Health Organization recently reviewed all available research on the issue and concluded that, other than extremely rare allergic manifestations, the vaccine does not cause serious adverse effects or chronic illness. On the contrary, use of the hepatitis B vaccine has proven to reduce the incidence of and serious complications from the disease in countries where immunization programs exist."

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1997, 72, 149-156 No. 21

World Health Organization, Geneva Organisation mondiale de la Santé, Genève

W E R
R E H

23 MAY 1997 • 72nd YEAR 72e ANNÉE • 23 MAI 1997

Expanded Programme on Immunization (EPI)

Lack of evidence that hepatitis B vaccine causes multiple sclerosis

During the past year, articles in the French popular press and television programmes have raised concerns among the French public that hepatitis B (HB) immunization may be linked to new cases or flare-ups of multiple sclerosis (MS) or other demyelinating diseases. These concerns have led to significant reductions in the uptake of HB vaccine in France, and misinformation on this subject may spread to other countries. Since the scientific data do not support the idea that HB vaccine causes or exacerbates MS, and since universal childhood and/or adolescent immunization with HB vaccine is now a policy in 85 countries, this has the potential to cause significant damage to important public health programmes.

HB immunization of health care workers, which has been recommended in most countries, became mandatory in France in 1991, ensuring HB immunization of hundreds of thousands of young and middle-aged adults, many of them women who are in the age group at the highest risk of MS. More recently, one neurologist publicized the fact that he had seen several cases of MS or demyelinating disease in women who had received HB vaccine. This was picked up by anti-vaccination groups, and a number of patients with MS now claim that their disease was caused or exacerbated by HB vaccine.

The cases of MS which occur following HB immunization do not themselves constitute evidence of an association between immunization and disease beyond pure coincidence. Because most MS occurs in individuals who have never received HB vaccine, and because there are no unique laboratory or clinical features linking MS to HB vaccine, epidemiological studies are needed to assess

Programme élargi de vaccination (PEV)

Manque de preuves de l'existence d'un lien entre la vaccination contre l'hépatite B et la sclérose en plaques

Au cours de l'année écoulée, la presse populaire et la télévision françaises ont propagé des rumeurs faisant état d'un lien possible entre la vaccination contre l'hépatite B et de nouveaux cas ou des poussées de sclérose en plaques ou d'autres maladies démyélinisantes. A la suite de ces rumeurs, on a enregistré un recul considérable de la vaccination contre l'hépatite B en France et cette désinformation pourrait se répandre dans d'autres pays. Bien qu'il n'existe aucunes données scientifiques à l'appui de la thèse selon laquelle la vaccination contre l'hépatite B serait à l'origine de nouveaux cas ou de poussées de sclérose en plaques, et étant donné que la vaccination universelle des enfants et des adolescents contre l'hépatite B est maintenant pratiquée dans 85 pays, il est probable que ces rumeurs vont causer un tort considérable à de grands programmes de santé publique.

La vaccination du personnel médical contre l'hépatite B, recommandée dans la plupart des pays, est devenue obligatoire en France en 1991 et a permis de vacciner des centaines de milliers d'adultes jeunes ou d'âge moyen, dont de nombreuses femmes appartenant au groupe d'âge le plus exposé au risque de sclérose en plaques. Plus récemment, un neurologue ayant révélé qu'il avait observé plusieurs cas de sclérose en plaques ou de maladie démyélinisante chez des femmes qui avaient été vaccinées contre l'hépatite B, ses déclarations ont été montées en épingle par des milieux hostiles à la vaccination et plusieurs patients atteints de sclérose en plaques affirment maintenant que leur maladie a été provoquée ou aggravée par la vaccination contre l'hépatite B.

L'apparition de cas de sclérose en plaques à la suite de la vaccination contre l'hépatite B ne constitue pas en soi la preuve d'une association entre la vaccination et la maladie relevant d'autre chose que d'une pure coïncidence. Etant donné que la plupart des cas de sclérose en plaques surviennent chez des sujets qui n'ont jamais été vaccinés contre l'hépatite B, et qu'aucunes données de laboratoire ou cliniques ne permettent d'établir un lien entre la

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whether observed reports are causal or coincidental. Epidemiological evidence for a causal association requires showing that MS or exacerbations of MS occur more frequently in HB vaccine recipients than in a comparable (age, sex and ethnicity matched) population of unvaccinated individuals. This has never been demonstrated. In fact, in all studies which have examined this issue, no increase in the incidence of MS or MS exacerbations have been found in recipients of HB vaccine.

MS is a disease of the central nervous system (CNS) characterized by the destruction of the myelin sheath surrounding neurons. Clinically, MS is usually defined as 2 separate episodes of disease with evidence of at least 2 separate CNS lesions, and it may take years or even decades to diagnose MS in a particular patient. Clinical episodes may occur as optic neuritis, transverse myelitis, weakness, or sensory abnormalities. MS is a progressive, often fluctuating disease with exacerbations and remissions over many decades usually resulting in permanent disability and sometimes death. The pathological processes underlying MS begin many years or decades before symptoms occur.

The cause of MS is unknown. The most widely accepted hypothesis is that MS occurs in patients with a genetic susceptibility, and that some environmental factor or factors "trigger" clinical exacerbations. The genetic predisposition is well supported by many studies showing an increased risk of MS in family members of cases, identical twins, certain ethnic populations such as northern Europeans, and an association of MS with certain HLA subtypes.

Many neurologists and immunologists believe that MS is an autoimmune disease whereby the immune system attacks myelin. One hypothesis of how this may occur is called "molecular mimicry", where an immune system attack on myelin is induced by a foreign antigen which has an immunogenic region resembling human myelin. One investigator found an amino acid sequence on the hepatitis B DNA polymerase molecule similar to a sequence in rabbit myelin. However, it is unlikely that this has clinical relevance, because rabbit and human myelin differ in this region, HB infection is not associated with MS, and, most relevant to this discussion, HB vaccines do not contain any DNA polymerase.

The environmental factors "triggering" exacerbations are unknown. Dozens of factors have been proposed (but never proven) including infectious diseases (at least 17 viruses have been suggested), vaccines, climate, latitude, stress, trauma, pregnancy, dogs as pets, occupational exposures, contaminated food, and metals. An association between MS exacerbations and infectious diseases has been suggested, but there is little evidence to support this. Aside from hypotheses and individual case reports, there is no actual evidence supporting a causal association between MS exacerbations and any vaccine.

(1) There is no evidence of an association between hepatitis B virus (HBV) infection and MS or other demyelinating diseases. Globally, there are 350 million chronically infected carriers of HBV and 2 000 million persons

sclérose en plaques et le vaccin contre l'hépatite B, des études épidémiologiques sont nécessaires afin d'évaluer si les cas observés relèvent ou non d'une coïncidence. Pour apporter la preuve épidémiologique d'une association causale, il faut montrer que les cas de sclérose en plaques ou les poussées de la maladie sont plus fréquents chez les personnes vaccinées contre l'hépatite B que chez les personnes non vaccinées (de même âge, sexe et ethnie). Cela n'a jamais été démontré. Qui plus est, dans toutes les études consacrées à cette question, on n'a constaté aucune augmentation de l'incidence de la sclérose en plaques ou aggravation de la maladie chez les personnes vaccinées contre l'hépatite B.

La sclérose en plaques est une maladie du système nerveux central (SNC) caractérisée par la destruction de la gaine myélinique qui entoure les neurones. D'un point de vue clinique, la sclérose en plaques est généralement décrite comme une maladie qui se présente sous la forme de 2 épisodes distincts, avec au moins 2 lésions distinctes du SNC et qui peut n'être diagnostiquée chez un patient qu'au bout de plusieurs années, voire de dizaines d'années. Les signes cliniques habituels sont la névrite optique, la myélite transverse, une grande faiblesse ou des anomalies sensorielles. L'évolution de la sclérose en plaques est progressive, souvent irrégulière, avec une alternance de poussées et de rémissions; elle peut s'étendre sur plusieurs dizaines d'années et aboutit généralement à une incapacité permanente et, dans certains cas, à la mort. Le processus pathologique qui est à l'origine de la sclérose en plaques débute plusieurs années ou plusieurs dizaines d'années avant l'apparition des symptômes.

On ne connaît pas la cause de la sclérose en plaques. L'hypothèse la plus communément admise est que cette maladie frappe les patients ayant une prédisposition génétique et que certains facteurs environnementaux peuvent favoriser les poussées de la maladie. La thèse de la prédisposition génétique est amplement confortée par de nombreuses études qui révèlent l'existence d'un risque accru dans les familles où il existe déjà un cas de sclérose en plaques, chez les vrais jumeaux, dans certaines populations ethniques telles que les Européens du Nord et en cas d'association avec certains sous-types de HLA.

De nombreux neurologues et immunologues considèrent que la sclérose en plaques est une maladie auto-immune, à savoir que le système immunitaire attaque la myéline. L'une des explications avancées de ce phénomène est le «mimétisme moléculaire», en vertu duquel l'attaque de la myéline par le système immunitaire est provoquée par un antigène étranger possédant une région immunogénique semblable à la myéline humaine. Un chercheur a trouvé dans la polymérase ADN de l'hépatite B une séquence d'acide aminé identique à celle de la myéline du lapin. Toutefois, il est peu probable que cela soit pertinent sur le plan clinique car la myéline du lapin et celle de l'homme diffèrent dans cette région, l'infection par l'hépatite B n'est pas associée à la sclérose en plaques et, avant tout, les vaccins contre l'hépatite B ne contiennent pas de polymérase ADN.

Les facteurs environnementaux favorisant les poussées de sclérose en plaques n'ont pas été découverts. Parmi les dizaines de facteurs avancés (mais jamais prouvés) figurent les maladies infectieuses (17 virus au moins ont été mis en cause), les vaccins, le climat, la latitude, le stress, les traumatismes, la grossesse, la cohabitation avec un chien, les risques professionnels, les aliments contaminés et les métaux. On a évoqué la possibilité d'une association entre les poussées de sclérose en plaques et les maladies infectieuses, mais on ne possède guère d'éléments à ce sujet. En dehors des hypothèses et des études de cas individuels, il n'existe aucune preuve réelle d'un rapport quelconque entre des poussées de sclérose en plaques et des vaccins, quels qu'il soient.

1) Il n'existe aucune preuve d'une association entre l'infection par le virus de l'hépatite B (VHB) et la sclérose en plaques ou une autre maladie démyélinisante. On dénombre dans le monde 350 millions de porteurs chroniques du VHB et 2 milliards de

have evidence of past infection. The geographical incidence and prevalence of HB are the opposite of those for MS, Scandinavia and Northern Europe having the highest rates of MS and the lowest rates for HBV infection, while sub-Saharan Africa and Asia have the lowest rates of MS and the highest rates of HBV. If the virus does not cause MS, it is unlikely that the vaccine, which is the surface coat of the virus, could do so.

(2) Published and unpublished studies looking for an increased rate of MS, exacerbations of MS, or other demyelinating disease in recipients of HB vaccines have found no such increase. Among the more than 550 million individuals who have been immunized with HB vaccines since 1982, no evidence of a causal association with MS or other demyelinating diseases has ever been demonstrated.

Post-marketing surveillance (reports of adverse events following licensure of a vaccine) data from the United States of America were examined in 1987 and 1996, and from Canada in 1992. No increased rate of MS or other neurological diseases was found compared to background. The sensitivity of passive reporting of adverse events, however, is low, and population-based controlled studies are currently planned or under way.

Studies in Alaska, United States, following more than 43 000 HB vaccine recipients, found no increase in any neurological diseases. Native Alaskans have very low rates of MS and may have low genetic susceptibility, but the vaccine clearly did not induce neurological disease.

Post-marketing surveillance studies conducted by Merck and Company, Pasteur-Mérieux-Connaught, and SmithKline Beecham Biologicals in France and other countries found no evidence of an increased rate of MS or any demyelinating disease in HB vaccine recipients.

(3) Analysis of the reported cases in France

The results of an official pharmacovigilance study on the neurological tolerance of all HB vaccines available in France (Engerix B, GenHevac and HB-VAX DNA) were presented to the National Commission of Pharmacovigilance in December 1994 and in December 1996. The data showed the following:

Over 60 million doses of HB vaccine had been distributed in France between January 1989 and December 1996 and a total of 106 case reports describing CNS and peripheral nervous system demyelinating diseases had been notified in vaccine recipients. The notification rate of demyelinating diseases in temporal association with HB vaccination was 1.8 cases per million doses or approximately 0.6 cases per 100 000 vaccinees. The latter rate is significantly lower than the expected incidence of demyelinating diseases in the same population which, for multiple sclerosis alone, is 1 to 3 cases per 100 000 persons.

The epidemiological patterns of the notified cases were similar to those expected in a similar non-vaccinated population in terms of age distribution, gender ratio, and the nature and severity of neurological symptoms. The time between vaccination and occurrence of neurological symptoms was random.

personnes présentant des signes d'une infection passée. L'incidence géographique et la prévalence de l'hépatite B sont à l'opposé de celles de la sclérose en plaques puisque les taux les plus élevés de cette maladie et les taux les plus faibles d'infection à VHB se rencontrent en Scandinavie et dans l'Europe septentrionale alors que l'Afrique subsaharienne et l'Asie ont les taux les plus faibles de sclérose en plaques et les taux les plus élevés d'infection à VHB. Si le virus n'est pas responsable de la sclérose en plaques, il est fort peu probable qu'il en soit ainsi du vaccin, qui est préparé à partir de l'enveloppe du virus.

2) Diverses études, publiées ou non, cherchant à déterminer si l'on observe une augmentation des nouveaux cas ou des poussées de sclérose en plaques ou des cas d'autres maladies démyélinisantes chez les personnes vaccinées contre l'hépatite B, n'ont pas été concluantes. Parmi les plus de 550 millions de personnes qui ont été vaccinées contre l'hépatite B depuis 1982, aucun cas d'association avec la sclérose en plaques ou une autre maladie démyélinisante n'a été constaté.

Des études des données de surveillance après la mise sur le marché (rapports sur les réactions indésirables après la commercialisation d'un vaccin) effectuées en 1987 et en 1996 pour les Etats-Unis d'Amérique et en 1992 pour le Canada n'ont pas permis de conclure à une augmentation des cas de sclérose en plaques ou d'autres maladies neurologiques. Toutefois, la sensibilité de la déclaration passive des réactions indésirables est faible, et des études contrôlées dans la population sont actuellement prévues ou en cours.

Des études conduites en Alaska (Etats-Unis) sur plus de 43 000 personnes vaccinées contre l'hépatite B n'ont permis de constater aucune augmentation des cas de maladie neurologique. L'incidence de la sclérose en plaques est très faible parmi la population autochtone de l'Alaska, qui a peut-être une faible prédisposition génétique à cette maladie, mais il est clair que le vaccin n'a pas favorisé l'apparition de maladies neurologiques.

Des études après la mise sur le marché réalisées en France par Merck and Company, Pasteur-Mérieux-Connaught, et SmithKline Beecham Biologicals n'ont pas permis de conclure à une augmentation des cas de toute maladie démyélinisante ou de sclérose en plaques parmi les personnes vaccinées contre l'hépatite B.

3) Analyse des cas signalés en France

Les résultats d'une étude officielle de pharmacovigilance sur la tolérance neurologique de tous les vaccins commercialisés en France (Engerix B, GenHevac et HB-VAX DNA) ont été présentés à la Commission nationale française de Pharmacovigilance en décembre 1994 et en décembre 1996. Ces résultats sont les suivants:

Plus de 60 millions de doses de vaccin contre l'hépatite B ont été distribuées en France entre janvier 1989 et décembre 1996, et un total de 106 études de cas décrivant des maladies démyélinisantes du SNC et du système nerveux périphérique ont été notifiées chez des personnes vaccinées. La proportion des cas de maladie démyélinisante consécutifs à une vaccination contre l'hépatite B s'établit par conséquent à 1,8 par million de doses, soit environ 0,6 cas pour 100 000 personnes vaccinées. Ce dernier taux est nettement inférieur à l'incidence escomptée des maladies démyélinisantes dans la même population qui, pour la seule sclérose en plaques, est de 1 à 3 pour 100 000 personnes.

Les caractéristiques épidémiologiques des cas notifiés étaient analogues à celles que l'on observe habituellement dans une population comparable de personnes non vaccinées, en ce qui concerne l'âge, la proportion respective des deux sexes et la nature et la gravité des symptômes neurologiques. L'intervalle de temps écoulé entre la vaccination et l'apparition de symptômes neurologiques a été extrêmement variable.

Observations in other countries show similar patterns to that observed in France: 0.1 to 0.8 cases of demyelinating disease per 100 000 vaccinees (Australia, Belgium, Canada, Germany, India, United Kingdom, United States).

These data are consistent with the normally expected incidence of demyelinating diseases in the vaccinated population and do not suggest a link between vaccination and CNS demyelinating disorders. After having examined the evidence, French authorities (*Ministère des Affaires sociales, Direction générale de la Santé, Agence française du Médicament*) concluded that there were no scientific data suggesting a causal link between hepatitis B vaccination and multiple sclerosis, and that control of hepatitis B was of major importance, justifying the continued implementation of the HB vaccination programmes.

While any risk of MS following HB immunization is hypothetical, the risk of HB infection and disease in non-immunized individuals is real. HB causes an estimated 4 million acute infections worldwide each year, and currently there are more than 350 million chronic carriers of HBV, approximately 25% of whom will die from cirrhosis of the liver or primary liver cancer, diseases which kill more than 1 million persons per year. For these reasons, WHO has called for all countries to include routine HB immunization in their national immunization programmes. More than 85 countries have done so and many more are planning for the introduction of the vaccine. HB vaccines are safe, more than 90% effective in preventing disease, and very cost-effective. It is extremely unfortunate that unsubstantiated claims that HB vaccines might cause MS are reducing the uptake of this important vaccine.

D'après les observations effectuées dans d'autres pays, l'incidence et les caractéristiques épidémiologiques sont analogues à celles que l'on a observées en France: de 0,1 à 0,8 cas de maladie démyélinisante pour 100 000 personnes vaccinées (Allemagne, Australie, Belgique, Canada, Etats-Unis, Inde, Royaume-Uni).

Ces données sont conformes à l'incidence habituelle des maladies démyélinisantes que l'on peut escompter dans la population des personnes vaccinées et ne semblent pas indiquer l'existence d'un lien entre ces maladies et la vaccination. Après avoir examiné ces preuves, les autorités françaises (Ministère des Affaires sociales, Direction générale de la Santé, Agence française du Médicament) ont conclu qu'il n'existait aucunes données scientifiques laissant à penser qu'il y aurait un lien de cause à effet entre la vaccination contre l'hépatite B et la sclérose en plaques et que la lutte contre l'hépatite B revêtait une importance capitale qui justifiait la poursuite de la mise en œuvre des programmes de vaccination.

Si le risque de sclérose en plaques consécutive à une vaccination est hypothétique, le risque de contracter une infection à VHB ou une hépatite B est bien réel pour les individus non vaccinés. On estime à 4 millions le nombre d'infections aiguës à VHB survenant chaque année dans le monde et à 350 millions le nombre d'individus qui sont des porteurs chroniques du VHB dont près de 25% décéderont d'une cirrhose du foie ou d'un cancer primaire du foie, maladies qui tuent plus d'un million de personnes par an. C'est pourquoi l'OMS a demandé à tous les pays de mettre en place une vaccination systématique contre l'hépatite B dans leurs programmes nationaux de vaccination. Plus de 85 pays se sont déjà exécutés et bien davantage sont en train de planifier l'introduction du vaccin. Le vaccin HB est un vaccin sûr, efficace à plus de 90% pour la prévention de la maladie et d'un bon rapport coût/efficacité. Il est extrêmement regrettable que des rumeurs non fondées selon lesquelles le vaccin HB pourrait provoquer des scléroses en plaques fassent reculer l'utilisation de cet important vaccin.

A large outbreak of epidemic louse-borne typhus in Burundi

In Africa, epidemic louse-borne typhus is reported sporadically in the highlands. The pathogenic agent for epidemic louse-borne typhus is *Rickettsia prowazekii* and man is the only reservoir. Typhus is transmitted exclusively by the body louse, *Pediculus hominis corporis* (head lice play no role in transmission). The body louse lives in clothing and multiplies very rapidly under poor conditions of hygiene which particularly exist in refugee camps.[1] The infection of the louse by *R. prowazekii* causes it to die. The disease is transmitted through the faeces of the lice, which humans inoculate by scratching. Lice proliferate rapidly in the refugee camps and the risk can be expected to grow in cold rainy seasons, which will increase overcrowding and the amount of clothing and blankets used.

Since World War II, cases have been reported from Africa, mainly in Ethiopia, as well as in Burundi and Rwanda. The last outbreak of louse-borne typhus occurred in Burundi in 1975, when 9 000 cases were reported. No cases had been reported since 1990. Starting in 1993, with the civil strife in Burundi, an estimated 500 000 people have lived in refugee camps in the highlands. Several cases

[1] See No. 34, 1994, p. 259.

Importante épidémie de typhus exanthématique au Burundi

En Afrique, on signale souvent des épidémies sporadiques de typhus exanthématique dans les régions montagneuses. L'agent étiologique de cette affection, appelée aussi typhus à poux, est *Rickettsia prowazekii* et l'homme en est l'unique réservoir. Le typhus est transmis exclusivement par le poux de corps, *Pediculus hominis corporis* (le poux de tête ne joue aucun rôle dans la transmission). Le poux de corps vit dans les vêtements et se multiplie rapidement lorsque les conditions d'hygiène sont médiocres, comme c'est le cas, en particulier, dans les camps de réfugiés.[1] L'infection par *R. prowazekii* est mortelle pour le pou. La maladie est transmise par les déjections du pou qui infectent l'homme par l'intermédiaire des lésions de grattage. Dans les camps de réfugiés, les poux prolifèrent rapidement et l'on peut s'attendre à ce que le risque s'accroisse pendant les saisons froides et pluvieuses, lorsque se manifeste une tendance à la surpopulation et que l'on utilise davantage de vêtements et de couvertures.

Depuis la seconde guerre mondiale, on signale des cas de typhus en Afrique, surtout en Ethiopie, mais aussi au Burundi et au Rwanda. La dernière flambée de typhus exanthématique, au cours de laquelle on a dénombré 9 000 cas, s'est produite au Burundi en 1975. Depuis 1990, aucun cas n'avait été signalé. A partir de 1993, lorsque la guerre civile a éclaté, on estime que 500 000 personnes ont vécu dans des camps de réfugiés dans les régions d'altitude

[1] Voir N° 34, 1994, p. 259.

Fact Sheet WHO/204
November 1998

HEPATITIS B

Hepatitis B is one of the major diseases of mankind, and is now preventable with safe and effective vaccines. Out of the 2,000 million people who have been infected with the virus, more than 350 million are chronic carriers of the virus. These chronic carriers are at high risk of death from cirrhosis of the liver and liver cancer, diseases that kill about one million persons each year. Although the vaccine will not cure chronic carriers, it is 95% effective in preventing the carrier state from developing, and is the first vaccine against a major human cancer. The World Health Organization has called for all children to receive this vaccine, and 100 countries have added it to their routine immunization programmes. However, the children in the poorest countries, who need the vaccine the most, are not receiving it because their governments cannot afford it. This is medically and morally unacceptable, and is the major problem to be solved before we can control this disease on a global basis.

What is Hepatitis?

Hepatitis means inflammation of the liver, and the most common cause is infection with one of 5 viruses, called hepatitis A, B, C, D, and E. All of these viruses can cause an acute disease with symptoms lasting several weeks including yellowing of the skin and eyes (jaundice), dark urine, extreme fatigue, nausea and vomiting, and abdominal pain. It can take several months to a year to feel fit again. Some of these viruses can cause a chronic carrier state in which the patient never gets rid of the virus, and many years later develops cirrhosis of the liver or liver cancer. Hepatitis B is a virus of this type and the most serious type of viral hepatitis. It is also the only type causing chronic disease for which a vaccine is available.

Who gets hepatitis B?

Most people in much of the developing world (sub-Saharan Africa, most of Asia, and the Pacific) become infected with the virus during childhood, and 8% to 15% of people in the general population become chronic carriers. In these regions liver cancer caused by hepatitis B is the number one or two cause of cancer death in men. High rates are also found in the Amazon and the southern parts of Eastern and Central Europe. In the Middle East and the Indian sub-continent, about 5% of people are carriers. Infection is less common in Western Europe

and North America, where less than 1% are chronic carriers.

How do people get hepatitis B?

Hepatitis B is transmitted by blood and close personal contact, much like AIDS, but hepatitis B is 50 to 100 times more infectious than AIDS. In developing countries newborns may be infected if their mother is a chronic carrier. Unlike AIDS, the virus is transmitted within households between young children. Injections with reused unsterilized needles and syringes is another important route. In many developing countries almost all children become infected with the virus, and the younger they are, the more likely they will become a chronic carrier. This is also why we need to use the vaccine in young children in most of the world.

In Western Europe and North America, the pattern of transmission is different. Although there is still some transmission from carrier mother to child, most of this is prevented because all pregnant women are screened to detect hepatitis B infection, and babies are treated at birth with vaccine and other medicines. Most transmission in these countries occurs during young adulthood due to sexual activity, needle sharing, occupational exposure, travel, or being in an ethnic group from a country with high rates of infection. Hepatitis B is the major infectious occupational hazard of health workers, and most health care workers have received hepatitis B vaccine. Hepatitis B is not spread by contaminated food or water, and cannot be spread casually in the workplace.

Can chronic hepatitis B and liver cancer be treated?

Liver cancer is almost always fatal, and usually develops between the age of 35 and 65 years of age, when people are maximally productive and are trying to raise their own children. The loss of a mother or father in a developing country can devastate the entire family. In developing countries most people die within months of diagnosis. In industrial countries surgery and chemotherapy can prolong life up to a few years. Chronic hepatitis in some patients is treated with a drug called interferon which can help some patients. However, interferon therapy costs thousands of dollars and will never be available to most patients in developing countries. Patients with cirrhosis are sometimes given liver transplants, with varying success. It is much preferable to prevent this disease with vaccine than to try and cure it.

How safe and effective is the vaccine?

Hundreds of millions of people have received this vaccine, which became available in 1982, and has an outstanding record of safety and effectiveness. Studies have shown that the vaccine is 95% effective in preventing children or adults from developing the chronic carrier state if they have not yet been infected. In many countries where 8% to 15% of children used to become chronic carriers, this has been reduced to less than 1% in immunized groups of children. Other studies have shown a direct reduction in liver cancer in immunized children. It is

important to realize that this is the first vaccine against a major human cancer.

How is WHO trying to control hepatitis B?

In 1991 WHO called for all countries to add hepatitis B vaccine into their National Immnization Programmes, and so far 100 countries have done so. This includes all industrial countries in Western Europe, North America, and Australia, with the exception of the Scandanavian countries, the Netherlands, and the UK and Ireland. Fortunately, most countries in Eastern Asia and the Middle East use the vaccine, but it is not used in many countries in sub-Saharan Africa, the Indian subcontinent, and in the Newly Independent States. The poorest countries in the world cannot afford this vaccine, and their children are unprotected. The cost vaccine to immunize a child with hepatitis B vaccine in a developing country is about 3 Swiss franks, the cost of a bottle of mineral water in a Geneva cafe. We need to raise the awareness of donor agencies that buy vaccines for the poorest developing countries so that they will begin to supply the vaccines, especially in Africa.

For further information, journalists can contact the Office of Public Relations, WHO, Geneva. Telephone (41 22) 791 2584. Fax (41 22) 791 4858. Email: info@who.ch .

All WHO Press Releases, Fact Sheets and Features as well as other information on this subject can be obtained on Internet on the WHO home page http://www.who.ch/

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Hepatitis B vaccine and MS

Hepatitis B vaccine and Multiple Sclerosis (MS)

A number of anecdotal reports have linked the administration of hepatitis B vaccine with the onset of multiple sclerosis (MS). WHO reported on this in late 1997 with an article in the Weekly Epidemiological Record: Lack of evidence that hepatitis B vaccine causes multiple sclerosis *(PDF file)*. Subsequently a number of scientific investigations have been carried out to examine the issue. WHO held a three-day meeting with world experts on 28th to 30th September 1998 in Geneva to review all available data on the subject. The meeting's draft report is available on the web. In summary, the draft report states:

"The data available to date, although limited, does not demonstrate a causal association between HB immunization and CNS demyelinating diseases, including MS. No evidence presented at this meeting indicates a need to change public health policies with respect to HB immunization. Therefore, based on demonstrated important benefits including the prevention of cirrhosis and cancer, and a hypothetical risk, the group supports the WHO recommendations that all countries should have universal infant and/or adolescent immunization programs and continue to immunize adults at increased risk of HB infection as appropriate."

The press release from that meeting is also available below. See also a related web site from the National Multiple Sclerosis Society.

Sequel

On 15 March 1999, the French Minister of Labour and Solidarity put out a press release indicating the school programme was not likely to be reinstated yet.

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H-440.932 Hepatitis B Vaccine

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The AMA (1) calls for the implementation of a nationally mandated **Hepatitis B** vaccination program for all infants; (2) will alert and educate the public, physicians and other health care providers, and legislators to the importance of **Hepatitis B** vaccine inoculation of all infants and groups at high risk; and (3) recommends to state and local health departments that all healthy full term infants born in the U.S. receive the first dose of **Hepatitis B** vaccine before discharge from the newborn nursery regardless of the mother's HBsAg (**Hepatitis B** surface antigen) status. (Res. 403, A-93)

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H-440.958 Universal Immunization For Hepatitis B Virus

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For enhanced effectiveness in decreasing the incidence of **hepatitis B** in the United States, it appears to be necessary to broaden current immunization strategies. Safe and effective vaccines are available for prevention of the disease but this use is limited by cost. Eradication of the disease on a national and international basis is a definite hope, but may not be possible without the development of antiviral treatments to control or eliminate the virus in the carrier state and in infected vaccine nonresponders. Education about the disease and its transmission is an essential element for any effective program to reduce the incidence of **hepatitis B**. Therefore, (1) The AMA endorses the principle of the universal immunization with **hepatitis B** vaccine of all infants, adolescents, military recruits, and students entering colleges and technical schools. While the ultimate goal is the complete immunization of all these groups, the process will need to be a gradual one beginning with the immunization of high-risk groups and then the phasing-in of infants, adolescents, and the other groups. (2) The AMA encourages the immunization of all students entering medical school. The costs for the immunizations should be included in the school tuition. (3) The Association supports the immunization of all other risk groups with special emphasis on patients attending sexually transmitted disease clinics and drug rehabilitation centers. (4) The Association supports the proposed regulation of OSHA requiring the vaccination of all healthcare workers at risk of **hepatitis B** virus infection. (5) The Association encourages further professional and public education on **hepatitis B** disease, its transmission, and prevention. Such education should include state and federal legislators and emphasize the need for funding for immunization programs. In addition, education concerning **hepatitis B** should be a part of every sex and AIDS education course in the nation. (6) The Association encourages the scientific community to intensify its efforts to find effective therapies for patients infected with **hepatitis B** virus. (7) The Association encourages the U.S. Public Health Service and the World Health Organization to develop strategies for the elimination of **hepatitis B** both nationally and globally. (BOT Rep. AA, A-90; Reaffirmation I-96)

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American Liver Foundation

STATEMENT
OF
THE AMERICAN LIVER FOUNDATION

PROVIDED
TO
THE UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY AND HUMAN RESOURCES

BY
ALAN P. BROWNSTEIN,
AMERICAN LIVER FOUNDATION
PRESIDENT & CEO

MAY 18, 1999

75 Maiden Lane, Suite 603, New York, NY 10038-4810 • (212) 668-1000 • (800) GO-LIVER (465-4837) • (888) 4HEP-ABC (443-7222) • Fax: (212) 483-8179
Member National Health Council, Inc.

THE AMERICAN LIVER FOUNDATION

Mr. Chairman and members of the Subcommittee, my name is Alan Brownstein and I am the president and chief executive officer of the American Liver Foundation. Thank you for giving our organization the opportunity to provide a statement to you in conjunction with the Subcommittee's hearing about the hepatitis B vaccine.

The American Liver Foundation (ALF) is a national voluntary health organization dedicated to the prevention, treatment and cure of hepatitis and other liver and gallbladder disease through research and education. ALF has 30 Chapters nationwide and provides information to 300,000 patients and families. More than 70,000 scientists and physicians, including primary care practitioners and liver specialists, also receive information from ALF.

The ALF Board of Directors is composed of scientists, clinicians, patients and others who are directly affected by liver disease. Every month, ALF receives approximately 15,000 calls requesting information about hepatitis and other liver diseases.

ALF was founded 23 years ago by the American Association for the Study of Liver Diseases. In recent years, ALF has provided more than $8 million to support hepatitis/liver disease research.

THE INCIDENCE, PREVALENCE, AND IMPACT OF HEPATITIS B

Chronic or long-term infection with the hepatitis B virus (HBV) is very serious, and can lead to cirrhosis, liver cancer, and death. There are 1.25 million people in the U.S. who are chronically infected with HBV, and each year an estimated 200,000 people contract this potentially life-threatening liver disease. An estimated 4,000 to 5,000 people in this country die annually due to complications associated with hepatitis B.

HBV is a virus that causes the liver to become inflamed. Most people who become infected with HBV have no recognizable signs or symptoms. The only way the disease can be positively identified is through a blood test. Hepatitis blood tests are not usually included in routine blood tests conducted during a physical examination. Many people only learn that they are infected with HBV after they donate blood and it is found that they test positive for the virus.

According to the Centers for Disease Control and Prevention (CDC), HBV is about 100 times easier to transmit than HIV, the virus that causes AIDS.

HBV is transmitted sexually and through exposure to infected blood and other body fluids, including semen, vaginal secretions, open sores and, in rare cases, saliva (through bites that break the skin). However, in about 30 percent of hepatitis B cases, the cause of infection is unknown.

While hepatitis B is more frequent among some groups, it occurs among people of all ages, race, sexual orientation, and gender. The greatest number of reported HBV infections are in young adults, due to sexual transmission of the disease, as well as other youth-associated risk factors.

Up to 90% of pregnant women who are HBV carriers pass the virus on to their newborns at delivery. Infants infected with HBV have a 70% to 90% chance of becoming chronically infected with the virus. About 25% to 50% of young children under the age of 5 who become infected with HBV are unable to clear the infection from their bodies within six months and go on to be chronically infected with HBV. In other words, when a child acquires hepatitis B infection, he or she is more likely than an adult to become chronic with potentially severe consequences.

Left undiagnosed, individuals infected with HBV can unknowingly spread the virus to others. Universal infant immunization ensures that those who become exposed without their knowledge are protected against the disease.

HEPATITIS B VACCINATION

Antibiotics cannot cure hepatitis B infection. Prevention is our most effective weapon against this potentially deadly disease, thereby providing the rationale for universal childhood hepatitis B vaccination.

The American Liver Foundation supports routine immunization against hepatitis B, and stands by the Advisory Committee on Immunization Practices in its recommendations that all infants, adolescents and adults at risk for HBV infection be vaccinated to the widest extent possible.

The hepatitis B vaccine is our nation's most effective means to prevent transmission of HBV, and to offset the clinical consequences and healthcare costs associated with this potentially life-threatening disease. It also offers, for the first time in modern medicine, an effective vaccine to prevent a deadly form of cancer.

Hepatitis B vaccines have been shown to be very safe when given to infants, children and adults, according to CDC. More than 20 million people have received hepatitis B vaccine in the U.S. and more than 500 million people have received the vaccine worldwide. Studies show that the most common side effects from hepatitis B vaccination are pain at the injection site and mild to moderate fever, and that these side effects are reported no more frequently among those vaccinated than among those not receiving vaccine.

According to CDC, studies also demonstrate that serious side effects reported after receiving hepatitis B vaccine are very uncommon. There is no confirmed scientific evidence that hepatitis B vaccine causes chronic illness, including multiple sclerosis, chronic fatigue syndrome, rheumatoid arthritis, and autoimmune disorders. Case reports of unusual illnesses following vaccines are most often related to other causes and not related to a vaccine.

Large-scale hepatitis B immunization programs in Taiwan, Alaska, and New Zealand have observed no association between vaccination and the occurrence of serious adverse events. Furthermore, surveillance of adverse events in the U.S. after hepatitis B vaccination have shown no association between hepatitis B vaccine and the occurrence of serious adverse events.

Any presumed risk of adverse events associated with hepatitis B vaccination must be balanced with the expected 4,000 to 5,000 HBV-related liver disease deaths that would occur without immunizations, assuming a 5% lifetime risk of HBV infection.

ALF believes that any possible adverse effects of hepatitis B vaccine should be taken seriously and, although scientific evidence to date does not support hepatitis B vaccination causing multiple sclerosis or other demyelinating diseases, we are pleased that a study is currently being organized in the Vaccine Safety Datalink Project at CDC because of public concern about this issue.

DECREASED IMMUNIZATION RESULTS IN INCREASED DISEASE, REMEMBERING THE PAST TO PROTECT OUR FUTURE

It is easy to forget that a good number of preventable diseases today, including hepatitis B, were major public health threats just a decade ago. The American Liver Foundation believes firmly that we must not allow complacency to offset tremendous strides made in the prevention of hepatitis B and the health of our nation today and into the future. Any drop in immunization levels will bring about an increased incidence of hepatitis B and its complications, including cirrhosis and liver cancer.

Routine infant immunization against hepatitis B is recommended because there is a large disease burden attributable to HBV infections that occur among children. According to CDC, approximately 30,000 infants and children in the U.S. were infected with HBV each year *before* routine infant hepatitis B immunization began, and CDC estimates that one-third of the chronic HBV infections in the U.S. come from infected infants and young children. The majority of these infections occur among children of mothers who are not HBV infected and thus would not be prevented by perinatal hepatitis B prevention programs.

Today, hepatitis B vaccination is saving lives. The hepatitis B vaccine has contributed to a substantial decrease in HBV infection, particularly in children and adolescents among whom vaccination coverage has been the highest.

The American Liver Foundation remains firm in its support of routine infant immunizations to prevent hepatitis B infection, as it ensures that those who become exposed without their knowledge are protected against this potentially deadly disease.

On behalf of the American Liver Foundation – its Board of Directors, medical and lay leadership, and nationwide network of Chapters that serve millions of Americans – I thank the Subcommittee Chair and its members for their consideration of these important issues and for allowing our organization to share important information about the hepatitis B vaccine.

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NATIONAL MULTIPLE SCLEROSIS SOCIETY

National Multiple Sclerosis Society
733 Third Avenue
New York, NY 10017-3288
Tel 212 986 3240
1 800 FIGHT MS
Fax 212 986 7981
E-Mail: Nat@nmss.org
www.nmss.org

PROGRAMS

August 21, 1998

HEPATITIS B VACCINE AND MULTIPLE SCLEROSIS

Summary: Media attention has been drawn to anecdotal reports suggesting that vaccination against hepatitis B virus may increase risk for multiple sclerosis.

- Such reports have NOT been confirmed by any statistically significant scientific studies to date;
- Because of the potential for public concern about this issue, further studies of the possibility of association of hepatitis B vaccine and demyelinating disease, including MS, are underway in the U.S. and Europe;
- Hepatitis B infection can result in a serious, sometimes fatal disease and vaccination is effective in its prevention;
- In the view of the Medical Advisory Board of the National Multiple Sclerosis Society, there is no evidence of a link between hepatitis B vaccination and MS;
- People with MS are encouraged to discuss the small general risks of any viral immunization with their physicians.

Details: Media attention has been drawn to the possibility that vaccination against hepatitis B virus may increase risk for developing multiple sclerosis. These concerns have been raised by anecdotal reports from France of a possible increase in autoimmune disease, including MS, after hepatitis B vaccination. Since in many parts of the world, vaccination against hepatitis B virus is mandatory, especially for health care workers, the possibility that such vaccination may increase risk of other diseases has raised public concern.

The anecdotal reports from France have NOT been confirmed by any scientific study in Europe or in the United States to date. A study by the French National Drug Surveillance Committee among recipients of over 60 million doses of hepatitis B vaccine delivered between 1989 and 1997 found that the frequency of neurological disease, including MS, that might be linked to the vaccination was in fact LOWER than the frequency of MS in the general population.

Similar results have been reported from Australia, Belgium, Canada, Germany, India, the United Kingdom and the United States. Analyses by the World Health

Organization and the U.S. Institute of Medicine conclude that there is no demonstrated causal relationship between hepatitis B vaccination and neurological disease or demyelinating disorders such as MS. An expert panel assembled by the U.S. Centers for Disease Control (CDC) in 1997 also concluded that there was no scientific evidence of a link between hepatitis B vaccination and MS. The panel's assessment included a review of data from the CDC's "Vaccination Adverse Experience Reporting System" database, which records adverse reactions to vaccinations reported around the country.

However, even though there are no current data to support such a connection, because of the potential for public concern about this issue, the CDC has undertaken a further prospective clinical study of the possible association of hepatitis B vaccine and demyelinating disease, including MS. Results from that study should be available by mid-1999. Additional studies are underway in Europe.

Hepatitis B virus causes some 4 million acute infections worldwide annually. More than 350 million individuals are chronic carriers of the virus after infection, and some 25% of those will die as a consequence of cirrhosis of the liver or liver cancer brought on by the viral infection. Vaccination against hepatitis B has been established to be safe, 90% effective in preventing disease and cost-effective.

The cause of MS remains unknown, but is believed to be due to the impact of an environmental or infectious trigger on the immune system of an individual who carries a genetic predisposition for the disease. After decades of searching, no environmental or infectious trigger for MS has been identified. There is no indication that infection with hepatitis B leads to MS, and there are no statistically significant data to support a link between hepatitis B vaccination and MS.

In the view of the Medical Advisory Board of the National Multiple Sclerosis Society, there is no current evidence of a link between hepatitis B vaccination and MS. Individuals at risk for hepatitis B infection and their physicians should consider the vaccine safe, and should consider the substantial risk for hepatitis B infection if not vaccinated. While supporting wide and general use of hepatitis B vaccine, the Medical Advisory Board encourages individuals with MS to discuss the small general risks of any viral immunization with their physician.

Stephen C. Reingold, Ph.D.
Vice President, Research Programs

Stanley van den Noort, M.D.
Chief Medical Officer

#3

MS International Supports Statement on Safety of Hepatitis B Vaccination Programmes

The World Health Organisation has issued a statement saying there is *"no scientific justification to suspend hepatitis B immunisation"*. This statement was issued in response to the French Ministry of Health's announcement of its decision to suspend routine hepatitis B (HB) immunisation of adolescents but it is continuing the immunisation of infants and high risk adults. This action was taken following concerns, despite lack of scientific evidence, that HB immunisation might be linked to the development or flare-up of demyelinating disease such as MS.

In anticipation of the French announcement on 1st October, the World Health Organisation's collaborating centre for the prevention of viral hepatitis (The Viral Hepatitis Prevention Board) called a technical consultation meeting on the safety of HB vaccines. This was held 28th - 30th September 1998.

The accumulated data was reviewed and it was concluded that there was *"no evidence whatsoever of a link between hepatitis B virus infection and CNS demyelinating disorders including multiple sclerosis".*
"Altogether, evidence in favour of an increased risk following vaccination is weak and does not meet the criteria for causality".
"No evidence presented at this meeting indicates a need to change public health policies with respect to HB immunisation".
"It is clear that the benefit of HB vaccination outweighs any claimed risk in all age groups".

Prof. Ian McDonald, Chairman of the International Medical Advisory Board of MS International said:

"People with MS should be reassured that scientific data provides no support for an association between hepatitis vaccine and MS. With over a billion doses of HB vaccine used since 1981, the evidence does show that it has an outstanding record for safety and efficacy."

05 October 1998

President Peter A. Schwartzer Secretary General Richard Hamilton

International Federation of Multiple Sclerosis Societies
10 Norris Street, London W1R 1LJ, England. Telephone: +44 (0) 171 734 8120 Fax: +44 (0) 171 287 2097
Email: info@ifmss.org.uk
"World of MS" Website: http://www.ifmss.org.uk

NACCHO
1100 17TH STREET, NW, SECOND FLOOR
WASHINGTON, DC 20036
(202) 783-5550 (202) 783-1583 (FAX)

NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

May 17, 1999

The Honorable Henry G. Waxman
2204 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Congressman Waxman:

The National Association of County and City Health Officials (NACCHO) has requested that Chairman Mica include the attached letter in the record of the May 18, 1999 hearing on Hepatitis B vaccine. NACCHO strongly supports the routine use of Hepatitis B vaccine as a public health strategy essential to preventing the toll of illness and death due to Hepatitis B-related disease.

Sincerely,

Ralph D. Morris, MD, MPH
lbg

Ralph D. Morris, MD, MPH
President

NACCHO
1100 17TH STREET, NW, SECOND FLOOR
WASHINGTON, DC 20036
(202) 783-5550 (202) 783-1583 (FAX)

NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

May 17, 1999

The Honorable John Mica, Chair
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
B-373 Rayburn House Office Building
Washington, DC 20515

RE: Hearing on Effectiveness of Hepatitis B Vaccine

Dear Chairman Mica:

The National Association of County and City Health Officials (NACCHO) respectfully requests that this letter be included in the record of the Subcommittee's May 18, 1999 hearing on Hepatitis B vaccine.

NACCHO represents the nearly 3000 local public health departments, in cities, counties and townships, who work on the front lines to protect and promote the health of their communities. We support the recommendations of the Centers for Disease Control and Prevention concerning the use of Hepatitis B vaccine routinely for infants and adolescents. Liver disease due to the Hepatitis B virus has been a serious public health problem, causing chronic infection in an estimated 1.25 million people in the United states, and 4,000 to 5,000 deaths annually from Hepatitis-B related chronic liver disease or liver cancer. The strategy of vaccinating only persons thought to be at risk for Hepatitis B infections due to occupational exposures, sexual activity or illicit drug use, has not been successful. Moreover, CDC estimates that one-third of the chronic Hepatitis B infections in the United States come from infected infants and young children.

We believe that the benefits to the health and safety of the public from routine use of Hepatitis B vaccinations are great and that there is no current evidence that justifies turning away from a public health strategy that will prevent a large toll of human suffering and save lives. We also support continuing epidemiologic surveillance to measure the effects of Hepatitis-B related disease and to detect any previously undetected risks of the vaccine, so that individuals and health professionals can make judgments and recommendations based on all available information.

Thank you for your consideration of our views.

Sincerely,

Ralph D. Morris, MD, MPH

Ralph D. Morris, MD, MPH
President

Testimony on the Advisability and Safety of Hepatitis B Vaccination

Submitted to the
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
United States House of Representatives

May 18, 1999

Submitted by
H. R. Shepherd, Chairman
Albert B. Sabin Vaccine Institute
58 Pine Street
New Canaan, CT 06840
Tel. 203-972-7907 · Fax 203-966-4763
www.sabin.georgetown.edu

Hepatitis B is the most common form of hepatitis, an inflammation of the liver that often leads to serious liver disease and liver cancer. It is caused by a virus and is extremely contagious – 100 times more contagious than HIV, the virus that causes AIDS. According to the World Health Organization (WHO), hepatitis B leads to more than one million deaths a year. In the United States, more than 100,000 people become infected with hepatitis B each year. Five thousand to 6,000 Americans die from cirrhosis or liver cancer to which the infection was a precursor.

In a majority of cases, we know how hepatitis B is transmitted from one person to another. But in one-third of the cases, the cause is unknown. Within the family unit, the virus can spread from adults to children. This happens more often than one might think because carriers of the virus often show no symptoms and, therefore, do not know they are infected. Unaware that they are infected, they do not take precautions to prevent transmitting the virus to others, including their own family members.

Children are more vulnerable to hepatitis B than adults. Between 5%-10% of adults who are infected with the virus become chronic (long-term) carriers of hepatitis B. But 25% or more of children infected become chronic carriers.

Fortunately, hepatitis B infection can be prevented. The hepatitis B vaccine is 95% effective in preventing the viral infection and liver disease. In fact, the hepatitis B vaccine is the first vaccine proven to protect against cancer; it prevents *hepatocellular carcinoma*, the most prevalent form of liver cancer. The Centers for Disease Control and mainstream physicians' and patients' organizations recommend universal hepatitis B vaccination.

Universal vaccination – immunization of the entire population – is the most powerful weapon in medicine's arsenal against disease. Mass vaccination programs have saved millions of lives and billions of dollars in health care costs by eradicating two terrible diseases – smallpox and polio – in North America. Measles, which kills one million children a year worldwide, is largely unknown today in the United States because we have universal measles vaccination.

Vaccines are cost-effective, too. For example, the CDC estimates that each $1 spent on diphtheria, pertussis and tetanus vaccine saves $29 in health care expenditures.

It is lamentable that, despite the facts about the public health threat posed by hepatitis B and the infection's scientifically proven connection to liver disease and cancer, a small number of activists are raising unfounded fears about hepatitis B vaccination. These activists engage families with children who suffer from serious maladies by persuading them of a false connection between the maladies and hepatitis B vaccine. There are huge gaps in the "logic" behind the alleged connection as the preponderance of evidence proves.

International health officials are alarmed that France suspended routine hepatitis B immunization of school children last year. France acted after anecdotal reports raised

questions about a link between the vaccine and various neurological injuries, including multiple sclerosis. The WHO and other health authorities roundly criticized the French move because there is no credible scientific evidence to support the allegation and it jeopardizes public health.

The evidence tells us that the hepatitis B vaccine is safe. The WHO reports, "Over 1 billion doses of Hepatitis B (HB) vaccine have been used since 1981 with an outstanding record of safety and efficacy."[1] The WHO also declared, "Among the more than 550 million individuals who have been immunized with HB vaccines since 1982, no evidence of a causal association with MS or other demyelinating diseases has ever been demonstrated."[2] Indeed, the French National Drug Surveillance Committee, a drug safety agency, found *lower* frequency of neurological diseases including MS among those vaccinated against hepatitis B than in the population at large. These are not knee jerk, defensive reactions; these agencies took the allegations seriously and conducted extensive scientific investigations. Their findings underscore the safety of hepatitis B vaccine.

Credible patient organizations stand behind the vaccine, as well. The National Multiple Sclerosis Society, an organization whose mission puts it on the forefront of vigilance against MS, declared, "there is no current evidence of a link between hepatitis B vaccination and MS," and issued a statement "supporting wide and general use of hepatitis B vaccine."[3]

Others, notably parents of children who died from undetermined or non-specific causes, such as sudden infant death syndrome (SIDS), have questioned whether their children's deaths were linked to hepatitis B vaccination. It is understandable that they desperately seek explanations for their tragic losses. When medical science is unable to provide conclusive answers, they accept the alleged deadly vaccine reaction. But such emotion and grief-driven reactions do not validate the allegations in the absence of supporting scientific data.

Some of these parents join the activists who argue that infant vaccination against hepatitis B is unnecessary because most infants face a low risk of contracting the virus during their lifetimes. The low likelihood of infection is true. However, some of those infants *will* be exposed during their lifetimes. The trouble is, we cannot know *which* infants and children will, when they grow up, join the 1.2 million Americans who are chronically infected with hepatitis B. The only way to prevent the spread of the disease and to ensure that we protect all of today's children is universal vaccination. Sustained universal immunization could eradicate hepatitis B.

This in no way diminishes the anguish of those afflicted by MS or other terrible neurological conditions. Nor does it reduce the pain of parents whose children were vaccinated but died for some other reason. But no matter how badly they want explanations for their woes, it is unjust to them and to society to draw an invalid conclusion and allow it to jeopardize public health.

Public officials and health authorities are right to investigate concerns that are raised about vaccine safety, and to inform the public of their findings and take other appropriate actions. They should continue to do so. It is equally incumbent on public officials to protect public health through prudent vaccination requirements. Hepatitis B vaccine now is one of the most closely scrutinized vaccines and the scientific evidence tells us it is safe and effective. It is rightly part of the recommended vaccination schedule.

---

[1] "No Scientific Justification to Suspend Hepatitis B Immunization," World Health Organization, October 2, 1998

[2] "Lack of Evidence that Hepatitis B Vaccine Causes Multiple Sclerosis," *Weekly Epidemiological Record,"* World Health Organization, May 23, 1997, p. 152

[3] "Hepatitis B Vaccine and Multiple Sclerosis," National Multiple Sclerosis Society, statement issued August 14, 1998 and re-issued January 22, 1999

The State

109th Year, No. 65 South Carolina's Largest Newspaper COLUMBIA, SOUTH CAROLINA • SATURDAY, MARCH 6, 1999 The Newsroom (803) 771-8415 STATE EDITION

France's medical meddling could cost millions their lives

By H.R. SHEPHERD

Some of the world's top thinkers are debating what to do about smallpox, a disease that ravaged humanity for at least 12,000 years. It struck the mighty and the powerless, from Marcus Aurelius to Ali Maow Maalin, a cook in Somalia who in 1977 was the last person to catch smallpox naturally.


Shepherd

The debate now is what to do with the remnants of the virus, whether to destroy them or keep them in secure laboratories for further study. The breathtaking part is that we're in a position to be holding such a discussion.

Thanks to vaccines, smallpox is all but extinct. We're lucky to have had a 200-year head start on wiping out smallpox because today political roadblocks would impede use of the vaccine.

Take a look at the status of the vaccine for hepatitis B, one of the most prevalent and deadly infectious diseases in the world. Over 300 million people are chronically infected with hepatitis B, the leading cause of liver cancer. According to the World Health Organization (WHO), hepatitis B leads to more than 1 million deaths a year.

Last October, the French government suspended routine hepatitis B immunization of school children because of anecdotal reports that the vaccine caused multiple sclerosis. The French took action without any scientific evidence to back them up. Indeed, since this vaccine became available in 1982, more than 1 billion doses have been administered worldwide. It is 95 percent effective in preventing infection.

In countries where 8 percent to 15 percent of children were chronic carriers, vaccination has cut the rate to less than 1 percent. The WHO calls hepatitis B vaccine "one of the safest" vaccines available.

Never mind all that. The French government had something more pressing to worry about: politics. Some activists intent on curtailing vaccinations latched onto a combustible accusation — the alleged hepatitis B vaccine-MS connection — and they demanded action. The French government hastily bowed to their demands.

In contrast, the WHO turned to science. If the vaccine caused MS, somewhere in a billion doses, something ought to turn up. But an exhaustive search came up empty. The WHO reiterated the vaccine's safety. This message was reinforced by the Multiple Sclerosis Society of Canada, which cited "the lack of any scientific evidence" of a link between hepatitis B vaccine and MS.

Ironically, the French National Drug Surveillance Committee, a drug safety agency, found lower frequency of neurological diseases, including MS, among those vaccinated against hepatitis B tha the population at large.

The international health munity is concerned abou French action because it c erode confidence in vacci France's announcement result a 20 percent drop in hepatitis B immunization rates.

Activists are trying to raise similar concerns in the United States. They have launched Internet sites that attack universal vaccination, a principle widely advocated by public health experts and medical practitioners. A recent television news magazine reported that since 1991, when the Centers for Disease Control and Prevention endorsed hepatitis B vaccination of infants, 274 deaths have been reported. For most, the cause of death was listed as sudden infant death syndrome (SIDS). In contrast, 140,000 unvaccinated Americans become chronically infected with hepatitis B each year.

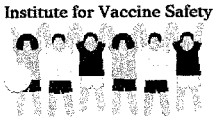
Does this mean some people might be considered expendable for the common good? No, of course not. It means we cannot precisely forecast the future. We don't know who is going to catch a disease, or who may have a reaction to a vaccine, or who will get sick from something completely unrelated right after getting vaccinated.

But we do know this: Vaccination prevents millions of deaths every year. Thanks to vaccines, diseases that once struck fear in every town in every nation have been eradicated in every corner of the world (smallpox) or nearly eradicated (polio).

Without universal vaccination, we would not be arguing over whether to preserve the last remnants of the smallpox virus. Instead, in the case of smallpox, we'd be digging graves — about 40 million of them in the last 20 years by the WHO's reckoning.

Dr. Shepherd is chairman of the Albert B. Sabin Vaccine Institute at Georgetown University, a nonprofit research and educational center. Previously, he led the team that developed the inhaler that asthma patients use to take their medications, and was chief executive of a pharmaceutical company.

Institute for Vaccine Safety



Johns Hopkins University

615 N. Wolfe Street
Suite 5515
Baltimore, Maryland 21205

Telephone
(410) 955-2955

Facsimile
(410) 502-6733

Director
al A. Halsey, MD
nhalsey@jhsph.edu

Co-Director
Lawrence H. Moulton, PhD
lmoulton@jhsph.edu

Coordinator
Tina Proveaux
tproveau@jhsph.edu

Executive Committee
Donald S. Burke, MD
Diane E. Griffin, MD, PhD
Neal A. Halsey, MD
Richard T. Johnson, MD
Lawrence H. Moulton, PhD

The Honorable Henry A. Waxman
House of Representatives
2204 Rayburn House Office Building
Washington, D.C. 20515

RE: May 18, 1999 Subcommittee hearing on Hepatitis B vaccine

Dear Representative Waxman:

The Institute for Vaccine Safety has participated in a review of hepatitis B vaccine safety. A copy of that report is enclosed (Pediatric Infectious Disease Journal 1999;18:23-4.). We request that the report and this letter be incorporated into the record of the hearings.

We sympathize with individuals who have developed multiple sclerosis and other disorders that the subcommittee is reviewing and we do not doubt that the witnesses on Panel II believe that they have been harmed by hepatitis B vaccine. However, their belief does not make it so. A detailed review of all of the scientific data reveals no convincing evidence of a causal relationship between hepatitis B disease or vaccine and multiple sclerosis or other demyelinating diseases. Unfortunately, confusion between temporal relationships and causality are made frequently by individuals, physicians and sometimes legislative bodies because there is a basic human need to find something to blame for unexpected illnesses of unknown cause.

Public health policy should be based on good science. There are rigorous scientific methods for determining causal relationships between medications, vaccines or other biological products and adverse events; a full description of these methods is beyond the scope of this letter or the congressional hearing. Observing a disorder in a vaccinated person does not constitute evidence of a causal relationship. Scientific studies conducted to date reveal no evidence of an increased risk of the disorders in question in individuals who have received vaccine as compared to those who have not.

After a careful three-day review of all available data, the Viral Hepatitis Prevention Board concluded that the World Health Organization (WHO) recommendation for universal immunization against hepatitis B that is in place in more than 100 countries should continue. WHO has made remarkable strides in implementing programs to control this infectious disease which causes more than 1 million deaths per year. We would hate to see any decisions made in the course of a brief review that would jeopardize the health benefits for people in the United States from hepatitis B vaccination.

The Institute for Vaccine Safety is committed to continuing to investigate possible causal relationships between vaccines and adverse events using objective scientific methods. Any additional information that we uncover regarding this issue we would be happy to share with the subcommittee on Criminal Justice, Drug Policy and Human Resources.

Sincerely,

Neal A. Halsey, MD
Director, Institute for Vaccine Safety
Professor/Director,
Division of Disease Control
Department of International Health
Johns Hopkins School of Public Health
Professor, Department of Pediatrics
Johns Hopkins School of Medicine
Chair, Committee on Infectious Disease
American Academy of Pediatrics

Lawrence H. Moulton, PhD
Co-Director, Institute for Vaccine Safety
Associate Professor,
Division of Disease Control
Department of International Health
Associate Professor,
Department of Biostatistics
Johns Hopkins School of Public Health

Pediatr Infect Dis J, 1999;18:23–4

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Hepatitis B vaccine and central nervous system demyelinating diseases

NEAL A. HALSEY, MD, PHILIPPE DUCLOS, MD, PIERRE VAN DAMME, MD, PHD AND
HAROLD MARGOLIS, MD, PHD, ON BEHALF OF THE VIRAL HEPATITIS PREVENTION BOARD

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Hepatitis B vaccine and central nervous system demyelinating diseases

NEAL A. HALSEY, MD, PHILIPPE DUCLOS, MD, PIERRE VAN DAMME, MD, PHD AND
HAROLD MARGOLIS, MD, PHD, ON BEHALF OF THE VIRAL HEPATITIS PREVENTION BOARD

On October 1, 1998, French authorities suspended temporarily the widespread school-based adolescent hepatitis B vaccine programs while continuing the universal infant immunization program. The French authorities continue to recommend hepatitis B vaccine for older children and adults at high increased risk of hepatitis B. Concerns had been raised by reports of multiple sclerosis or other demyelinating diseases occurring in adults who had recently received hepatitis B vaccine. The Viral Hepatitis Prevention Board, whose activities are incorporated into the Centre for the Evaluation of Vaccination, a World Health Organization collaborating center, called together a panel of experts to review the available data from several countries, including unpublished case-control studies from two countries, and issued the following brief summary. A complete report is available on the Viral Hepatitis Prevention Board Website, and a commentary from WHO reaffirming the strong support for universal hepatitis B vaccination programs is available at the WHO website.

New concerns about the safety of vaccines or other medical interventions capture public attention and can undermine confidence in physicians and governments. We must use sound scientific methods to assess these concerns and provide the public with objective information to allow for informed decision making and to maintain confidence in vaccines, which are one of our most effective tools for preventing disease in children.

Hepatitis B (HB) is one of the major diseases of mankind and is preventable with safe and effective vaccines. More than 2000 million persons have serologic evidence of past or current HB virus infection and there are >350 million chronic carriers of the virus at high risk of death from cirrhosis and liver cancer, diseases that kill almost 1 million persons a year. HB vaccine has been available since 1982 and >1 thousand million doses have been used. HB vaccine has been considered one of the safest and least reactogenic vaccines. The vaccine is ~95% effective in preventing the HB virus chronic carrier state, and direct reduction of liver cancer has already been documented in immunized children. Approximately 100 countries, consistent with World Health Organization policy, have added HB vaccination into their routine childhood immunization programs and most countries have in addition a policy to vaccinate adults at increased risk.

In recent years several case reports have raised concern that HB immunization may be linked to the onset of new cases or reactivation of multiple sclerosis (MS) or other demyelinating diseases within 2 to 3 months after vaccination. Since many countries use HB vaccine in their immunization program, a thorough scientific evaluation of these concerns was needed. The Viral Hepatitis Prevention Board, a World Health Organization Collaborating Centre for the prevention and control of viral hepatitis, therefore called a technical consultation on the safety of HB vaccines to review accumulated data and policy implications. This consultation took place in Geneva from September 28 through September 30, 1998, and brought together representatives from national public health and regulatory authorities, academia, the hospital sector, the pharmaceutical industry and the World Health Organization. Participants included experts in the fields of public health, epidemiology, immunology, neurology and pharmacology.

Participants were presented with data: (1) on the epidemiology of hepatitis B; (2) on the epidemiology of multiple sclerosis; (3) from national reporting systems of the US, Italy and Canada; (4) from one active surveillance system using pediatric hospitals in Canada; (5) from industry pharmaco-vigilance including postmarketing surveillance and clinical studies; (6) from published studies of hepatitis B vaccine safety; (7) from a small number of recent and still unpublished

Accepted for publication Oct. 26, 1998.

From the Institute for Vaccine Safety, Johns Hopkins University School of Public Health, Baltimore, MD (NAH); the Expanded Programme on Immunization, World Health Organization, Geneva, Switzerland (PD); the WHO Collaborating Centre for the Prevention and Control of Viral Hepatitis and the Viral Hepatitis Prevention Board (http://esoc-www.mia.ac.be/esoc/vhpb), University of Antwerp, Antwerp, Belgium (PVD); and the Hepatitis Branch, Centers for Disease Control and Prevention, Atlanta, GA (HM).

Key words: Vaccine safety, hepatitis B, central nervous system demyelinating disease, hepatitis B vaccine, multiple sclerosis.

Address for reprints: Dr. Neal A. Halsey, Institute for Vaccine Safety, Johns Hopkins School of Public Health, 615 Wolfe Street, Room 5515, Baltimore, MD 21205.

analytic epidemiologic studies conducted in France, the UK and the US (these were preliminary results).

The various theories used to explain a potential association between HB immunization and demyelinating diseases including MS in relation to biologic plausibility were also discussed, particularly with respect to immunologic theories.

The group reviewed the epidemiology and current understanding of the pathogenesis of MS. Current understanding of these diseases indicates a multifactorial pathogenesis and the contribution of both genetic and environmental factors. Numerous environmental factors including infectious agents have been evaluated in studies conducted throughout the world. Both the age distribution of onset of disease and migration studies suggest that exposure to an environmental agent in early childhood or adolescence contributes to the pathogenesis of MS with a 10- to 15-year interval to onset of disease. An increase in risk with increase in latitude has been consistently demonstrated, but this is a marker for an as yet unidentified factor.

There are three hypotheses that could explain the observed cases of demyelinating diseases following HB vaccine: (1) coincidence, because of the large number of HB vaccine doses administered, many of them in age groups where symptoms of MS first occur; (2) "triggering": an increased risk of symptomatic demyelination following HB vaccine, which would act as a "trigger" in individuals predisposed to develop MS or central nervous system (CNS) demyelinating diseases. These individuals would have developed demyelination with or without an altered natural history after some immunologic or other precipitating factor; (3) a true causal relationship between HB vaccination and MS or other CNS demyelinating disease.

Evidence to support the first hypothesis includes the fact that no statistically significant association was found between hepatitis B vaccine and MS in the limited studies conducted to date. Further the age and sex distributions of MS cases reported through spontaneous reporting systems match the recognized age and sex distribution of MS cases that preceded the use of the vaccine and are not correlated with vaccine administration.

In support of the hypothesis of an increased risk of MS after HB vaccination seen as a precipitating factor is that some studies have shown slightly elevated odds ratios, although these were not statistically significant. Evidence inconsistent with this hypothesis is the observation that no increased risk was found in another study.

No tangible evidence was presented for the biologic plausibility of any association: there is no evidence whatsoever of a link between hepatitis B virus infection and CNS demyelinating disorders including multiple sclerosis. Additional epidemiologic and immunologic research is ongoing or planned to further examine any association between vaccination, including hepatitis B, and CNS demyelinating disease. Altogether evidence in favor of an increased risk after vaccination is weak and does not meet the criteria for causality.

The data available to date, although limited, do not demonstrate a causal association between HB immunization and CNS demyelinating diseases, including MS. No evidence presented at this meeting indicates a need to change public health policies with respect to HB immunization. Therefore based on demonstrated important benefits, including the prevention of cirrhosis and cancer, and a hypothetical risk, the group supports the WHO recommendations that all countries should have universal infant and/or adolescent immunization programs and continue to immunize adults at increased risk of HB infection as appropriate.

Immunization Action
COALITION

1573 Selby Avenue, Suite 234
St. Paul, Minnesota 55104
phone: 651-647-9009
fax: 651-647-9131
e-mail: mail@immunize.org
website: www.immunize.org

May 13, 1999

Karen Nelson, Staff
Criminal Justice, Drug Policy and Human Resources Subcommittee
United States House of Representatives
B-373 Rayburn House Office Building
Washington, DC 20515

Dear Ms. Nelson:

The Hepatitis B Coalition, of which I am the executive director and medical director, strongly supports the recommendation to vaccinate children against the hepatitis B virus. Hepatitis B virus infection is a life-threatening disease that anyone of any age can come into contact with at any time in his or her life.

Children can get hepatitis B. Prior to the infant vaccination program which began in 1991, approximately 25,000 children under 10 years of age were infected with hepatitis B each year in the United States.

Anyone who is unvaccinated or not immune can get hepatitis B. Sexual activity is *only one form* of transmission. Hepatitis B can also be spread by sharing toothbrushes, washcloths, razors, or needles used by an infected person. Earpiercing and tattooing with unsterile equipment, a common practice among adolescents, also puts people at risk for hepatitis B.

I myself have administered thousands of doses of this vaccine in my practice, and have never received a report from a patient or a parent of an adverse reaction to this particular vaccine. Also, all three of my children have been vaccinated against this disease. My youngest child received his first dose of hepatitis B vaccine when he was one-day old.

The hepatitis B vaccine has a long-standing record of safety and efficacy. Every major medical organization in the United States stands behind the safety of the hepatitis B vaccine -- the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Medical Association.

More than 20 million people in the United States have been vaccinated against this disease and so have more than 500 million people throughout the world.

Hepatitis B is a very serious liver disease. It is spread by contact with blood or other body fluids from an infected person. In some cases, the virus can remain in the body for a lifetime and can cause ongoing liver damage, liver cancer, and death. Approximately 5,000 deaths occur in the United States each year due to hepatitis B-related liver failure or liver cancer.

What follows is a list of 128 important reasons why hepatitis B vaccine is recommended for all children, newborn through 18 years of age. None of these 128 people were ever given the opportunity to be vaccinated as infants or children. If somehow these people could have known six months ahead of time that they were going to come in contact with the hepatitis B virus, they could have begun the series of three simple shots that would have protected them. But, of course, no scientist, no doctor, no parent, no anti-immunization advocate, or no pro-immunization advocate could have predicted six months ahead of time that any of these people were going to come in contact with the hepatitis B virus. Consider the following:

- A 14-year-old Minneapolis, MN, student died of fulminant hepatitis B virus infection she contracted from an unknown source
- 4 junior high students in Minnesota contracted hepatitis B by sharing a contaminated needle to tattoo themselves
- 22 cases of hepatitis B were linked to a dermatologist's practice in Florida
- 26 patients in a California hospital contracted hepatitis B infection from medical equipment
- 35 patients of an acupuncturist in Rhode Island became infected with hepatitis B
- 31 cases of hepatitis B occurred among clients of a weight loss clinic in California
- 5 members of a high school sumo wrestling club in Japan developed hepatitis B from body contact
- A teacher in an elementary school setting in New Hampshire contracted hepatitis B from an infected student
- A homemaker from the East Coast with three children who has no idea how she contracted the virus
- Congressman Joe Moakley who had a liver transplant because of hepatitis B and has no idea how he contracted the disease
- A young woman who had two liver transplants as a result of hepatitis B and has no idea how she contracted the disease

I've attached documentation for all of these reports. I have also attached personal stories I have received from people who suffered or who had family members who suffered or died as a result of hepatitis B virus infection. Please read their stories. I believe all of these people would give anything to have had the opportunity to be vaccinated against hepatitis B when they were children.

The most important thing for all of us to remember is that anyone can get hepatitis B. The nation's hepatitis B prevention strategy is essential for the well-being of our nation's children and for their futures. Permanent disability and death from fulminant hepatitis B infection, liver failure, or liver cancer is preventable in the United States today thanks to this vaccine. We should embrace its availability and widespread use.

Please continue to support this safe, effective, and life-saving public health intervention.

Sincerely,

Deborah L. Wexler

Deborah L. Wexler, MD
Executive Director

Unprotected People index

IAC Home page

STORY #2
Parent of child with HBV testifies about importance of hepatitis B vaccination

A parent whose son is chronically infected with the hepatitis B virus delivered the following testimony in 1997 at a public hearing on the implementation of a hepatitis B school entry law.

The parent spoke on a personal level of the pain her entire family has suffered because of one family member's chronic illness. She concluded by urging parents to learn as much as they can about hepatitis B so that they can make truly informed decisions regarding school immunization and how to best protect their children.

The testimony is as follows:

I'm here to talk about my family. I'm not here to add to the list of statistics related to immunization issues. I'm here to personalize them, to bring them to a level that you can relate to from the heart rather than from a business, political, or clinical standpoint. My husband and I have three young children. One is a hepatitis B carrier. Although he is asymptomatic, biopsies at ages 3 and 4 confirmed that he already has cirrhosis. He did not respond to a 7-month course of interferon, a form of chemotherapy, and no other treatment has been available for him.

There is a four-letter "F" word which we try to shield our children from. It's something they shouldn't know anything about at such a young age. The word is Fear. Fear of social repercussions, fear of financial ruin, fear of sickness, death and loss.

You may have noticed that I have not provided our family name. I can't. The first thing hep B families learn, usually after rejection by friends or family, is to go to extreme lengths to protect their child's privacy. We desperately want to reach out for comfort when we learn our child has an incurable illness, but we can't. Local hospitals offer support groups for parents of children with cancer, but no help is available for parents of children who have life-threatening infectious diseases.

We feel an overwhelming need to warn day care workers, teachers, Sunday school caretakers, babysitters, playmates and their parents that extra care needs to be exercised if our child scrapes his knee, bites or is bitten, has a bloody nose, and so on. We want to tell everyone to get the shots. Yet we agonize over the negative consequences of "telling"....Will our child be treated fairly? Will he be ostracized on the playground? Will we ever find a babysitter? Will he have any friends or will our children be singled out as the kids to avoid? Will information given to the school nurse in confidence wind up as the topic of conversation at a PTA meeting? There are discrimination and disability laws that guarantee our child a public education, but there are no laws to protect my child's heart....

My husband and I attended a school meeting regarding one of our other children. During casual conversation, a mom mentioned that she'd heard that there was a child with hep B in our school district. She went on to tell the other concerned parents that she had visited the school superintendent in an effort to identify the child so that she could better protect her son. We sat paralyzed in silence, waiting for glances to turn in our direction (they didn't!), and all I could think was, get your kid the shots if you want to protect him. We supervise our child's play, we coach his soccer games, we are there as much as possible in order to protect other people's children. But it's obviously impossible to continue this vigilance as the children grow older. A neighbor tried to bandage our child's bleeding cut and I body slammed her away. She thinks I'm overprotective. She has no idea I was protecting her. No one else should have to live with this virus. It's preventable.

We worry about our ability to provide the best care for our child. His interferon treatment cost well over $20,000 and only a portion was covered by insurance. We are self-employed and we watched our health insurance premiums triple. We can't change carriers because we fear he could become sick or need a transplant during the "pre-existing condition exemption period" with a new policy. If no cure or control is found in the very near future, the likelihood that he will need a transplant is high. We have been warned that transplant and post-transplant care will most likely ruin us financially, and it is

only a temporary solution. The virus would eventually attack the new liver as well. We wonder whether we will be able to afford to put our children through college, how we will manage to retire.

I call this virus IT. Capital I, capital T. Stephen King fans will understand why. IT invades our lives, our thoughts, our spiritual beliefs, no matter what defenses we erect. I watch my happy children playing and IT reminds me that we will soon have to tell my son that he has a serious illness. Whenever he doesn't feel well, I wonder, "Is this IT"? How long will IT allow him to play the sports he loves? How will IT affect his school performance? The quality and length of my son's life are frightening unknowns, but statistics related to the progression and characteristics of this disease make it difficult to be optimistic. You can all look at your young children and fantasize about their senior proms and weddings. I cannot.

My son is a leader. He is clever, creative, charming. He is very protective of our other children and they look up to him. I fear the effect IT will have on his siblings, worry about how they will deal with their brother's illness, or worse. I fear that I will watch my child die, the worst possible thing that can happen to a parent. Doctors and parents have no control over the course this illness chooses within our children's bodies. However, the availability of the hep B vaccine allows us to control the spread of the disease to others. No other family should ever have to experience this pain. Three shots can prevent IT.

Hepatitis B is transmitted primarily through blood and sexual contact with infected persons. There are young, asymptomatic carriers who have not yet been diagnosed. Infected children will be socializing with and dating your children. It is clear to me that those of you who oppose immunizing our state's children are well informed about vaccine composition and side effects. I beg you to learn as much about the hepatitis B virus and disease progression as well. Only then will you be able to make a truly informed decision regarding school immunizations and how to best protect your children.

A Parent

Editors' note: The Immunization Action Coalition is collecting stories of people who have suffered or died from vaccine-preventable diseases.

Please let us know if you have personal stories, or if you know of stories that have appeared in the media, of the suffering that occurred because someone wasn't immunized. We also request case reports to help us illustrate the morbidity and mortality caused by vaccine-preventable diseases.

If you have stories and/or case reports that can help save lives, e-mail them to us at **deborah@immunize.org** or fax them to 651-647-9131.

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*E-mail: **admin@immunize.org** Web: http://www.immunize.org/*
Tel: 651-647-9009 Fax: 651-647-9131

This page was updated on October 14, 1998

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Story #3
Family remembers hepatitis B victim as a girl with promise

Two weeks after being diagnosed with acute hepatitis B virus infection, Kesha Johnson, a 15-year-old Minneapolis teenager, died of fulminant liver failure. Although Kesha's death occurred over four years ago, the Coalition continues to tell her story to illustrate why hepatitis B vaccine should be available for all children and teenagers.

To read "Family Remembers Hepatitis B Victim as a Girl with Promise," Kesha's story and her family and friends' reaction to her death, click here: **http://www.pioneerplanet.com/archive/docs/hepb1002.htm**. This story, which appeared in the "St. Paul Pioneer Press" on August 6, 1994, is copyrighted and has been placed on the Pioneer Planet website for our subscribers to read.

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FAMILY REMEMBERS HEPATITIS B VICTIM AS A GIRL WITH PROMISE

Molly Guthrey Staff Writer
Originally printed Saturday, Aug. 6, 1994

The family huddled quietly on the eve of their child's funeral in a home cloaked with almost tangible sorrow.

The North Minneapolis house used to be filled with 15-year-old Arkesha Johnson's easy peals of laughter. But on Thursday, it was painfully silent with grief-stricken relatives.

Terry Johnson, the girl's mother, sat at the kitchen table, her shoulders hunched as she talked about her daughter's sudden death of hepatitis B. She spoke softly and her eyes still had a glaze of shock about them, as if her mind was still trying to process her eldest daughter's death six days earlier.

Known to friends and family as Kesha, she was an honors student who excelled at math and science and who would have been a junior this fall at South High School in Minneapolis. She had a boyfriend and a best friend. She loved Janet Jackson and rap music and gospel music, too. She dreamed of becoming a surgeon or a pediatrician and planned to attend college - maybe Temple University - on grants and scholarships.

She was determined to be a success in life. Renee Johnson, one of her aunts, was so sure of her niece's academic talents that she was convinced that someday she would watch as Kesha was awarded the Nobel Prize after discovering a cure for cancer or AIDS.

Now, the family is trying to cope with the death of all those dreams surrounding their Kesha.

"I think any time you lose a child, you feel shock, hurt and pain, everything pretty negative rolled up into one," Renee Johnson said.

Kesha died on July 29 of hepatitis B, family members said, after being diagnosed about two weeks before. Until then, she had been

a seemingly healthy and active teen-ager - but then she started having stomach pains. She was nauseated and throwing up on July 14, the day her mother took her to the Hennepin County Medical Center.

The doctors ran some tests and found her liver badly damaged, family members said. They wouldn't let Kesha go home again, even to pack. She was transferred to the University of Minnesota Hospital, where her illness quickly worsened as family members tried to assimilate what was happening.

She never went home again.

She was removed from life support on July 29 as about 40 family members and close friends filled the room and cried. Only her aunt could bear to watch as Kesha stopped breathing. Some left the room, sobbing.

"I knew Kesha's spirit had already left us," said Renee Johnson.

She was the same Kesha they loved for the first nine days in the hospital, before the disease overtook her body and her mind. She giggled and watched television, visited with friends and family and hoped for the best.

None of them thought she would die. Family members said she was put at the top of a transplant list.

"There was always hope," said Kim Johnson, an aunt from Chicago. "We didn't think it would happen like this. The doctors had hoped it wouldn't. It was just so sudden."

There were so many relatives visiting that they filled up two waiting rooms. The operators at the university received hundreds of calls from well-wishers.

Family members said they have been told by doctors that it is rare for a person to be overcome so quickly by hepatitis. They're not sure how she caught the disease or why it happened so fast.

Hepatitis B is a highly infectious virus that attacks the liver. Infection can lead to severe illness, liver damage and sometimes death. Nationally, about 300,000 acute cases and 6,500 deaths occur annually, health officials say.

Last year in Minnesota, there were 77 cases of hepatitis B reported in Minnesota, 56 cases involving people aged 15 to 39. The infection has slowly been declining in Minnesota since 1988. Deaths are rare, health officials said.

"It is often a silent disease," said Dr. Deborah Wexler, of the St.

Paul-based Hepatitis B Coalition. "This is a perfect example of why every child in the United States needs to be vaccinated against hepatitis B."

Last year, Minnesota became the first state in the nation to recommend that all adolescents be immunized against the hepatitis B virus. State health officials took the step after they discovered the disease was becoming more prevalent among adolescents 15 and older.

At her funeral on Friday at St. John's Missionary Baptist Church on Morgan Avenue, Kesha looked a little bit like an angel in her casket, dressed in a cream dress with sparkly rhinestones sprinkled across her chest, resting in a bed of white velvet.

It was a girlish casket, brown with tiny pink flowers etched onto the sides.

It was a simple service, filled with simple words and songs and prayers. The choir she used to sing with sang for her. Her friend Cornell Washington also sang a song about their friendship, a cappella. He bowed his head to compose himself for minutes before he began.

"You never miss a good friend until she's gone," the boy sang in a shaky voice from the front of the church. "Life goes on, but it's not the same."

And her family and friends bowed their heads and began sobbing openly as the boy's song for Kesha filled the small church.

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Story #9
"I was at no risk for ever having hepatitis B!"

The following letter is written by a 35-year-old woman who contracted hepatitis B virus (HBV) infection. This mother of three children, like at least one third of people who contract hepatitis B, had no known risk factors for HBV infection. We are printing her story because, as she says, "I hope my story helps convince people to get their children and themselves immunized. No one should have to go through what I went through."

The letter is as follows:

I am a married 35-year-old woman and a stay-at-home mother of three young daughters -- ages 4, 7, and 10. I live in a small town on the New Hampshire seacoast. I've always been extremely healthy and active.

Last November 12th, I woke up and my joints were aching, especially my hips, knees, and ankles. I had just started an intense walking program, so my first thought was that I had "overdone" it. Each day, I felt progressively worse, and I finally made a doctor's appointment after suffering for about a week.

At the doctor's, I described my symptoms. He said that he thought my symptoms indicated "stress." He took some blood work to rule out rheumatoid arthritis and sent me home with a prescription for ibuprofen and the advice that I should consider going on antidepressants to eliminate the symptoms of "fibromyalgia." I felt devastated because I was sure something was wrong with me.

I continued to feel worse and worse every day. I began to feel more nauseated and exhausted than I can describe. Worse yet, my doctor had made me feel that it was "in my head" even though I told him that I did not feel depressed and was under very little stress!

After getting sicker and sicker, I finally made another appointment ten days later. The nurse practitioner took one look at me and noticed how jaundiced I looked. Also, my stools had become pasty looking and my urine quite dark. I thought I was just dehydrated from not eating for so long. She took blood work to determine if I had hepatitis and what type. I knew absolutely nothing about hepatitis at this point. I was just relieved that I had a diagnosis for what was wrong with me. She then described the ABC's of hepatitis.

I immediately assumed that I had hep A because I am in a category not considered "at risk" for the other types. Two days later, she called back with the results that I had hepatitis B. I felt as if my whole world had caved in.

My husband had to be tested. During the two days that we had to wait for the results, I felt that everything I believed about my marriage had to be a lie. When the results came back negative on my husband, he had to receive immunoglobulin because I had potentially infected him. I then had my two older daughters begin the vaccination series (my youngest had completed the series).

During the approximately six weeks that I felt so sick with this infection, I was so ill that I couldn't even take care of my kids. This whole experience was so incredibly demoralizing and humiliating. I believe that most people know nothing about hepatitis -- I know I didn't. If I had known that I had even the minutest chance of becoming infected with hep B, I would have run to my doctor's to get immunized. I've never felt so ill.

I can't describe how it felt to have to wait for six months to finally have the blood work done to rule out the chance that I had become a chronic carrier. No amount of reassurance from the nurse practitioner could convince me that my chance was minimal that I would be chronic. After all, I was considered at no risk for ever having hep B at all!

In June, I received my blood work results and the knowledge that I am completely recovered from hep B. I thank God for that. But I'm still dealing with the after effects of what I went through. My husband and I went to a counselor to deal with the stress that this whole situation placed on our marriage and how angry my husband felt because I hadn't trusted him. I feel sick at the thought that during the time of my acute infection, I could have infected my children or my husband.

This virus has such a stigma attached to it! I stopped telling anyone that I had been infected with hep B.

If my story makes even one person reconsider and have their child or themselves immunized, then it will make me feel better.

Over one third of all people who are infected each year with hep B are in the "no risk" category for infection. I'm one of them, and even a year later, I'm trying to put my horrible experience behind me. No one should ever have to suffer through being infected with this virus -- it is totally preventable with a series of three shots. "No risk" living is a meaningless term. If you go to dentist, borrow a toothbrush, get your ears pierced, get a manicure, or engage in countless other mundane activities, you could become infected.

I hope my story helps convince people to get their children and themselves immunized. No one should have to go through what I went through.

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Please let us know if you have personal stories, or if you know of stories that have appeared in the media, of the suffering that occurred because someone wasn't immunized. We also request case reports to help us illustrate the morbidity and mortality caused by vaccine-preventable diseases.

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Story #15:
MOTHER'S DEATH FROM HEPATITIS B MOVES DAUGHTER TO ACTION

In May 1998, IAC EXPRESS received an e-mail from a first-year Asian American medical student in which she shares the details of her mother's sudden death from hepatitis B. The tragedy has motivated this student to educate herself and her family and other Asian Americans about the risks of this vaccine-preventable disease.

The student's e-mail, printed with her permission, is as follows:

I recently suffered an immense loss. In the middle of January of this year, my mother experienced a sudden onset of peripheral edema and ascites. She tested negative for hepatitis B, but the doctors said that she had either liver cancer or severe cirrhosis. In the middle of February, a liver biopsy definitively diagnosed my mother as having hepatocellular carcinoma. This time, her hepatitis B serology came back positive, but her virus levels were low and nonreplicative. By the beginning of April, to the dismay of my family and all those who knew her, my mother fell into hepatorenal syndrome. She died while I was holding her days afterward, only two months after the diagnosis and one month after her intended early retirement.

Being a medical student, I could not help but feel helpless as I watched my mother slip away. What disturbed me even more was how unknowledgeable my cousins and I, all of whom are most likely infected with the same virus, were on the topic. I am writing to you today because I would like to stop feeling helpless. I would like to help educate my cousins, and other Asian Americans like us, of the risk that we face. Therefore, I would greatly appreciate it if you could inform me of the services that you provide, of the resources that you offer, and of the projects you plan. Please let me know how I can best join your effort, and how I can become actively involved with your organization. Thank you.

A First-Year Medical Student

Editors' Note: The Coalition sent this student a packet of our hepatitis B educational materials and referred her to other national organizations that are involved in hepatitis B activities in Asian Pacific Islander American communities. The Coalition's hepatitis B educational materials for providers and patients (some available in 16 languages) can be downloaded from our website at **http://www.immunize.org**.

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If you have stories and/or case reports that can help save lives, e-mail them to us at **deborah@immunize.org** or fax them to 651-647-9131.

No Risk?? No Way!!

Reprinted from *Hepatitis B Coalition News* Volume 4 - Number 1, September - December 1994

A common argument against routine hepatitis B immunization for infants is the belief that many of these infants have virtually no risk or an extremely low risk of ever contracting the hepatitis B virus in their lifetimes.

These low-risk individuals are usually defined by their race, socioeconomic status, geographic residence, and the lack of obvious risk factors. For example, a fourth generation farmer in northern Wisconsin is presumed to be safe from hepatitis B virus (HBV) while an Asian immigrant or pregnant teenager is considered to be "high risk." While degrees of risk certainly exist, facts do not support the existence of a "no risk" category, however comforting this notion might be to those who consider themselves in this group.

There are two major problems with not vaccinating all infants due to "low risk." The first is that transmission can sometimes occur in uncommon ways. Consider the six following documented cases:

1. Twenty-two cases of hepatitis B were linked to a Florida dermatologist's practice. Since the dermatologist was not a carrier, the outbreak is believed to have resulted from inadequate sterilization methods after surgical procedures. One of the cases was not a patient of the dermatologist, but the sexual partner of one of the infected patients (1).

2. From June 1989 through March 1990, 26 patients in a California hospital contracted acute HBV infection. A retrospective cohort study indicated that transmission of the virus occurred percutaneously through contamination of the stabilizing platform on a spring-loaded finger-stick device. Many medical offices use these devices to obtain capillary blood samples for checking hemoglobins and blood sugars (2).

> 22 cases of hepatitis B were linked to a Florida dermatologist's practice

3. In Rhode Island, 35 patients of an acupuncturist became infected with HBV, the primary source for the outbreak being a patient. Investigators were not able to determine the precise mechanism of transmission but it was possibly due to inadequately sterilized needles or the transfer of infectious material from the acupuncturist's hands to sterilized needles (3).

4. Thirty-one clinical cases of hepatitis B occurred among clients of a weight loss clinic in California. Infected persons had all received daily parenteral injections of human chorionic gonadotropin via a jet injector. The CDC proved that such a jet injector could transmit HBV despite proper swabbing of the tip, due to the inaccessibility of contaminated surfaces under the nozzle and cap (4).

5. In Israel, a butcher who was an asymptomatic hepatitis B carrier, infected three of his coworkers who in turn infected all of their spouses. Because of the nature of a butcher's work, the virus could have been transmitted through contact with HBV contaminated blood on the shared knives, either through hand cuts or punctures of the skin by the knife (5).

> 26 patients in a California hospital contracted acute HBV

6. In Japan, during a one-year period, hepatitis B developed in five of ten members of a high school sumo wrestling club. The asymptomatic index case had often bled from injuries received while wrestling, thereby transmitting HBV percutaneously to his teammates through cuts and abrasions (6).

The second problem with not vaccinating all infants against hepatitis B is that it is dangerous to make vaccination decisions based on a person's ethnicity, geographic area, or income. While farm families in northern Wisconsin may have a low risk of contracting hepatitis B, any individual within that group may have risk factors associated with family history or life style that make infection more likely. The following two histories involve persons traditionally considered at low risk for hepatitis B:

1. In August of 1977, physicians in northern Minnesota reported an unusual cluster of hepatitis B cases in their area. The outbreak continued for a year, beginning in International Falls then spreading to Hibbing, Ely, Bemidji, and Grand Marais, and eventually included 100 persons, four of whom suffered hepatic coma. Investigators discovered that the outbreak began in International Falls, a "low risk" town, best known for its cold temperatures, where workers in a paper mill shared a needle while injecting drugs (7).

2. In the same year, four cases of hepatitis B were reported in the northern suburbs of Minneapolis, after junior high students used a contaminated needle to tattoo themselves. Amateur tattooing is engaged in by young people from every socioeconomic group. Unfortunately, hepatitis B can have more lasting consequences than a poorly executed cross or heart (8).

These aforementioned cases of hepatitis B have not been highlighted to imply that the hepatitis B virus is hiding on every available surface just waiting to jump on the next unsuspecting victim. They do, however, indicate that one does not need to be sexually promiscuous or an inner-city IV drug abuser to come into contact with HBV. One can simply be the sexual partner of a man with a skin condition requiring treatment. These cases merely illustrate that a clinician cannot accurately determine all risk factors without knowing what goes on behind the closed doors of a patient's life.

While there are degrees of risk involved in contracting hepatitis B, these cases show there is no such thing as "no risk." On the average, any baby born in the United States has a five percent chance of acquiring HBV infection during his or her lifetime. By avoiding obvious means of exposure, people can reduce their odds of becoming infected. If they never go to the physician or dentist, never get their ears pierced or get a tattoo, never get bitten by a classmate, never engage in contact sports, never indulge in sex, never become a dentist, physician, nurse, medical assistant, laboratory technician, paramedic, police officer, maintenance worker, or butcher, they could possibly be considered "no risk." But in reality, as the U.S. Public Health Service so succinctly states, "Anyone can get HBV infection" (9). The good news is that since the advent of hepatitis B immunization, no one has to.

1. Florida State Health Office. Hepatitis B infection associated with a dermatologist's practice. Epi-Gram, Nov 1991;12:6.
2. Polish LB et al. Nosocomial transmission of hepatitis B virus associated with the use of a spring-loaded finger-stick device. N Engl J Med 1992;326:721-5.
3. Kent GP et al. A large outbreak of acupuncture-associated hepatitis B. Am J Epidemiol 1988;127: 591-8.
4. Canter J et al. An outbreak of hepatitis B associated with jet injections in a weight reduction clinic. Arch Intern Med 1990;150:1923-27.
5. Mevorach D et al. Hepatitis B - an occupational risk for butchers?Ann Intern Med 1992; 116:428.
6. Kashiwagi S et al. An outbreak of hepatitis B in members of a high school sumo wrestling club. JAMA 1992;248:213-214.
7. International Falls: hepatitis increase worries health officials. Minneapolis Tribune, July 4, 1978.
8. Cope L. Amateur tattooing causes hepatitis. Minneapolis Tribune, May 16, 1978.
9. U.S. Dept. of Health and Human Services. Important information about hepatitis B, hepatitis B vaccine, and hepatitis B immune globulin. May 1992. ✦

Item #P2100 (9/94)

Brief Report

Hepatitis B Virus Transmission in an Elementary School Setting

Ian Williams, PhD, MS; M. Geoffry Smith, MD; Dolly Sinha; Donald Kernan, MD; Gail Minor-Babin, RN; Enid Garcia, MD; Betty H. Robertson, PhD; Richard Di Pentima, RN; Craig N. Shapiro, MD

Context.—The risk of transmission of hepatitis B virus (HBV) in day care centers and schools is low.

Objective.—To investigate the source of HBV transmission for an elementary schoolteacher with acute hepatitis B.

Design.—Serologic survey for HBV infection among elementary school students, school staff, and household members of an HBV-infected teacher and student.

Setting.—General community and elementary school.

Patients.—Elementary school students and staff members and household members of an HBV-infected teacher.

Main Outcome Measures.—Elementary school students, school staff, and household members of an HBV-infected teacher were tested for markers of HBV infection. Samples positive for hepatitis B surface antigen (HBsAg) were tested for HBsAg subtype using monoclonal antibodies and examined for HBV DNA homology by polymerase chain reaction techniques.

Results.—An HBV-infected student and the teacher were found to have the same HBV subtype (ayw1-2) and to have identical HBV DNA sequences. The teacher reported none of the usual risk factors for acquiring HBV infection, and none of her family members had been infected prior to her illness. The specific means of HBV transmission from student to teacher was not identified. Of 108 total children in the same grade as the HBV-infected student, 102 (94%) were tested for serologic markers of HBV infection, and none was positive.

Conclusions.—This investigation documented transmission from an HBV-infected student to a teacher in an elementary school setting without a reported overt percutaneous or permucosal exposure to blood or infectious body fluids. Transmission of HBV to other students or staff members in the school was not observed.

JAMA. 1997;278:2167-2169

From the Hepatitis Branch, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Ga (Drs Williams, Garcia, Robertson, and Shapiro and Ms Sinha); the New Hampshire Division of Public Health Services, Concord (Dr Smith, Ms Minor-Babin, and Mr Di Pentima); and Mountain Health Services, Gorham, NH (Dr Kernan). Dr Smith is now with IPRO, Lake Success, NY.

Reprints: Ian Williams, PhD, MS, Hepatitis Branch, MS G-37, Centers for Disease Control and Prevention, 1600 Clifton Rd, Atlanta, GA 30333.

THE RISK OF hepatitis B virus (HBV) transmission between students or between students and staff in day care centers and schools appears to be low. This is likely due to infrequent opportunities for overt percutaneous or permucosal exposures to blood or infectious body fluids in these settings. Several studies have not shown HBV transmission to other children or staff members in day care and school settings where HBV-infected children are in attendance.[1-4] Several serologic studies have found that acquisition of HBV infection is rare among children and staff in day care centers, although in the United States, such studies have not been performed among schoolteachers.[5-7]

Two national advisory groups, the American Academy of Pediatrics (AAP) and the Advisory Committee on Immunization Practices (ACIP), recommend that HBV-infected children can attend school and day care without restriction because of the presumed low risk of HBV transmission.[8,9] Moreover, routine hepatitis B vaccination of staff members in day care centers and schools is not recommended. Nevertheless, in rare instances, HBV transmission has been documented in day care centers after direct percutaneous exposures, presumably through bites and scratches or exposure to blood or body fluids.[4,10,11] Some studies suggest that unrecognized HBV transmission may occur in school and day care settings through inapparent exposures to blood or body fluids, with hepatitis B e antigen (HBeAg)–positive children playing an important role in transmission.[12-15] This article describes an episode of HBV transmission from an HBV-infected student to an elementary schoolteacher and reviews the risk of HBV transmission in the classroom setting.

Background

In June 1995, a grade-school teacher presented to her private physician with nausea, abdominal discomfort, and jaun-

dice. Serologic testing showed she was positive for hepatitis B surface antigen (HBsAg) and IgM antibody to hepatitis B core antigen (IgM anti-HBc). She denied usual risk factors for hepatitis B, including household or sexual contact with a person infected with HBV, injection drug use, or blood transfusion. A student in her class during the previous school year was known by both the teacher and the school administration to be chronically infected with HBV. Because the student did not exhibit aggressive behavior or have medical conditions that would have increased the risk of HBV transmission, the student had been admitted to school without restrictions.

Methods

The state Division of Public Health Services and the Centers for Disease Control and Prevention (CDC) began an investigation in July 1995 to determine the teacher's source of infection and the extent of transmission, if any, from the HBV-infected student to other students and school staff. The teacher was reinterviewed regarding potential risk factors for acquiring hepatitis B for the 6-month period prior to her onset of illness, including injection drug use, sexual activity, blood transfusions, employment in a health care setting or institution for the developmentally disabled, hospitalization, outpatient surgery, dental work, acupuncture, tattooing, and body piercing. Her history of blood exposures, including lacerations, scratches, or bites, was also explored. The teacher and the family of the HBV-infected student were interviewed about blood or body fluid exposures occurring in school during the previous year (eg, nosebleeds, cuts, abrasions, or biting incidents).

Serum samples were obtained from the teacher's family members, the HBV-infected student, and other students and school staff. Students in the same grade as the chronically infected child from both schools in the community (representing a total of 5 classes) were included in the study in an effort to protect the HBV-infected student's identity. Informed consent was obtained from participating students' parents or guardians and from participating staff members. Serologic testing was performed by the state Division of Public Health Services and included total anti-HBc, HBsAg, and antibody to HBsAg (anti-HBs). Samples positive for HBsAg were tested for HBeAg and HBsAg subtype by using monoclonal antibodies.[16]

Serum samples positive for HBsAg also were examined for HBV DNA by polymerase chain reaction (PCR) amplification. Serum (50 µL) was digested with proteinase K followed by phenol chloroform extraction and ethanol precipitation. A portion of the core region was amplified using external primers HBV 1821P (5′ TTT TTC ACC TCT GCC TAA TC 3′) and HBV 2437N (5′ TTG AGA TCT TCT GCG ACG CGG C 3′); nested amplification was done with internal primers HBV 1858P (5′ ACT GTT CAA GCC TCC AAG CTG 3′) and HBV 2298N (5′ ATA GGG GCA TTT GGT GGT C 3′) using 30 cycles at 95°C for 30 seconds, 55°C for 30 seconds, 72°C for 45 seconds for both the external and nested amplifications. The PCR products were purified, and cycle sequencing was performed using the internal primers in the presence of dye terminators (Applied Biosystem Division/Perkin-Elmer, Foster City, Calif) and 5% dimethyl sulfoxide. An HBV sequence of 160 bases was analyzed and compared with other strains of HBV using Pileup (version 8.0, University of Wisconsin Genetics Computer Group, Madison).

Results

On reinterview, the teacher reported no risk factors for acquisition of hepatitis B and denied sexual partners other than her husband. She had 3 children, including a full-term infant born by vaginal delivery 3 weeks prior to her onset of illness. No invasive procedures had been performed during the course of her pregnancy. A routine screening performed in the first trimester of her pregnancy was HBsAg negative. When she was diagnosed as having hepatitis B, her infant received hepatitis B immune globulin and began hepatitis B vaccine (at 1 month of age). The infant's vaccine series was completed at 7 months of age. On testing at 8 months of age, the infant was HBsAg positive. Serologic testing of the teacher's spouse and 2 older children showed no evidence of HBV infection.

The HBV-infected student's mother was also chronically infected with HBV, and transmission was thought to have occurred at birth. A serum sample from the student obtained in August 1995 was found to be HBeAg positive and to contain approximately 225 µg/mL of HBsAg (35 sample ratio units at 1:20 480). The student had a diagnosis of attention deficit hyperactivity disorder and had been prescribed methylphenidate hydrochloride (Ritalin) in the 1994-1995 school year, but did not have a reported history of aggressive behavior. The student was reported as having good dental hygiene and had no history of dermatitis, nosebleeds, cuts, or abrasions in the previous school year. The teacher recalled no exposure to the student's blood. In March 1995, the student had forcefully sneezed copious amounts of saliva and nasal secretions onto her cracked, chapped hands. Although the teacher washed her hands immediately, she did not seek medical attention since no blood was visible. The teacher and student's family had no known commonalities outside the school setting (eg, they did not share the same dentist, and the teacher and the student's mother used different obstetrician-gynecologists).

The student and teacher were found to have the same HBV subtype (ayw1-2) and to have identical HBV DNA sequences for the portion of the core region that was studied. The infant born to the teacher in May 1995 was also found to have an HBV DNA sequence identical to the HBV-infected student.

Of 108 children in the same grade as the HBV-infected student, 102 (94%) were tested for serologic markers of HBV infection, and none was positive. None of the children tested had detectable anti-HBs or a history of hepatitis B vaccination. Of approximately 150 staff members, 94 were tested, and only 1 had serologic markers of HBV infection (total anti-HBc and anti-HBs positive). On interview, this staff member was found to have no contact with the HBV-infected student, and her spouse was found to be chronically infected with HBV.

Comment

Hepatitis B virus is present in high titers in blood and serous fluids and in moderate titers in saliva, semen, and vaginal secretions of infected individuals. Transmission of HBV occurs by percutaneous or permucosal exposure to blood or infectious body fluids and may also occur through indirect percutaneous routes that involve transfer of infectious body fluids from one person to another (eg, bites, scratches, and skin lesions). The most frequently reported risk factors for acquisition of hepatitis B in the United States are high-risk sexual activity and injection drug use.[17,18]

Person-to-person transmission of HBV has been well documented in situations of close personal contact, specifically among household members.[19,20] It is presumed that in these settings transmission occurs from skin lesions (such as eczema or impetigo) or sharing of blood-contaminated objects (such as toothbrushes or razors), although the specific pathway of percutaneous exposure is rarely identified. Since HBV has been found to be stable on environmental surfaces for at least 7 days, indirect inoculation may occur via inanimate objects.[21]

The epidemiologic investigation in this report supports the conclusion that the teacher acquired HBV infection in the school setting from the HBV-infected student, and the laboratory investigation showed sequence identity of isolates from

the student and teacher. While the teacher recalled no overt exposure to blood, she reported an instance when the student's saliva and nasal secretions had come into contact with her chapped hands. Although the concentration of virus in saliva of HBV-infected persons is several orders of magnitude lower than that found in blood,[22,23] it is possible that transmission occurred through exposure of the teachers' nonintact skin to the student's saliva. The risk of transmission may have been increased because of the relatively high titer of virus in the student's blood. Transmission from saliva has not been documented before except through percutaneous exposures (eg, a bite that broke the skin). Alternatively, transmission may have occurred through an event not recalled by either the teacher or the student.

Even though transmission from a student to a teacher was documented, transmission to other students or staff did not occur. While lists of class members from previous years were not reconstructed, many of the students included in this study had classroom contact with the HBV-infected student in several of the previous school years.

Direct or indirect exposure to infectious body fluids may occur in school settings; however, effective HBV transmission depends on several factors, including (1) a high concentration of virions circulating in the infectious body fluid, (2) a large volume of infective material transferred, (3) little loss of infectivity during transport of the inoculum, and (4) a percutaneous or permucosal inoculation.[24] In school settings, in contrast with household settings, these factors do not frequently come together to facilitate transmission of HBV from person to person. A possible explanation for this difference is that day care centers and schools may offer more structure and supervision than households, which may result in decreased opportunity for exposure to an HBV-infected individual's body fluids.

This single unusual case of HBV transmission from student to teacher does not suggest that the current AAP and ACIP recommendations that advocate inclusion of HBV-infected children in day care centers and schools should be changed or that routine HBV screening of children is warranted as a criterion for school entry.[8,9] However, appropriate prophylaxis after exposure should be considered in instances of percutaneous or permucosal exposure to HBsAg-positive blood or body fluids.[3] As the strategy of vaccinating all newborns and 11- to 12-year-old children against hepatitis B in the United States begins to decrease the pool of susceptible children,[25] the risk of HBV transmission in school settings will be virtually eliminated.

We would like to acknowledge Stephen Lambert, PhD, of the Hepatitis Branch, Centers for Disease Control and Prevention; Veronica Malmberg, MS, of the New Hampshire Division of Public Health Services; Robert Delisle and Jeannette Lozier, RN, of the Berlin Department of Health, Berlin, NH; Coos County Family Health Services; and the officials, staff, parents, and students for their assistance in conducting this investigation. Paul Swenson, PhD, of the Seattle-King County Department of Health, Seattle, Wash, performed the tests for HBeAg and HBsAg subtypes.

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niversal Prenatal Screening for Hepatitis B

Deborah Freese, MD
Mayo Clinic

Editors' note: Dr. Freese, pediatric gastroenterologist, is associate professor, Department of Pediatrics, Mayo Clinic. She is a member of the Liver Transplant Group at Mayo Clinic as well as an Advisory Board member of the Hepatitis B Coalition.

Based on phone calls to Minnesota hospitals, both rural and metropolitan, the Coalition found that the national recommendations from ACIP, ACOG, AAFP, AAP, as well as the Minnesota Department of Health and many other state health departments, to screen pregnant women for HBsAg before admission to labor and delivery, are not being followed universally. For this reason, the Coalition has asked Dr. Freese to address the issues of perinatal prevention and universal hepatitis B vaccination.)

Hepatitis B in the United States

Regular readers of this newsletter are certainly aware that hepatitis B poses a significant health risk to patients who become infected with the virus. In the United States, concern has been raised that the incidence of HBV infection is increasing, despite the availability of effective preventive strategies. Current estimates of the incidence of hepatitis B infection in this country suggest that approximately 300,000 new cases are noted annually, an increase of over 37% in the last 20 years. The point should be made that these figures are truly "estimates," since the calculated rate of infections per year is based on reported, clinically evident cases. Under-reporting and the observation that, particularly in young children, clinically evident disease may be absent (and therefore unnoticed), may result in underestimation of the true incidence of infection.

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In this country, adults and adolescents account for the majority of new cases of HBV infection. However, significant numbers of infants and young children are infected in specific settings, and the epidemiology of the infections in this group is quite distinct from those in older patients. Over 95% of otherwise healthy adults and older children who acquire HBV recover from the infection and suffer no long-lasting effects. In contrast, children who are infected under the age of 1 year stand a 90% chance of developing chronic infection, those under 5 years, a 40-50% chance. Indeed, in the United States, infants and young children account for fewer than 5% of acute HBV infections, but represent 30% of newly diagnosed chronic infections. In addition, although the majority of early childhood HBV infections are initially asymptomatic, young children appear to be at somewhat greater risk for the development of fulminant hepatitis, a frequently fatal complication. Clearly, children who become infected with HBV are at a disproportionate risk for the development of major complications, including chronic hepatitis with cirrhosis and liver failure, fulminant hepatitis, and the development of hepatocellular carcinoma. It stands ...ason that measures aimed at preventing HBV ...ction in this particularly vulnerable population could have a significant impact on the medical, social, and economic consequences of this disease.

Prevention of Neonatal HBV Infection

The first significant development in prevention of neonatal HBV infection came in the late 1970's when several studies convincingly showed that administration of hepatitis B immune globulin (HBIG) in the first two days of life and again at regular intervals throughout the first six months of life could prevent neonatal acquisition of the virus. Unfortunately, although this treatment was effective in preventing HBV in infancy, it provided no long-term protection. In fact, children born to HBsAg-positive women remain at high risk of infection for the first five years of life, with as many as 60% becoming infected during this period. This latter problem was solved in the early years of the last decade when researchers demonstrated that immunization with hepatitis B vaccine, given in combination with HBIG in the first 24 hours, not only prevented infection in infancy but also conveyed lasting protection in over 95% of treated infants.

The availability of effective prevention of both vertical and early horizontal transmission of HBV provided a rationale for attempts to identify HBsAg-positive pregnant women. If HBV carrier mothers could be identified prenatally, appropriate treatment could be administered to their offspring in the immediate postnatal period. In 1984, the Immunization Practices Advisory Committee of the U.S. Public Health Service (ACIP) issued recommendations for prenatal HBsAg testing of certain pregnant women deemed to be at substantially higher risk of HBV infection than the general population. These recommendations were based primarily on the premise that the majority of perinatal HBV transmission in the United States arose from Asian women, predominately first-generation immigrants. It was believed that the HBV carrier rate in other ethnic populations was substantially lower, and that infected women in these groups could be easily identified by life-style, occupational, or medical circumstances.

The Rationale for Universal Screening

In recent years, the correctness of these assumptions has been called into question. Five years of experience with prenatal screening of high-risk women did not result in a significant decrease in perinatal HBV transmission. Moreover, two separate studies of pregnant women in inner-city public health clinics showed that even when well-qualified observers were involved, the ACIP criteria for high-risk women were capable of identifying only 40% of HBV carriers. In other words, 60% of HBV carrier mothers did not fit into any known risk group. In these studies, the only risk factor for HBV carrier status that could be identified was low socioeconomic status. Thus, even when properly applied, the strategy of screening only "high-risk" women did not appear to be effective in preventing perinatal HBV transmission.

Recent surveys showed that only 60%(of obstetric health care providers) could name just two groups thought to be at high risk of HBV infection and only 28% knew the appropriate treatment of infants born to infected mothers.

In fact, there were probably several reasons for the apparent failure of the high-risk screening strategy when it was applied to the general U.S. population.

First, the majority of obstetric health-care providers appeared to lack sufficient knowledge to effectively implement the ACIP recommendations. Recent surveys showed that only 60% could name just two groups thought to be at high risk of HBV infection and only 28% knew the appropriate treatment of infants born to infected mothers. Second, many providers, especially those in busy inner-city clinics, lack the time to administer a careful medical history and many of their patients have not sought adequate

prenatal care even if time were available. Third, patients may not be honest about behaviors which could put them at risk for HBV infection. Finally, and perhaps most importantly, the epidemiology of HBV infection in the U.S. population has changed significantly over the last ten years, and previous assumptions of high-risk groups may no longer be valid. For example, the proportion of HBV infections in the general population attributed to homosexual and occupational exposure has declined significantly while that related to parenteral drug use and multiple heterosexual partners has increased dramatically.

Risk Factors Associated with HBV Infection (Ref. #1)

Unknown	37%
Heterosexual Activity	26%
Drug Abuse	23%
Homosexual Activity	8%
Health Care Employment	3%
Household Contact	2%
Transfusion, Dialysis, Other	1%

It appears that rates of HBV infection in blacks, Hispanics, and other minority groups are much higher than had previously been assumed, and there has been a major increase in the incidence of HBV in adolescents of all ethnic groups.

These observations led many investigators to conclude that the policy of screening only high-risk women was not a workable solution to the problem of perinatal HBV transmission. The Centers for Disease Control (CDC) has now developed a comprehensive prevention strategy for HBV which includes recommendations for universal screening of all pregnant women for HBsAg during an early prenatal visit. Testing should be repeated in women who are negative but who are at high risk of HBV infection, i.e., IV drug users, those with intercurrent sexually transmitted diseases, or those who have had clinically evident hepatitis.

Studies have shown that up to 30% of neonates infected at birth with HBV will die of chronic liver disease by the age of 50 and another 3-5% will develop hepatocellular carcinoma.

Recommendations for universal prenatal HBsAg screening make abundant sense, both medically and economically. Screening not only allows for the prevention of HBV in the neonate, but also identifies infected carrier women who can then be monitored and treated appropriately. It also enables health care providers to detect other susceptible family members who may then be immunized. The medical consequences of failing to identify and treat infants of HBV carriers are significant. Studies have shown that up to 30% of neonates infected at birth with HBV will die of chronic liver disease by the age of 50 and another 3-5% will develop hepatocellular carcinoma. Arevalo and Washington (6) calculated the direct and indirect cost of caring for patients with HBV-associated chronic liver disease and concluded that universal screening was cost effective at a disease prevalence of 0.06%, a figure significantly lower than the estimated national prevalence of 0.2-0.3%. Although some dispute these findings, the figures used to arrive at these conclusions were very conservative estimates of the cost of caring for patients with chronic liver ailments. New technological developments such as interferon therapy and liver transplantation, while effective in some patients, likely push the costs up substantially.

An Infant with Fulminant Hepatitis B

The medical and economic costs of failing to screen for HBV can be illustrated on a more personal level by the case of a single infant recently cared for in the Twin Cities. This patient was the child of a middle class couple from a farming community in a neighboring state.

During her initial prenatal visit, the mother gave a history of having had hepatitis of some sort 20 years previously. She was told at that time that she had recovered from the disease and would subsequently be immune to further hepatitis infections. Despite the fact that a previous history of hepatitis would place her in the "high-risk" category, no prenatal HBV screening was done. Pregnancy and delivery were uncomplicated, and the baby did well for the first two months of life. At that time, the parents began noting

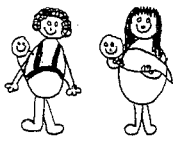
Despite the fact that a previous history of hepatitis would place her in the "high-risk" category, no prenatal HBV screening was done.

feeding difficulties, irritability, and jaundice. Evaluation revealed severe coagulopathy, markedly elevated liver tests, and hypoglycemia. The infant was eventually referred for liver transplantation with the diagnosis of fulminant hepatitis B. The infant was admitted to the intensive care unit, received very aggressive medical management, and an urgent search for donor was initiated. No suitable donor could be located, the child continued to deteriorate and died after two weeks from hepatic encephalopathy and herniation.

Hepatitis B screening was then done for the surviving family members. It was found that mother, father, and the other two young children were all positive for HBV. Mother and one child had significantly elevated liver tests and are undergoing further evaluation. It seems clear that had HBV screening been carried out, none of the children would have been infected and the death of the youngest could have been prevented. The economic impact on the health care system from this one family alone is significant. It includes the costs of hospitalizations at two hospitals of the infant who died (approximately $100,000), the immediate costs of evaluation and possibly therapy for the surviving child with evidence of chronic hepatitis, and the long-term costs of monitoring and observation in both chronically infected children. Had successful liver transplantation been possible for the infant, the costs of that procedure and lifetime immuno-suppression would have further increased the costs.

Is Universal Screening Still Necessary?

Some would suggest that current recommendations for universal infant vaccination make prenatal screening unnecessary. Indeed, in some areas of world where HBV is endemic, laboratory facilities are scarce, and disease prevalence is high, no screening is done and all infants are vaccinated in the first hours of life. There are several arguments to suggest



Vaccinate all babies against hepatitis B!

that this may not be an appropriate strategy in this country. First, there remains considerable controversy about universal infant vaccination in areas where disease prevalence is low, and this policy has not been put into effect in many states. In Minnesota, a recent Health Department newsletter states that there were no plans to mandate infant HBV vaccination. Universal HBV screening then remains the only modality to assure appropriate treatment of infants at risk for infection. Second, there is no general agreement in this country about HBV vaccination schedules, with many suggesting incorporation of the HBV antigen into a single injection "megavaccine" to be given at 2, 4, and 6 months along with other childhood immunizations. This would obviously not be a correct approach for children with HBV positive mothers. Finally, some recent studies have suggested that sick neonates and prematures less than 34 weeks of gestation may not be capable of mounting an adequate immune response to the vaccine. These infants would then require HBIG for protection if mothers are positive. Until all infants are routinely immunized against HBV, universal screening appears to be the most effective strategy for control of HBV transmission in the early years of life. To place this concept in perspective, Kane et al have compared the impact of screening 3.5 million pregnant women yearly with that of our currently policy of universal screening of 9 million units of blood annually. Maternal screening would allow for the treatment of the infants of the estimated 22,000 HBsAg-positive pregnant women who deliver each year. This would prevent 3,500 to 4,000 children from becoming chronically infected. Untreated, 25% of these children will ultimately die of liver disease. Blood bank screening is estimated to prevent approximately 9,000 HBsAg-positive transfusions yearly which would result in 3,000 clinical cases of hepatitis, most of which occur in adults. Since the incidence of chronic infection in adults is much lower than in infants, current blood screening practices prevent chronic infection in 500 to 900 patients, substantially l preventable mortality than universal prena screening could achieve. If we can afford to prevent HBV in the adult population of the country, can we afford to do any less for our children?

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Mr. MICA. Also, since notice of the hearing, we have many associations and groups from all over the country providing us with remarks they have requested be entered in the record. I would like to ask unanimous consent that they also be made part of the record and without objection, so ordered.

I would now like to recognize the gentleman from Massachusetts, Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman, and thank you for holding this hearing on the important topic of hepatitis B vaccine.

Less than 100 years ago, infectious diseases were the most common cause of death, disability, and disease in the United States. Polio, pertussis, measles, and diphtheria killed and disabled millions of people. However, because of the development and use of vaccines, these diseases are a distant memory for most Americans. Unfortunately, as old threats fade away, new threats to public health emerge.

Today hepatitis B, an infectious disease which can be eliminated with universal vaccination, unnecessarily kills thousands of people a year in the United States. According to the CDC, in the United States, 200,000 people contract hepatitis B each year.

Each year over 11,000 people are hospitalized and 20,000 remain chronically infected. Overall, an estimated 1.25 million people in the United States have chronic hepatitis B infection; and 4,000 to 5,000 die each year from hepatitis B, related chronic liver disease or liver cancer.

Hepatitis B vaccine prevents both hepatitis B infection and those diseases related to hepatitis B infection. The vaccine has been available since 1982. The CDC has recommended the hepatitis vaccine as part of the routine infant vaccination schedule since 1991.

Prior to the CDC recommendations, approximately 30,000 infants and children became infected with hepatitis B each year. Hepatitis B vaccines are safe and effective. More than 20 million people have received the hepatitis B vaccine in the United States and more than 500 million have received the vaccine worldwide.

Mr. Chairman, I am glad to hear all of our witnesses today, but particularly honored with the presence of Representative Joe Moakley, dean of the Massachusetts delegation. We all know Mr. Moakley as the voice of the 9th Congressional District of Massachusetts and the ranking Democrat on the Rules Committee.

However, many of us are not aware of his personal experience with hepatitis B. In the 1980's he was diagnosed with hepatitis B. For several years he didn't know that he had contracted the disease. However, in 1995 with only a few months to live because of the damage the disease had caused to his liver, he received a liver transplant. Today he is a healthy man, and he is here to share with us his thoughts about the hepatitis B vaccine, and I look forward particularly to hearing his testimony.

Mr. Chairman, thank you again for this important hearing.

Mr. MICA. Thank you again for your opening statement and also for your comments and introductory remarks about our colleague, Mr. Moakley.

[The prepared statement of Hon. John F. Tierney follows:]

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OPENING STATEMENT OF

REP. JOHN F. TIERNEY

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

MAY 18, 1999

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dean of the Massachusetts delegation. We all know Mr. Moakley as the voice of the 9th congressional district of Massachusetts and the ranking democrat of the Rules Committee. However, many of us are not aware of his personal experience with hepatitis B. In the 1980's he was diagnosed with hepatitis B. For several years, he did not know that he had contracted the disease. However, in 1995, with only a few months to live because of the damage the disease had caused to his liver, he received a liver transplant . Today, he is a healthy man and is here to share his thoughts about the hepatitis b vaccine. I look forward to hearing his testimony.

Mr. Chairman, thank you for holding this important hearing.

Mr. MICA. Our first panel is made up of individuals who have had some personal experience with hepatitis B, including our colleague. Let me introduce the panel, and I think Mr. Tierney has given an introduction to Joe Moakley.

We have Michael Belkin, Judy Converse, Marilyn and Lindsay Kirschner, Barbara Hahn, Karen with PKIDS, and we have Betty Fluck.

That is our first panel, and again all of these individuals have some personal relationship and experience with the problem of hepatitis B.

Except for Mr. Moakley—we don't swear in our Members of Congress—this subcommittee is an investigations and oversight subcommittee, and so we do swear in our witnesses. Again, with the exception of our Member, if you could all please stand.

[Witnesses sworn.]

Mr. MICA. The witnesses have answered in the affirmative and I would like to take this opportunity to welcome each and every one of you for participating and for coming forward and providing this subcommittee with your important testimony and personal experience.

Since we have such a large number of requests for witnesses, we are going to try to adhere pretty strongly to the 5-minute rule. If you have a lengthy statement or additional information you would like made part of the record, upon request we will have that entered into the record.

So with those opening remarks and welcome, I would like to now recognize the distinguished gentleman from Massachusetts and ranking member, former chairman of the Rules Committee, Mr. Moakley.

STATEMENTS OF HON. JOHN JOSEPH MOAKLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MASSACHUSETTS; MICHAEL BELKIN; JUDY CONVERSE; MARILYN AND LINDSAY KIRSCHNER; BARBARA HAHN; KAREN WITH PKIDS; AND BETTY FLUCK

Mr. MOAKLEY. Thank you very much, Chairman Mica and Congressman Waxman and my colleague from Massachusetts, Congressman Tierney. I thank you very much for allowing me to testify today and give my perspective on the hepatitis B immunization.

As Congressman Tierney said, I was diagnosed with hepatitis B in the early 1980's. The doctors thought I may have gotten it on a congressional fact-finding trip to China, but they were not sure.

Mr. Chairman, this is one of the frightening aspects of hepatitis B. Thousands and thousands of people contract it and have no idea how they got it. In fact, 40 percent of the people who get hepatitis B aren't in the so-called high-risk categories and don't even realize that they have it for many, many years.

I was sick for years, and had no idea that my liver was failing. In the spring of 1995, after a thorough examination, my doctor told me I had 2 months to live. The hepatitis virus had led to cirrhosis of my liver. I was very sick, had no strength; and I was severely jaundiced, but I was one of the lucky ones.

I was put on a waiting list for an organ transplant and received a donor organ just before it was too late. This July it will be 4

years since my successful liver transplant, and there is not a day that goes by that I don't thank God for my renewed health.

Unfortunately, 1.25 million Americans have hepatitis B and are potentially infectious to others. Each year 150,000 Americans get hepatitis B and 4,000 to 5,000 die from it. These are very alarming statistics, made even more tragic by the sad reality that we have a severe shortage of organ donors in this country, and many of these people with hepatitis B will eventually require a liver transplant.

That is why immunization is still the most effective means of preventing hepatitis B and its consequences. Hepatitis B vaccines are safe and highly effective in preventing hepatitis B infection amongst susceptible children and adults.

You say 42 States; I don't know. It is somewhere between 38 and 42, including my own State of Massachusetts, that have enacted laws requiring children to be vaccinated against hepatitis B before they enter kindergarten. Immunization is still the best weapon and by far the most cost-effective way we have to prevent this devastating disease.

I have heard of the recent reports which question the safety and the efficacy of the hepatitis B vaccine. Some of them link the vaccine to multiple sclerosis and other autoimmune diseases. But, Mr. Chairman, I have some of the same information that Mr. Waxman has. The World Health Organization, the American Academy of Pediatrics, and the Multiple Sclerosis Society have all recommended that the hepatitis B vaccine not be suspended.

Experts have reviewed the data and determined that there is no clinical or scientific evidence whatsoever linking the hepatitis B vaccine with multiple sclerosis or other autoimmune disorders. The fact of the matter is that the benefits of the hepatitis B vaccine far outweigh any of the claimed risks.

Hepatitis B infection is still a real threat in this Nation and throughout the globe. That is why it is so important to continue with this immunization. These are programs to prevent the spread of this terrible disease. Hepatitis B is a highly contagious disease, 100 times more contagious than HIV; and we have to continue to immunize our infants and children.

The truth is, when immunization rates fall the disease returns. We saw this a few years ago when there were huge outbreaks of measles, which everybody assumed was under control. So even though these reports of people developing disorders after vaccinations are very, very tragic, we need to look at the clinical and scientific evidence.

The Institute of Medicine, the World Health Organization, and the French Government have all conducted studies that conclude there is no evidence of a causal relationship between hepatitis B and multiple sclerosis or other disorders. As sad as these stories are, and I have heard them all, Mr. Chairman, they should not determine public health policy in this country. Because, Mr. Chairman, if we suspend immunization programs, we will only end up with more cases of hepatitis B that could be even more tragic.

Take it from me. I don't wish this terrible disease on anyone. There is no reason for anyone to suffer from this disease. It is totally preventable. So I look forward to the day that hepatitis B

meets the same fate as small pox. Mr. Chairman, this vaccination will help get us there.

Thank you very much, and I have a conflict of time so if there are any questions, I would be glad to answer them now, and then I would like to be excused.

Mr. MICA. Thank you. We would be glad to extend that courtesy to you.

[The prepared statement of Hon. Joe Moakley follows:]

Testimony of Congressman Joe Moakley (D-MA)
Government Reform Subcommittee on Criminal Justice,
Drug Policy and Human Resources
May 18, 1999

GOOD MORNING.

THANK YOU CHAIRMAN MICA AND RANKING MEMBER WAXMAN FOR ALLOWING ME TO TESTIFY TODAY AND GIVE MY PERSPECTIVE ON HEPATITIS B IMMUNIZATION.

I WAS DIAGNOSED WITH HEPATITIS B IN THE EARLY 1980'S. THE DOCTORS THOUGHT I MIGHT HAVE GOTTEN IT DURING A CONGRESSIONAL FACT FINDING TRIP TO CHINA, BUT THEY WERE NOT SURE.

AND MR. CHAIRMAN THAT IS ONE OF THE VERY FRIGHTENING ASPECTS OF HEPATITIS B. THOUSANDS OF PEOPLE GET IT AND HAVE NO IDEA HOW. IN FACT, 40% OF THE PEOPLE WHO GET HEPATITIS B AREN'T IN ANY OF THE HIGH RISK CATEGORIES AND DON'T EVEN REALIZE THAT HAVE IT.

LOOK AT ME. I WAS SICK FOR YEARS AND I HAD NO IDEA THAT MY LIVER WAS FAILING.

IN THE SPRING OF 1995, AFTER A THOROUGH EXAMINATION, MY DOCTOR TOLD ME THAT I HAD TWO MONTHS TO LIVE.

THE HEPATITIS B VIRUS HAD LED TO CIRRHOSIS OF MY LIVER WHICH WAS BASICALLY NOT WORKING AT ALL. I WAS VERY SICK. I HAD NO STRENGTH AND I WAS SEVERELY JAUNDICED.

BUT, I WAS ONE OF THE LUCKY ONES. I WAS PUT ON A WAITING LIST FOR AN ORGAN TRANSPLANT AND RECEIVED A DONOR ORGAN JUST BEFORE IT WAS TOO LATE.

THIS JULY IT WILL BE FOUR YEARS SINCE MY SUCCESSFUL LIVER TRANSPLANT AND THERE ISN'T A DAY THAT GOES BY THAT I DO NOT THANK GOD FOR MY RENEWED HEALTH.

UNFORTUNATELY, MORE THAN ONE AND A QUARTER MILLION AMERICANS HAVE HEPATITIS B AND ARE POTENTIALLY INFECTIOUS TO OTHERS. EACH YEAR, 150,000 AMERICANS GET HEPATITIS B AND 4,000 TO 5,000 DIE FROM IT.

THESE ARE VERY ALARMING STATISTICS MADE EVEN MORE TRAGIC BY THE SAD REALITY THAT WE HAVE A SEVERE SHORTAGE OF ORGAN

DONORS IN THIS COUNTRY AND MANY OF THESE PEOPLE WITH HEPATITIS B WILL EVENTUALLY REQUIRE A LIVER TRANSPLANT.

THAT'S WHY IMMUNIZATION IS STILL THE MOST EFFECTIVE MEANS OF PREVENTING HEPATITIS B AND ITS CONSEQUENCES. HEPATITIS B VACCINES ARE SAFE AND HIGHLY EFFECTIVE AMONG SUSCEPTIBLE CHILDREN AND ADULTS.

42 STATES, INCLUDING MY HOME STATE OF MASSACHUSETTS, HAVE ENACTED LAWS THAT REQUIRE CHILDREN TO BE VACCINATED AGAINST HEPATITIS B BEFORE THEY ENTER KINDERGARTEN. IMMUNIZATION IS STILL THE BEST WEAPON AND BY FAR THE MOST COST-EFFECTIVE WAY WE HAVE TO PREVENT THIS DEVASTATING DISEASE.

I'VE HEARD OF THE RECENT REPORTS WHICH QUESTION THE SAFETY AND EFFICACY OF THE HEPATITIS B VACCINE. SOME OF THEM LINK THE VACCINE TO MULTIPLE SCLEROSIS AND OTHER AUTOIMMUNE DISEASES. BUT, MR. CHAIRMAN, I HAVE SOME OF THE SAME INFORMATION MR. WAXMAN HAS, THE WORLD HEALTH ORGANIZATION, THE AMERICAN ACADEMY OF PEDIATRICS AND THE MULTIPLE SCLEROSIS SOCIETY HAVE ALL RECOMMENDED THAT THE HEPATITIS B VACCINE NOT BE SUSPENDED. EXPERTS HAVE REVIEWED THE DATA AND DETERMINED THAT THERE IS NO CLINICAL OR SCIENTIFIC EVIDENCE WHATSOEVER LINKING THE HEPATITIS B VACCINE WITH THE MULTIPLE SCLEROSIS OR ANY OTHER AUTOIMMUNE DISORDERS.

THE FACT OF THE MATTER IS THE BENEFITS OF HEPATITIS B IMMUNIZATION FAR OUTWEIGH ANY OF THE CLAIMED RISKS.

HEPATITIS B INFECTION IS STILL A REAL THREAT TO THIS NATION AND THROUGHOUT THE GLOBE. THAT IS WHY IT IS SO IMPORTANT TO CONTINUE WITH THE IMMUNIZATION PROGRAMS. THESE ARE PROVEN TO PREVENT THE SPREAD OF THIS TERRIBLE DISEASE -- 100 TIMES MORE CONTAGIOUS THAN HIV -- AND WE HAVE TO IMMUNIZE OUR INFANTS AND CHILDREN.

THE TRUTH IS, WHEN IMMUNIZATION RATES FALL, THE DISEASE RETURNS. WE SAW THIS A FEW YEARS AGO WHEN THERE WERE HUGE OUTBREAKS OF THE MEASLES, WHICH EVERYBODY ASSUMED WAS UNDER CONTROL.

SO EVEN THOUGH THESE REPORTS OF PEOPLE DEVELOPING DISORDERS AFTER VACCINATIONS ARE VERY TRAGIC, WE NEED TO LOOK AT THE CLINICAL AND SCIENTIFIC EVIDENCE.

THE INSTITUTE OF MEDICINE, THE WORLD HEALTH ORGANIZATION AND THE FRENCH GOVERNMENT HAVE ALL CONDUCTED STUDIES THAT CONCLUDE THAT THERE IS NO EVIDENCE OF A CASUAL RELATIONSHIP BETWEEN HEPATITIS B AND MULTIPLE SCLEROSIS OR OTHER DISORDERS. AS SAD AS THESE STORIES ARE, THEY SHOULD NOT DETERMINE PUBLIC HEALTH POLICY IN THIS COUNTRY.

BECAUSE, MR. CHAIRMAN, IF WE SUSPEND THE IMMUNIZATION PROGRAMS, WE WILL ONLY END UP WITH MORE CASES OF HEPATITIS B -- AND THAT COULD BE EVEN MORE TRAGIC.

TAKE IT FROM ME, I DON'T WISH THIS TERRIBLE DISEASE ON ANYONE. THERE IS NO REASON FOR ANYONE TO SUFFER FROM THIS DISEASE. IT IS TOTALLY PREVENTABLE.

I LOOK FORWARD TO THE DAY THAT HEPATITIS B MEETS THE SAME FATE AS SMALL POX, MR. CHAIRMAN. THIS VACCINATION WILL HELP GET UP THERE.

THANK YOU VERY MUCH.

Mr. MICA. Mr. Waxman, do you have any questions of Mr. Moakley at this time?

Mr. WAXMAN. No. I want to thank you very much for your testimony. I think you have told us in a very eloquent way, from your own personal experience, if we can prevent this disease and how important it would be to do so. Thank you.

Mr. MICA. Mr. Tierney.

Mr. TIERNEY. I have no questions. Just to thank you and say that we are glad that the results are as they were.

Mr. MOAKLEY. I am, too. Thank you, Mr. Chairman.

Mr. MICA. Thank you, Mr. Moakley. I don't have any questions at this time, but I am going to listen to all of the panels that we have, and I may personally get back with you.

Mr. MOAKLEY. That would be great.

Mr. MICA. And, hopefully, have some more educated questions at that time.

Mr. MOAKLEY. And I would be willing to present myself to the panel once again, if necessary.

Mr. MICA. We will now hear from Mr. Michael Belkin.

Mr. BELKIN. Thank you for holding this hearing, Mr. Chairman.

First of all, I would like to submit for the record, the 25,000 adverse reaction reports from the government reporting system and my recorded testimony which is an investigation of those reports.

Mr. MICA. I don't know if we will be able to submit all of those in the record. But what we can do is make reference to them, and they can be kept with the committee. I think that would be appropriate. Is that acceptable?

Mr. TIERNEY. That is fine.

Mr. MICA. We will do that because it is almost impossible to include all of those in the report. We will make reference to them, and they will be kept with the committee records. Without objection, so ordered.

Mr. BELKIN. My daughter Lyla Rose Belkin died on September 16, 1998, at the age of 5 weeks, about 15 hours after receiving her second hepatitis B vaccine booster shot.

Lyla was a lively, alert 5-week-old baby when I last held her in my arms. Little did I imagine as she gazed intently into my eyes, with all of the innocence and wonder of a newborn child, that she would die that night. She was never ill before receiving the hepatitis B shot that afternoon. At her final feeding, she was extremely agitated, noisy and feisty and then she fell asleep suddenly and stopped breathing. The autopsy ruled out choking.

The New York medical examiner ruled her death sudden infant death syndrome, but in the notes and in the conversations with our pediatrician on the day of the autopsy—this is in the pediatrician's notes—what the coroner said, "Brain swollen. Not sure cause yet. Could not see how recombinant vaccine could cause problem."

SIDS is a diagnosis of exclusion. It means it is not this, it is not that. A swollen brain is not SIDS. It turns out in the medical literature a swollen brain, brain inflammation, is one of the most common signs of an adverse reaction to a vaccine.

I set out to do an investigation of this vaccine and adverse reactions, and these are my conclusions and I urge you to read them.

I have some prepared remarks that are far too lengthy to summarize here.

First of all, let's look at the vaccination policy in this country, this Rube Goldberg flowchart that I have. This committee has oversight over the CDC, which has oversight over the ACIP, the Advisory Committee on Immunization Practices.

This committee sets immunization policy, and I urge you to really concentrate on this. I think there is a conflict between the public interest and the private interest of drug companies and the interest of the bureaucracy that is violating the public interest. As an oversight committee, I think this is something that you should look into.

This committee sets mandates which go out to the States and go to the children, and some small percentage of children have adverse events which go into this thing called VAERS, Vaccine Adverse Event Reporting System. From VAERS they go into an empty drawer, and they pile up and go nowhere and nothing is done. The CDC and the FDA do studies saying we don't see any problem with anything.

Can you please change the chart.

First of all, newborn babies are not at risk of getting this disease. I quote you the risk groups from the CDC hepatitis B disease fact sheet: injection drug users, sexually active heterosexuals, homosexual men, infants from disease endemic areas, low socioeconomic levels, sexual household contacts of infected persons, infants born to infected mothers, healthcare workers, chemodialysis patients. Not newborn babies.

Then why do you say are newborn babies infected with hepatitis B? The vaccine is the first thing that they get in the first 24 to 48 hours of their lives in the hospital. Here is the ACIP's original statement from 1991. "In the United States, most infections occur among adults and adolescents. Efforts to vaccinate persons in the major risk groups have had limited success. In the long term, universal infant vaccination would eliminate the need for vaccinating adolescents and high-risk adults."

And then they say, "Hepatitis B vaccination is recommended for all infants. The first dose can be administered during the newborn period, preferably before the infant is discharged from the hospital." That is where it came from.

I quote you from government statistics, summary of notifiable diseases, 54 cases of hepatitis B in the 0 to 1 age group in 1996. And if we compare that, that is that. In the VAERS reports in that year, there is more than 1,000 adverse reaction reports, and there are 47 deaths of these reports. So this needs to be investigated.

I am not saying that every report in VAERS is directly related to the vaccine, but I have torn apart the VAERS data, and I am trained in statistics. I am an advisor to some of the largest financial institutions in the world and a former proprietary trading strategist at Salomon Brothers.

One of the most striking findings of this data is that almost 80 percent of the reports of hepatitis B, 77 percent are in females; only 23 percent in males. More than three times as many women are having adverse reactions reported in VAERS. No one is looking at this.

Dr. Chen of the CDC dismisses it and says nurses tend to over-report. I think that is a big mistake. Independent doctors with no financial interest should take a look at this.

I would just like to conclude with the way vaccine policy is set in this country. Dr. Modlin at the ACIP meeting on February 19, which I attended in Atlanta said—first of all he said at a debate in New Hampshire: "How do we decide something? Is the theory biologically plausible? Has it been tested by appropriate methods? Is the study well concluded? Are the results statistically sound?"

Now I read to you from the transcript of the ACIP meeting regarding the approved rotavirus for premature infants: "Available data are insufficient to fully establish the safety and efficacy of rotavirus vaccine in premature infants." There is a section under Adverse Events that details what little information there actually is with respect to premature infants. To my knowledge, we don't have data from a clinical trial specifically. Some bit of information, as I recall, suggested that there was a relative risk for hospitalization. Obviously, a situation where we have to make a judgment in the absence of data and with a vaccine that has not yet been tested in this group.

They voted 9 to 1 to approve rotavirus vaccine for premature infants with no scientific statistical studies on it. I think that is a big problem.

This is my charge to you. I am afraid that this vaccine policy is dominated by forces that are not in the public interest and this committee should investigate the 1991 ACIP recommendation establishing universal hepatitis B vaccination of newborn babies; and if, as with the rotavirus vaccine examples were done, no studies were done to prove that this was safe in a broad sample of racially and genetically diverse babies less than 24 to 48 hours old when they established this recommendation, we can find those studies.

We have a Freedom of Information Act request in from the National Vaccine Information Center. Then the CDC has been experimenting on babies like guinea pigs, and this committee should suspend that universal at-birth immunization policy. Thank you.

Mr. MICA. Thank you for your testimony. We will hold questions until we have heard from all of the witnesses.

[The prepared statement of Mr. Belkin follows:]

MICHAEL BELKIN **TESTIMONY TO CONGRESS** **Tuesday May 18, 1999**

My daughter Lyla Rose Belkin died on September 16, 1998 at the age of five weeks, about 15 hours after receiving her second Hepatitis B vaccine booster shot. Lyla was a lively, alert five-week-old baby when I last held her in my arms. Little did I imagine as she gazed intently into my eyes with all the innocence and wonder of a newborn child that she would die that night. She was never ill before receiving the Hepatitis B shot that afternoon. At her final feeding that night, she was extremely agitated, noisy and feisty -- and then she fell asleep suddenly and stopped breathing. The autopsy ruled out choking. The NY Medical Examiner ruled her death Sudden Infant Death Syndrome (SIDS).

But the NY Medical Examiner (Dr. Persechino) neglected to mention Lyla's swollen brain or the hepatitis B vaccine in the autopsy report. The coroner spoke to my wife and I and our pediatrician (Dr. Zullo) the day of the autopsy and clearly stated that her brain was swollen. The pediatrician Dr. Zullo's notes of that conversation are "***brain swollen ... not sure cause yet ... could not see how recombinant vaccine could cause problem.***"

SIDS is a diagnosis of exclusion .. "it wasn't this, it wasn't that, everything has been ruled out and we don't know what it was." ***A swollen brain is not SIDS.*** Through conversations with other experienced pathologists, I subsequently discovered that brain inflammation is a classic adverse reaction to vaccination (with any vaccine) in the medical literature.

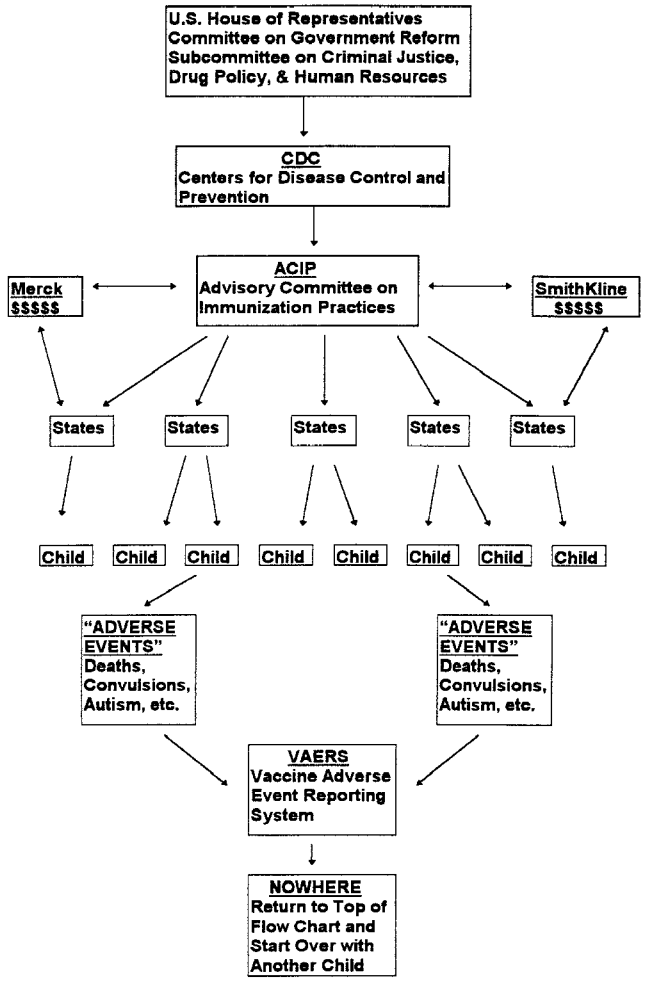
I set out to do an investigation of the hepatitis B vaccine and attended a workshop at the National Academy of Sciences, Institute of Medicine on "Neo-Natal Death and the Hepatitis B Vaccine," the Advisory Committee on Immunization Practices (ACIP) February meeting and a debate in New Hampshire between the Chairman of the ACIP Dr. Modlin and Dr. Waisbren about the safety of the hepatitis B vaccine. I also obtained the entire Vaccine Adverse Events Reporting System (VAERS) database on hepatitis B vaccine adverse reactions and have investigated it thoroughly.

These are my conclusions, supported by the following pages of text and analysis that are too lengthy to present in entirety in the time allotted for this appearance. Please read the results of my investigation, as it will help you understand the magnitude of the hepatitis B vaccine issue.

- *Newborn babies are not at risk of contracting the hepatitis B disease unless their mother is infected*
- *Hepatitis B is primarily a disease of junkies, gays, and promiscuous heterosexuals*
- *The vaccine is given to babies because health authorities couldn't get those risk groups to take the vaccine*
- *Adverse reactions out-number cases of the disease in government statistics*
- *Nothing is being done to investigate those adverse reactions*
- *Those adverse reactions include numerous deaths, convulsions and arthritic conditions that occur within days after hepatitis B vaccination*
- *The CDC is misrepresenting hypothetical, estimated disease statistics as real cases of the disease*
- *The ACIP is recommending new vaccines for premature infants without having scientific studies proving it is safe*
- *The US vaccine recommendation process is hopelessly compromised by conflicts of interest with vaccine manufacturers, the American Academy of Pediatrics and the CDC*

Conclusion: If (as with the recently-recommended rotavirus vaccine) hepatitis B vaccine was recommended in 1991 without scientific proof that it was safe in a broad sample of racially and genetically diverse babies less than 48 hours old before they established that recommendation, then the CDC has been experimenting on babies like guinea pigs and this Committee should suspend that universal immunization policy.

UNITED STATES VACCINATION POLICY FLOWCHART



CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

HEPATITIS B DISEASE
Fact Sheet

Hepatitis B

CLINICAL FEATURES	• Jaundice, fatigue, abdominal pain, loss of appetite, intermittent nausea, vomiting
ETIOLOGIC AGENT	• Hepatitis B virus
INCIDENCE	• 140,000-320,000 infections/yr in United States • 70,000-160,000 symptomatic infections/yr
SEQUELAE	• Of symptomatic infections, 8400-19,000 hospitalizations/yr and 140-320 (0.2%) deaths/yr; • Of all infections, 8,000-32,000 (6%-10%) chronic infections/yr, and 5,000-6,000 deaths/yr from chronic liver disease including primary liver cancer
PREVALENCE	• Estimated 1-1.25 million chronically infected Americans
COSTS	• Estimated $700 million (1991 dollars)/yr (medical and work loss)
TRANSMISSION	• Bloodborne • sexual • perinatal
RISK GROUPS	• Injection drug users • Sexually active heterosexuals • Homosexual men • Infants/children of immigrants from disease-endemic areas • Low socioeconomic level • Sexual/household contacts of infected persons • Infants born to infected mothers • Health care workers • Hemodialysis patients
SURVEILLANCE	• National Notifiable Diseases Surveillance System • Viral Hepatitis Surveillance Program • Sentinel Counties Studies
TRENDS	Incidence increased through 1985 and then declined 55% through 1993 because of wider use of vaccine among adults, modification of high-risk practices, and possibly a decrease in the number of susceptible persons. Since 1993, increases observed among the three major risk groups: sexually active heterosexuals, homosexual men, and injection drug users.
PREVENTION	• Hepatitis B vaccine available since 1982 • Screening pregnant women and treatment of infants born to infected women • Routine vaccination of infants and 11-12 year olds • Catch-up vaccination of high-risk groups of all ages

Newborn babies are not a risk group

NOTIFIABLE DISEASES — Summary of reported cases, by age group,* United States, 1996

NAME	Total	<1 No.	<1 (Rate)	1–4 No.	1–4 (Rate)	5–14 No.	5–14 (Rate)	15–24 No.	15–24 (Rate)	25–39 No.	25–39 (Rate)	40–64 No.	40–64 (Rate)	≥65 No.	≥65 (Rate)	Age not stated
AIDS†	66,885	205	(5.33)	280	(1.78)	247	(0.65)	2,403	(6.69)	37,673	(59.68)	26,077	(24.61)	–	(–)	–
Botulism, total	119	78	(2.03)	1	(0.01)	–	(–)	1	(0.00)	10	(0.02)	20	(0.03)	7	(0.02)	2
Brucellosis	112	–	(–)	7	(0.04)	11	(0.03)	28	(0.08)	27	(0.04)	32	(0.04)	7	(0.02)	–
Cholera	4	–	(–)	–	(–)	–	(–)	–	(–)	1	(0.00)	2	(0.00)	1	(0.00)	–
Diphtheria	2	–	(–)	–	(–)	–	(–)	–	(–)	–	(–)	1	(0.00)	1	(0.00)	–
Escherichia coli O157:H7	2,741	61	(1.78)	610	(4.37)	598	(1.77)	317	(1.00)	314	(0.56)	466	(0.73)	322	(1.10)	53
Gonorrhea§	324,708	–	(–)	–	(–)	6,332	(16.60)	189,973	(528.51)	98,336	(155.78)	20,407	(28.18)	1,009	(3.01)	7,554
Haemophilus influenzae, invasive	1,170	159	(4.13)	114	(0.72)	54	(0.14)	41	(0.11)	122	(0.19)	237	(0.33)	421	(1.26)	22
Hansen disease (leprosy)	112	–	(–)	–	(–)	2	(0.01)	7	(0.02)	23	(0.04)	41	(0.06)	24	(0.07)	15
Hepatitis A	31,032	144	(3.74)	1,690	(10.72)	6,627	(17.38)	5,558	(15.46)	10,394	(16.47)	5,093	(7.03)	1,173	(3.50)	353
Hepatitis B	10,637	54	(1.40)	39	(0.25)	186	(0.49)	1,907	(5.31)	4,707	(7.46)	2,944	(4.06)	539	(1.61)	261
Hepatitis, C/non-A non-B	3,716	35	(0.91)	8	(0.05)	24	(0.06)	153	(0.43)	1,600	(2.54)	1,635	(2.26)	215	(0.64)	46
Legionellosis	1,198	4	(0.11)	3	(0.02)	5	(0.01)	32	(0.09)	142	(0.23)	484	(0.68)	516	(1.57)	12
Lyme disease	16,455	74	(1.92)	812	(5.16)	2,860	(7.50)	1,418	(3.94)	3,023	(4.79)	5,766	(7.96)	2,253	(6.72)	249
Malaria	1,800	15	(0.39)	95	(0.60)	238	(0.62)	334	(0.93)	578	(0.92)	408	(0.56)	84	(0.25)	48
Measles (rubeola)	508	39	(1.43)	89	(0.67)	115	(0.31)	131	(0.37)	104	(0.17)	27	(0.04)	–	(–)	3
Meningococcal disease	3,437	542	(14.08)	585	(3.72)	538	(1.41)	621	(1.73)	290	(0.46)	410	(0.57)	410	(1.22)	41
Mumps	751	7	(0.19)	151	(0.93)	335	(0.90)	89	(0.25)	97	(0.16)	55	(0.08)	5	(0.02)	12
Pertussis (whooping cough)	7,796	2,368	(61.53)	1096	(6.96)	2,144	(5.62)	902	(2.51)	628	(0.99)	551	(0.76)	82	(0.24)	25
Plague	5	–	(–)	–	(–)	–	(–)	3	(0.01)	–	(–)	2	(0.00)	–	(–)	–
Poliomyelitis, paralytic	5	3	(0.08)	–	(–)	–	(–)	–	(–)	1	(0.00)	1	(0.00)	–	(–)	–
Psittacosis	42	1	(0.03)	–	(–)	1	(0.00)	1	(0.00)	10	(0.02)	24	(0.03)	4	(0.01)	1
Rabies, human	3	–	(–)	–	(–)	–	(–)	–	(–)	1	(0.00)	2	(0.00)	–	(–)	–
Rocky Mountain spotted fever	831	3	(0.08)	57	(0.35)	168	(0.44)	89	(0.25)	196	(0.31)	239	(0.33)	71	(0.21)	8
Rubella (German measles)	238	7	(0.18)	11	(0.07)	10	(0.03)	100	(0.28)	83	(0.13)	25	(0.03)	–	(–)	2
Salmonellosis	45,471	5,440	(141.36)	1,507	(41.33)	4,932	(12.93)	3,697	(10.29)	6,871	(10.88)	6,488	(8.96)	3,796	(11.32)	7,740
Shigellosis	25,978	522	(13.56)	1,834	(43.47)	6,493	(17.03)	1,919	(5.34)	3,531	(5.59)	1,706	(2.36)	514	(1.53)	4,459
Syphilis, primary and secondary¶	11,366	–	(–)	–	(–)	50	(0.13)	3,058	(8.51)	5,745	(9.10)	2,375	(3.28)	108	(0.32)	19
Tetanus	36	–	(–)	–	(–)	–	(–)	2	(0.01)	14	(0.02)	7	(0.01)	13	(0.04)	–
Toxic-shock syndrome	145	2	(0.05)	4	(0.03)	18	(0.05)	30	(0.08)	47	(0.08)	33	(0.05)	10	(0.03)	1
Trichinosis	11	–	(–)	–	(–)	–	(–)	2	(0.01)	3	(0.00)	4	(0.01)	2	(0.01)	–
Tuberculosis**	21,337	111	(2.88)	673	(4.27)	588	(1.54)	1,856	(4.61)	5,481	(8.68)	7,711	(10.85)	5,103	(15.22)	14
Typhoid fever	396	6	(0.16)	35	(0.22)	101	(0.26)	65	(0.18)	110	(0.17)	53	(0.07)	25	(0.07)	1
Yellow fever	1	–	(–)	–	(–)	–	(–)	–	(–)	–	(–)	1	(–)	–	(–)	–

*July 1, 1994, post-censal population estimates were used to calculate incidence rates per 100,000 population.

†The total number of acquired immunodeficiency syndrome (AIDS) cases includes all cases reported to the Division of HIV/AIDS Prevention, Surveillance, and Epidemiology, National Center for HIV, STD, and TB Prevention (NCHSTP) through December 31, 1996. Reported cases for persons aged ≥65 years have been incorporated in the 40–64 years age group.

§Age-related data are collected on aggregate forms different from those used for the number of reported cases. Therefore, the total cases reported on this table may differ slightly from other tables. Cases among persons aged <5 years are not shown because some of these may not be caused by sexual transmission; these cases are, however, included in the totals. Cases were updated through the Division of Sexually Transmitted Diseases Prevention, NCHSTP, as of June 13, 1997. Age-related data for 1996 are unavailable for chancroid and chlamydia.

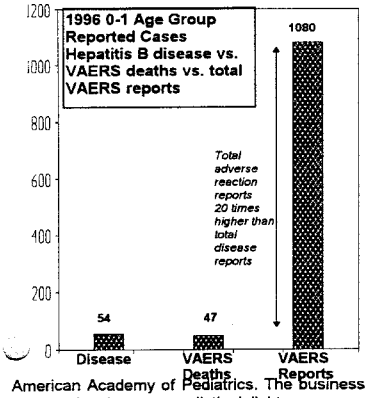
¶Cases were updated through the Division of Tuberculosis Elimination, NCHSTP, as of May 28, 1997.

The hepatitis B vaccine was effectively mandated in 1991 for universal immunization of newborn babies by the Advisory Committee on Immunization Practices (ACIP) -- an adjunct of the Centers for Disease Control and Prevention (CDC). Paradoxically, the CDC's own **Fact Sheet** on the hepatitis B disease does not include newborn babies as a risk group for that disease. That Fact Sheet lists the risk groups as *injection drug users, homosexual men, sexually active heterosexuals, infants/children of immigrants from disease-endemic areas, low socio-economic level, sexual/household contacts of infected persons, infants born to infected mothers, health care workers and hemodialysis patients* ***NOT NEWBORN BABIES***.

Question: *Why then, did the ACIP establish a policy mandating that newborn babies not at risk of the disease be automatically administered the 3-shot hepatitis B vaccine as their first involuntary indoctrination into the pediatric care of America?*

Answer: Here is that rationale from the original ACIP 1991 statement establishing the official vaccination policy **"Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination ..."** *"In the United States, most infections occur among adults and adolescents ... The recommended strategy for preventing these infections has been the selective vaccination of persons with identified risk factors ... However, this strategy has not lowered the incidence of hepatitis B, primarily because vaccinating persons engaged in high-risk behaviors, life-styles, or occupations before they become infected generally has not been feasible ... Efforts to vaccinate persons in the major risk groups have had limited success. For example, programs directed at injecting drug users failed to motivate them to receive three doses of vaccine ... In the United States it has become evident that HBV transmission cannot be prevented through vaccinating only the groups at high risk of infection ... In the long term, universal infant vaccination would eliminate the need for vaccinating adolescents and high-risk adults ... Hepatitis B vaccination is recommended for all infants, regardless of the HBsAg status of the mother ... The first dose can be administered during the newborn period, preferably before the infant is discharged from the hospital, but no later than when the infant is 2 months of age ..." (emphasis added).*

So in the CDC and ACIP's own words, almost every newborn US baby is now greeted on its entry into the world by a vaccine injection against a sexually transmitted disease for which the baby is not at risk -- because they couldn't get the junkies, prostitutes, homosexuals and promiscuous heterosexuals to take the vaccine. ***That is the essence of the hepatitis B universal vaccination program.***



Question: *What are the risks and benefits for administering this vaccine to infants?*

Answer: Hepatitis B is a rare, mainly blood-transmitted disease. In 1996 only 54 cases of the disease were reported to the CDC in the 0-1 age group. There were 3.9 million births that year, so the observed incidence of hepatitis B in the 0-1 age group was just 0.001%. In the Vaccine Adverse Event Reporting System (VAERS), there were 1,080 total reports of adverse reactions from hepatitis B vaccine in 1996 in the 0-1 age group, with 47 deaths reported. Total VAERS hepatitis B reports for the 0-1 age group outnumber reported cases of the disease 20 to 1.

Question: *Why don't they just screen the mother to see if she is infected with hepatitis B (since that's about the only way a baby is likely to get the disease), instead of vaccinating all infants?*

Answer: Selling vaccines is extremely profitable and the process of mandating vaccines is fraught with conflicts of interest between vaccine manufacturers, the ACIP and the American Academy of Pediatrics. The business model of having the government mandate everyone must buy your product is a monopolist's delight.

Question: *What studies are being done on the data from the FDA's Vaccine Adverse Event Reporting System (VAERS)?*

Answer: Absolutely nothing. The 25,000 reports are going into a drawer and being forgotten. How many reports are enough to show a drug or vaccine is dangerous -- 2,500? 25,000? 250,000? Chen of the CDC and Ellenberg of the FDA monitor this data, write reports and deliver speeches about how VAERS hepatitis B adverse reaction reports show nothing out of the ordinary and show "the relative safety of HB vaccine when given to neonates and infants." VAERS shows nothing of the kind. **TAKE A LOOK AT THE VAERS DATA YOURSELF.** The health authorities continue to negligently downplay the steady stream of serious adverse reactions to this vaccine and more infants and adults continue to die and suffer central nervous system and liver damage after HB vaccination.

Question: *Why do the CDC, ACIP and Merck say that there are 140,000-320,000 new infections/yr (70,000-160,000 symptomatic infections/yr) when their own CDC data shows only 10,000 reported cases year?*

Answer: They are passing off estimated, hypothetical numbers as actual cases. **This is statistical fraud.** In the financial world such mis-representation would lead to criminal charges. If a company inflated its earnings or revenues by 300% (as the CDC does hepatitis B disease statistics) and foisted those figures off as official data (and not some back-of-the-envelope guess-timate) - that company would be investigated by the SEC and sued by shareholders. Why doesn't that happen in the medical world? There's no regulator to keep the CDC honest. They do not say those figures are hypothetical estimates, they misrepresent the data. Go try to audit those 320,000 supposed new infections/yr. You will not find them. The whole exercise is designed to increase public hysteria about the risk of a low-risk disease so the CDC can extend it's pervasive influence and Merck can increase it's $900 million/year vaccine revenues.

Question: *What process does the Center for Disease Control employ to make a vaccine recommendation?*

I attended the February Advisory Committee on Immunization Practices (ACIP) meeting in Atlanta and was absolutely appalled. Every vote by the Committee on new vaccine mandates was unanimous (except for one dissenting vote on Rotavirus vaccine for premature infants). There was hardly any discussion of adverse reactions, the ACIP simply rubber-stamped every proposal on the agenda. I call it Vaccination Without Representation. In one instance, the ACIP passed a recommendation for Rotavirus vaccine for premature infants ***even though no scientific studies had been done showing it was medically safe.*** Dr. Modlin, (Chairman of the ACIP), said in a pro-hepatitis B vaccine debate in New Hampshire *"How do we determine whether something is scientifically valid or not? ... 1) Is the theory biologically plausible? 2) Has it been tested by appropriate methods? 3) Is the study well concluded? 4) Are the results statistically sound?"* But at the February ACIP meeting, when it came time for the ACIP to rubber-stamp approval of Rotavirus vaccine for premature infants, here are Modlin's quotes from the official transcript: *".. available data are insufficient to fully establish the safety and efficacy of rotavirus vaccine in premature infants ... there is a section under Adverse Events that details what little information there actually are with respect to premature infants ... To my knowledge we don't have data from a clinical trial specifically ... Some bit of information from Seattle, as I recall, that had suggested that was a slight increase in relative risk for hospitalization for premature infants ...* ***Obviously a situation where we have to make a judgment in the absence of data, and with a vaccine that has not yet been tested in the group ..."*** (ACIP transcript, pages 102-112) Modlin then held a vote and the recommendation for premature infants passed nine to one -- Modlin voted yes, Dr. Glode against. This is a clear example of how the medical bureaucracy (led by the CDC and ACIP), is recommending vaccines without scientific evidence that those vaccines are safe in a broad sample of racially and genetically diverse infants.

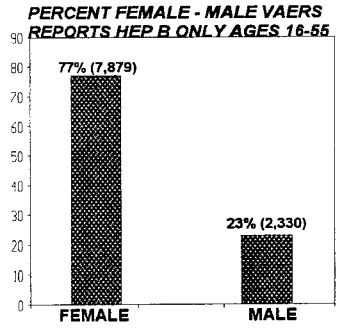
What Should Be Done? This Committee should investigate the 1991 ACIP recommendation establishing universal hepatitis B vaccination of newborn babies in the hospital -- and if (as with the Rotavirus vaccine example above) no studies were done to prove this was safe in a broad sample of racially and genetically diverse babies less than 48 hours old before they established that recommendation, then the CDC has been experimenting on babies like guinea pigs and this Committee should suspend that universal immunization policy.

AERS ANALYSIS (Vaccine Adverse Event Reporting System)

I studied statistics at the University Of California at Berkeley and went on to develop sophisticated proprietary risk/reward statistical models at Salomon Brothers from 1986-91 – and in my subsequent, ongoing business provide statistical economic and financial forecasts to mutual funds, investment banks, pension funds and hedge funds.

I studied VAERS hepatitis B vaccine data obtained by the National Vaccine Information Center (NVIC) under the Freedom of Information Act. The data has some flaws (incomplete fields, some multiple reports) but ***any qualified, impartial quantitative analyst or statistician not affiliated with Merck, Smithkline, the CDC, the FDA or the AAP who examines these reports will find a clear and undeniable pattern of central nervous system (CNS) and liver disease striking thousands of people within 0-4 days after vaccination with hepatitis B vaccine.*** These reports have been ignored, explained away, or considered "acceptable" by the FDA, CDC and drug companies. This Committee should launch an investigation of the VAERS hepatitis B data by a team of independent scientists not beholden to vaccine manufacturers or the FDA/CDC bureaucracy. The following is intended to be a starting point for such an investigation. This does not profess to be a complete, exhaustive analysis – simply an overview, highlighting aspects of the data that may not previously have been brought to your attention.

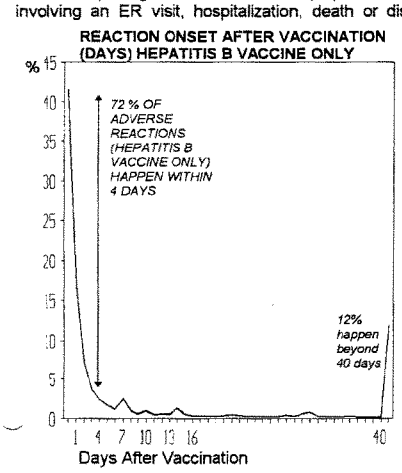
The total 24,775 VAERS hepatitis B reports from July 1990 to October 31, 1998 show 439 deaths and 9673 serious reactions involving emergency room visits, hospitalization, disablement or death. Therefore, more than one third of total reports were serious events. 17,497 of those total reports were for hepatitis B vaccine only, the remainder were vaccine cocktails where hepatitis B was administered along with DPT, HIB, IPV, OPV, etc.



The hepatitis-B-vaccine-only reports show a shocking cluster of reactions in females starting in their teenage years (the male/female reporting ratio is balanced before age 16). ***For ages 16-55, 77% of VAERS reports are women – more than three times as many women as men are reporting adverse reactions to hepatitis B vaccine.*** The median onset of adverse event after vaccination is one day, 70% of reactions happen within four days of vaccination. Independent scientists should investigate why females are more disposed to have adverse reactions to hepatitis B vaccine and/or report them to VAERS. One possible explanation is that nurses have to take this vaccine for their jobs and are thus more exposed than most adults to hepatitis B vaccine adverse reactions. Rather than dismiss that factor as an "over-reporting bias" as Dr. Chen of the CDC did at the February ACIP meeting, perhaps investigators might consider that nurses are alert health care workers and ought to be listened to with regard to the dangers of adverse events with any vaccine (rather than ignored). Personal case studies reported to the author have showed many teenage girls getting severe, debilitating adverse reactions to hepatitis B vaccine, having nothing to do with nursing. Do women have a greater vulnerability to auto-immune reactions to hepatitis B vaccine? ***Is the government discriminating against women by administering this vaccine without regard for genetic risk of CNS and liver disease?*** Those are questions that independent scientists should investigate.

A second area of concern is the VAERS reports involving hepatitis B vaccine administered with other vaccines (vaccine cocktails). Health officials are fond of dismissing those reports as being attributable to hepatitis B vaccine, because of the multiple other antigens present (almost as if they wanted to cloak hepatitis B vaccine reactions from scrutiny). Let's avoid that controversy and focus on the extremely disturbing VAERS data of hepatitis B vaccine with other vaccines. These reports amount to only one third of total reports (7,275), but account for two thirds of total deaths (291). The median onset of those deaths was 2 days after vaccination -- displaying a clear temporal association. The median age of death was 0.5 years in this group. 50% of all hepatitis-B-vaccine-cocktail reports were serious (died, emergency room, hospitalized, disabled). I grouped ***convulsive reactions*** together from the hep-B-vaccine-cocktail data and found a deeply disturbing pattern. These were anything labeled convulsions, seizures or tremors in the VAERS hep-B-cocktail data. Of the 1189 such reports, fully 80% (950) were serious (died, ER, hospitalized, disabled) median age 0.5 years, median onset after vaccination 0 days (less than one day). Someone should do follow-up and find out what happened to those poor infants who suffered severe convulsions after a hepatitis B-multi-vaccine cocktail. In the personal reports I've taken of similar adverse reactions, the children were left brain damaged and developmentally disabled. Looking beyond the debate over whether VAERS reports of vaccine cocktails can be attributed to hepatitis B, the data strongly suggests ***combining multiple vaccines may be convenient and profitable for pediatricians -- but fatal or debilitating for infants.*** Where are the scientific studies showing hepatitis B vaccine is safe to administer with DPT, HIB, IPV, OPV, etc.? Did anyone doing cost/benefit analysis for those studies include data showing the higher mortality and serious reactions present in the VAERS data? Why not? Is there an identifiable genetic marker in those who suffered convulsive reactions to screen out those vulnerable in the future? These are all matters for independent scientists to audit.

Another area that leaps out of the VAERS database is something I dubbed ***arthritic reactions***. These are joint pains, tingling, numbness, aching, fatigue, etc. I found 2,400 of those reports in just a quick survey of the first reporting column of VAERS (hepatitis B vaccine only). Almost one half of those are serious, involving an ER visit, hospitalization, death or disablement. These are the type of adverse reactions reported by many adults who are forced to take the hepatitis B vaccine for their jobs. In the reports of such adverse reactions I've taken, the symptoms do not go away, most patients complain it gets worse over time. Scientists not corrupted by drug company or CDC/FDA institutional bias should examine the thousands of VAERS hepatitis B arthritic reaction reports and develop a diagnosis of their hepatitis B vaccine-related illness.



Anyone who doubts if hepatitis B vaccine adverse reactions exist should sit down and read the symptoms and text comments of a random selection of VAERS reports. When one does so, they will find a similar but wide-ranging list of CNS and liver reactions that occur within days of vaccination. The Merck package insert claims ***"Injection site reactions and systemic complaints were reported following 17% and 15% on the injections, respectively."*** The standard rule of thumb is only about 10% of reactions are reported to VAERS. So the actual number and full horror of the hepatitis B vaccine reaction story is potentially much larger than even VAERS suggests.

THIS IS A SAMPLE OF VAERS REACTION REPORTS

VERS ID	SEX	AGE	DATE	ONSET DAYS	ER	HOSP	DIED	COSTART 1	COSTART 2	CASTART 3	REPORTED TEXT
25312	F		07/19/90		No	No	No	PARESTHESIA			NUMBNESS IN LEFT AND RIGHT INDEX FINGERS
25318	F		07/19/90	0	No	No	No	NECK RIGID	ARTHRALGIA		PT HAD SHOULDER PAIN AND NECK PAIN AFTER VAX (IM,DELT) ON 3-15-90. TREATMENT: NSAID T
25320	F	35	07/19/90	0	No	No	No	PARESTHESIA	TOOTH DIS	HEADACHE	PT RECVD 1ST INJECT(LF,DELT) 4-2-90 ONSET OF LF NECK, SHOULDER AND LF JAW PAIN. EXP T
25321	F	29	07/19/90	0	No	No	No	NEUROPATHY	PARALYSIS	ARTHRALGIA	PR RECVD 1ST INJECT(IM,DELT) 4-5-90 THAT NIGHT HAD ONSET OF PARESIS, LOSS OF MUSCULA
25327	F	40	07/20/90	14	No	No	No	PARESTHESIA	CEREBROVASC DIS	EYE DIS	1ST DOSE ENGERIX-B 3-15-90, ONSET OF UNILAT NUMBNESS & TINGLING(RT HAND & FOOT) ON 3-
25340	M	45	07/23/90	121	No	No	No	PARESTHESIA			PARESTHESIAS OF DORSUM OF FEET AND SHINS OCCURRED APPROX 4-01-90. UNSURE OF RELA
25350	F		07/24/90		No	No	No	PARESTHESIA	STOOL ABNORM		
25354	F	56	07/24/90	2	No	No	No	ASTHENIA	FEVER	PHARYNGITIS	ONSET OF SXS 3 DAYS P/ VAC. FATIGUE, FEVER, INFLAMED THROAT, HEAD TO TOE ITCHY RASH
25367	F	35	07/24/90	7	No	No	No	ARTHRALGIA	FLU SYND	JOINT DIS	ONE WEEK AFTER INJECTION, PT DEV ACHING AND STIFFNESS IN JOINTS OF HANDS, ELBOWS, E
25368	M	35	07/24/90	7	No	No	No	ARTHRALGIA	PAIN	FLU SYND	4 DAYS AFTER VAX, DEVELOPED ACHING IN JOINTS (KNEES, SHOULDERS, HANDS- WHOLE BODY
25389	M	59	07/24/90	2	No	No	No	ARTHRALGIA	MYALGIA	ASTHENIA	Vaccinee received second vaccination (IM-Deltoid) 2-Nov-89 experienced bilateral arthralgia of knees, mus
25391	F	48	07/24/90	0	No	No	No	ASTHENIA	EDEMA INJECT SITE		Vaccinee received first dose of Engerix-B at approx 3:30PM on 3-OCT or 4-OCT. About 2 hrs later she exp
25393	F	34	07/24/90	1	No	No	No	PARESTHESIA	PAIN INJECT SITE	ARTHRALGIA	Pt received Engerix-B & experienced numbness in L leg, lt deltoid soreness, bilateral arthralgias: tingling in
25403	M	37	07/25/90		No	No	No	PARESTHESIA	PAIN BACK	PAIN INJECT SITE	Pt received first dose of Engerix-B in rt arm and noticed numbness and tingling in the 4th and 5th fingers o
25416	M	26	07/25/90		No	No	No	ARTHRALGIA			PT EXP ARTHRALGIAS 24 HRS AFTER 1ST DOSE OF ENGERIX-B. RESOLVED WITHIN 24 HRS
25419	F	24	07/25/90	0	No	No	No	ARTHRALGIA			1.5 HRS AFTER INOC DEV OF GEN ARTHRALGIAS WHICH PEAKED AT 24 HRS(ESP IN MAJOR JOINT
25422	F	58	07/25/90	0	No	No	No	NECK RIGID	PAIN BACK	HYPERTONIA	SAME DAY PT EXP STIFFNESS, BACK AND SHOULDER PAIN, SORENESS IN BACK AREA FOR APPR
25481	F	41	07/27/90	3	No	No	No	ARTHRALGIA	PAIN	MYALGIA	3 DAYS AFTER 2ND DOSE OF ENGERIX-B, PT EXPERIENCED PAIN IN SHOULDER. EVENTS RESOLV
25488	M	26	07/18/90	0	No	Yes	No	MYALGIA	VERTIGO	CONFUS	Pt vaccinated w/ 1st dose of Recombivax, developed dizziness, blurred vision, jdizziness, sweating, myalgia
25564	F	36	07/25/90	1	No	No	No	ARTHRALGIA	FEVER	MALAISE	ACHES, PAIN (JOINT), SWEATS, LOW GRADE TEMP, MALAISE, N & V, AND SEVERE HEADACHE
25567	F	23	07/25/90	31	No	No	No	PARESTHESIA	MYASTHENIA	LAB TEST ABNORM	Pt received Heptivax 01Dec89, 29Dec89 pt developed paresthesia & in Jan90 she had muscle weakness (w
25610	F	37	07/30/90	1	No	Yes	No	ASTHENIA	FEVER	INSOMNIA	Pt developed fever of 100 F or greater for approx 3 days, 20Nov89 c/o muscles & bone aches, knees, ankl
921	F	58	08/01/90	78	No	No	No	PARALYSIS FACIAL	ARTHRITIS		Pt DX with Bell's Palsy possibly ran to vaccine ? Out of work X 3 months. 2 wks /p 2nd dose to Hep B dose
25650	F		08/17/90	0	Yes	No	No	PARESTH CIRCUMORAL	DYSPNEA	PAIN CHEST	Numbness @ lips, shortness of breath, heaviness in chest, lightheadedness, erythema around inject site
25661	M	47	08/17/90	1	No	No	No	ARTHROSIS	JOINT DIS	RASH	Pt received 3rd dose of Engerix B on 27-JUN-90 and on 28-JUN-90 noted mild arthralgias in hands on 29-
25715	F	54	08/23/90	0	Yes	Yes	No	PARESTHESIA	RASH VESIC BULL	DERM EXFOL	Pt vaccinated with Engerix-B and developed itching of hands, rash on arms and hands legs groin, club like f
25909	F	45	09/18/90		No	No	No	ARTHRALGIA	FEVER	RASH	Also five days 20AUG89 after receiving the second dose of vaccine experienced arthralgia and fever lasting
25982	F	32	09/25/90	1	Yes	No	No	MYALGIA	DIARRHEA	FEVER	Pt vaccinated with Recombivax developed myalgia, rigors, nausea, vomiting, temp 101.8, 12 hrs after 2nd d
26008	F	30	09/26/90	1	No	No	No	VISION ABNORM	NAUSEA	VOMIT	PT VACCINATED WITH RECOMBIVAX 36 HRS FOLLOWING THE INJECTION DEVELOPED BLURRED V
26079	F	64	09/27/90	45	Yes	No	No	PARALYSIS FACIAL			Pt vaccinated with Recombivax HB developed Bells Palsy R onset 2 wks post vaccine
26111	F	36	10/01/90	31	No	No	No	ARTHRALGIA			Pt vaccinated with Engerix and experienced generalized joint pain over several days; but forgot about it. She
26240	F	36	10/17/90	30	No	Yes	No	PARESTHESIA	HEADACHE	VOMIT	Pt vaccinated w/Recombivax HB developed tingling & pain in rt arm & shoulder, & back pain. Also rt hand cr
26242	F	23	10/17/90	31	No	No	No	PARESTHESIA	MYASTHENIA		Pt vaccinated with Heptavax B experienced paresthesia & muscle weakness described as "knee gave way". P
26264	F		10/18/90		No	Yes	No	PARALYSIS FACIAL	HEADACHE	AMBLYOPIA	Pt vaccinated with Recombivax HB experienced Bell's Palsy w/paresthesia of the lt side of her face, headach
26323			11/05/90		No	No	No	SCLEROSIS MULT			A RN nurse reported that 15 pt's developed symptoms of multiple sclerosis following vacc. w/Hepatitis B vacc
26362	F	26	11/02/90	0	No	No	No	PARESTHESIA	VISUAL FIELD DEFECT		Pt w/hx of allergy to penicillin,trimethoprim-sulfamethoxazole [Bactrim],& nitrofurantoin-macrocrystals (Macr
26371	F		11/30/90	0	No	No	No	MYASTHENIA	NAUSEA	DIZZINESS	Pt vaccinated with Engerix-B developed dizziness, nausea, arm felt heavy.
26374	M	72	11/30/90		No	No	No	VISION ABNORM	EYE DIS	VITREOUS DIS	Pt vaccinated with Engerix-B experienced star burst effect on vision in lt eye.
26409	F	24	01/15/91	0	Yes	No	No	PARESTHESIA	RASH	PAIN	Pt vaccinated w/Engerix-B developed feeling funny, inject site tender, chest pain, rt arm pain, rash at site of
26445	M	45	11/07/90	907	No	No	No	ARTHRALGIA			Pt vaccinated with Heptavax developed permanent arthralgia.
26448	F		11/07/90		No	Yes	No	PARALYSIS FACIAL	HYPOTENS	FEVER	Pt vaccinated with ENGERIX-B experienced Bell's Palsy w/paresthesia of the lt side of her face, headaches,
26450			11/07/90		No	No	No	SCLEROSIS MULT			Pt vaccinated with Recombivax HB MD reported pt developed multiple sclerosis following vaccination w/Hepa
26451			11/07/90		No	No	No	SCLEROSIS MULT			Pt vaccinated with Recombivax HB MD reported pt developed multiple sclerosis following vaccination w/Hepa
26453			11/07/90	1	No	No	No	SCLEROSIS MULT			Pt vaccinated with Recombivax HB developed multiple sclerosis following vaccination. Additional info being re
26468			11/09/90	0	No	No	No	ARTHRALGIA	ARTHRITIS	PARESTHESIA	Pt vaccinated with Recombivax HB experienced Temp 98.6, Arthergias & mono articulas, arthritis rt elbow, pa
26508	M	46	11/12/90	0	No	No	No	ARTHRALGIA			Pt vaccinated with Heptavax developed permanent arthralgia.
315	F	49	01/15/91	1	No	No	No	MYALGIA	ARTHRALGIA	FEVER	Pt vaccinated w/Engerix-B developed mild myalgia and arthralgia and 100 degree temperature with the first d
26517	F		01/15/91		No	No	No	PARESTHESIA	DIZZINESS	TACHYCARDIA	Pt vacc. w/ Engerix-B developed 'tingly feeling in arm' which progressed down to ankle, felt dizzy sometime
26523	F	39	01/15/91		No	No	No	ARTHRALGIA	MYALGIA	PAIN	Pt vacc. w/ Engerix-B experienced, on the same day, a sore shoulder which migrated to the right hip & othe

VAERS ID	SEX	AGE	DATE	ONSET DAYS	HOSP	DIED	COSTART 1	COSTART 2	COSTART 3	REPORTED TEXT
1361	F	45	01/15/91	2	No	No	ARTHRALGIA			Pt vaccinated with Engerix-B developed, within 4-5 days, arthralgia in ankles & wrist.
26543	F		01/15/91	0	No	No	ARTHRITIS	MYALGIA	GAIT ABNORM	Pt vacc w/Engerix-B developed arthritis, flare-up, problems walking, problems moving arms & legs
26562	F	57	01/15/91	380	No	No	ARTHRALGIA	PARALYSIS FACIAL	FEVER	Pt vaccinated with Engerix-B developed joint pain, which lasted 6 weeks. On 1/3/90, developed Bell's palsy,
26601	F	36	11/13/90	58	No	Yes	ARTHRALGIA	ARTHROSIS		Pt vaccinated with Engerix-B receive first & 2nd dose a month apart,reported having joint pains since the <
26644	F	34	11/19/90	7	No	No	PARESTHESIA	GUILLAIN BARRE SYND	REFLEXES DEC	Pt 5-7 days after receiving Hepatitis B vaccine 90CT90 pt developed progressive numbness & tingling in fe
26652	F	50	11/20/90	0	No	No	PARESTHESIA	PARALYSIS FACIAL		24 hours after thrd dose of Engerix-B pt presented with numbness & tingling of left arm and facial drop. Pt
26658	F	38	11/20/90	68	No	No	SCLEROSIS MULT	DEAF	AMBLYOPIA	Pt vax w/ Engerix-B dev achs in lt knee, brist hearing loss, blurred vision lt eye, eye muscle spasm, has no
26660	F	31	11/20/90	0	No	No	PARALYSIS FACIAL	NEURITIS OPTIC	CYST	Pt vaccinated with Heptavax-B w/allergy to sulfa drugs, two hrs after vaccination began experiencing chill
26661	F	36	11/20/90		No	Yes	ARTHRALGIA	ARTHROSIS	RASH	Pt vaccinated with Engerix-B developed eye problem, joint pains, severe swelling of the rt knee, skin rx., Pt
26663	F	55	11/20/90		No	No	ARTHRALGIA	SKIN DIS	SCLERITIS	Pt vaccinated with Engerix-B developed generalized aching, Sclerits in one eye, severe arthralgia, skin dis
26692	F	38	11/26/90	15	No	Yes	NEUROPATHY	ENCEPHALITIS	PAIN	Pt vaccinated with Hepatitis B vaccine severe progressive encephalomyelitis with chronic demyelenizing di
26964	M		12/13/90		No	No	ASTHENIA	MALAISE	FEVER	Pt vaccinated with Heptavax-B in 1987 developed pneumonia & bronchial spasms. On 8NOV90 developed
26987	F		12/14/90		No	Yes	PARALYSIS FACIAL	HEADACHE	AMBLYOPIA	Pt vaccinated with Engerix-B developed Bell's palsy, blurred vision lt eye, headaches, hypotension, low gr
27116	F	36	12/20/90	17	No	Yes	ASTHENIA	MYELITIS	CSF ABNORM	Pt vaccinated with Recombivax HB developed progressive weakness in rt leg dx as transverse myelitis. Por
27205	M	55	12/31/90		No	Yes	MYALGIA	MYASTHENIA	RESPIRAT DIS	Pt vaccinated w/Recombivax HB developed tonsilitis w/upper respiratory infection, paresis & tingling of the
27129	F	35	01/03/91	16	Yes	No	ARTHRITIS	ARTHRALGIA		Pt vaccinated with Recombivax HB developed polyarthritis/arthralgias.
27494	M	38	01/23/91	0	No	No	ARTHRITIS			No rxn to 1st vac, but after 2nd vac had arthritis like symptoms first lt shoulder, then rt shoulder, then rt kn
27527	F	38	01/25/91	3	No	Yes	MYALGIA	FEVER		1st dose Recombivax HB dev bronchitis, unspecified resp sts, lethargy, achiness, & fever. Tx Ansaid, Unis
27551	F	60	01/28/91	45	Yes	No	ARTHRITIS	PAIN	JOINT DIS	Developed mild arthritic pain shoulder & ankles with 1st dose, 2nd shot arthritic pain worsened extended to
27553	F	23	01/24/91	53	No	No	ARTHRITIS RHEUMAT			Acute flare up of rheumatoid arthritis
27603	F	34	01/30/91	2	No	No	ARTHRALGIA	PARESTHESIA	MALAISE	Pt vaccinated w/Engerix-B 1-2 days post vaccine shoulder aches-joints of upper body - intervals had numb
27555	F	44	02/01/91	0	Yes	No	PARESTHESIA	PAIN	PAIN NECK	Exacerbation of neck pain (due to whiplash), & elevated liver enzymes w/sx related to liver involvement. Pt
27589	F		02/06/91		No	No	NEUROPATHY	NEURITIS OPTIC		/P vax pt developed optic neuritis & peripheral neuropathy.
27735	F	42	02/07/91	4	No	No	PARALYSIS FACIAL			22DEC90 Bell's Palsy/facial paralysis. Pt recovering.
27830	F	34	02/13/91	7	No	No	GUILLAIN BARRE SYND	PARESTHESIA	REFLEXES DEC	Rec'd vax 90CT90 five to seven days post vax developed progressive numbness & tingling on feet, ascenc
27844	F	39	02/13/91	0	No	No	ARTHRALGIA	JOINT DIS	HEADACHE	Onset of events occurred on the same day vaccinee rec'd her final vax (third dose in series) No tx given.
27850	F	40	02/25/91		No	No	ARTHRALGIA	PRURITUS	PHARYNGITIS	1st Engerix-B vax given JAN90, 3-4 days p/ vax, experienced URI & sinusitis, sx resolved. p/2nd vax MAR
27851			02/25/91		No	No	MYALGIA	PAIN INJECT SITE		Vaccinees rec'd a series of 3 Engerix-B vax in APR, MAY & NOV90, & experienced pain on inject. Repor
27860	F		02/25/91		No	No	REACT AGGRAV	MYALGIA	MALAISE	Rec'd Engerix-B on 8JAN90, experienced a flare-up of arthritis. Also had shoulder aches, numbness & ty
27867	F		02/25/91	9	No	No	REACT AGGRAV	PAIN NECK		Rec'd a booster of Engerix-B on 22SEP90. Experienced arthritic back, knee, shoulder, & neck pain. Knee
27888	F	23	03/18/91		No	No	ARTHRITIS	REACT AGGRAV		Rec'd Engerix-B on 8JAN90 & 2MAR90. p/second vax experienced an acute flare-up of her arthritis which
27917	F	41	03/20/91	0	Yes	No	ARTHRALGIA	PARESTHESIA	NEUROPATHY	Vaccinee rec'd 1st dose of Engerix-B on 30SEP90 & experienced pain @ inject site. 24 hrs p/she rec'd 2
27948	F	54	03/21/91	1	No	No	VISION ABNORM	NO DRUG EFFECT		Pt had series of Engerix-B vaccinations. Did not respond to first 3 shots. P/given the 4th & 5th shots expe
27960	F	32	03/21/91	0	No	No	ASTHENIA	PAIN	SOMNOLENCE	28Sep90 pt (/p 2nd dose in series) developed heaviness in ankles in both feet (1st rt then l); 10 min /p vac
27980	F	44	03/26/91		No	No	ASTHENIA	PAIN INJECT SITE	PAIN	Rec'd 1 shot of Engerix B 26JUN90. Had pain on inject & experienced listlessness & fatigued for 3 4 wks
27989			03/25/91		No	No	MYASTHENIA			Two vaccinees experienced total muscle weakness following Engerix B vaccinations (mostly in legs, occu
28008	F	51	03/26/91	1	No	No	ARTHRALGIA	HYPERTENS	DIZZINESS	Vax given 8AUG90 & 1st signs of weakness occurred that afternoon, Next day @ 130 PM vaccinee c/o p
28013	F	52	03/26/91		No	No	ARTHRALGIA			Vaccinee rec'd series of 3 Hepatitis B vax according to 0, 1, 6 mo scendule. Arthralgia started JUL89 p/2
28030	F	41	03/27/91	1	No	No	MYELITIS	NEURITIS	PARESTHESIA	Given dose 1 of vax 24JUL90. Next morning had ex of cervical myelitis, Inflammation sp cord effected all
28032	F		03/27/91	0	No	No	ARTHRALGIA			Rec'd 1st & 2nd dose according to 0, 1 mo schedule w/each dose w/in 24 hrs post vax, experienced "pa
28034	M		03/27/91		No	No	ARTHRALGIA			Developed joint pain following + 2nd vax. Condition cleared spontaneously in 1 month.
28428	F	45	03/04/91	30	Yes	No	ARTHRALGIA			In admin immunization for pre-placement policy to employees in high risk areas of work, employee c/o h
28810	M	39	03/08/91	8	Yes	No	ARTHRITIS			Arthritis.
28858	F	45	03/14/91	1	No	No	ARTHRALGIA	MYALGIA	HEADACHE	Developed 3-4 days of arthralgias within 24 hrs of receiving 3rd dose of vax. c/o myalgias, HA, sore throa
29160	F	34	03/19/91	8	Yes	No	MYASTHENIA	MYALGIA		Muscle weakness of arms for 1 wk followed by muscle soreness in trunk & neck. Sore to touch & "achy".
29270	F	5	03/27/91	0	No	No	REACT AGGRAV	CONVULS		Pt wife of abd epilepsy rec'd a 2nd vax & experienced increased convulsive attacks. Pt mom noticed th
29435	F	58	04/04/91	0	No	No	ARTHRALGIA	PAIN	CHILLS	Immun given @ 245pm, watched for 20 min following, no problems. Pt states that evening lt elbow began
29504	M	42	04/04/91	0	No	No	ARTHRALGIA			Transient arthralgia which became permanent & * FDA did not test this drug on pt who has Ehler-Danlos
29537	M	51	04/23/91	640	No	Yes	GUILLAIN BARRE SYND			Physician reported 51yr white male was vacc w/ 1st,2nd,3rd dose of hep B vacc (recomb.) in Mar,apr, &a
29538	M	40	04/23/91	182	No	No	GUILLAIN BARRE SYND	PRURITUS	NEURITIS PERIPH	15may89 pt vax w/ 3rd Hepa B. 14 hrs after vax experienced h/a w/end & pain @ inject site. w/in 24 hrs t
29539	F	22	04/23/91	196	No	Yes	GUILLAIN BARRE SYND	PARALYSIS	RESPIRAT DIS	01may89 pt vax 3rd Hepa B. 2 weeks later developed GBS @ was hospitalized w/ resp & lower-extremity
29540	M	42	04/23/91	34	No	No	GUILLAIN BARRE SYND	FLU SYND	MYASTHENIA	11sep88 pt vax developed GBS w/ flu like symp, weakness and numbness in legs, tingling hands, bilateral

VAERS ID	SEX	AGE	DATE	ONSET DAYS	ER	HOSP	DIED	COSTART 1	COSTART 2	COSTART 3	REPORTED TEXT
29541	M	46	04/23/91	200	No	Yes	No	PARESTHESIA	REFLEXES DEC	PARALYSIS	10jan90 pt vacc on 17jan90 developed paresthesia/loss of deep tendon reflexes in lower extremities follo
29542	F		04/23/91	0	No	No	No	MYASTHENIA	ARTHRALGIA	GUILLAIN BARRE SYND	27jun89 pt vax hepta B w/in several days pt developed muscle weakness, joint pain & GB sx /w inability to
29544	M	50	04/23/91		No	No	No	MYALGIA	ARTHRALGIA	ARTHROSIS	14jul89 pt vax hepta B. pt developed myalgia & polyarthralgia w/ joint swelling. Lab evaluation revealed ES
29547	F		04/23/91	1	No	No	No	PARESTHESIA	HYPERVENTIL		Pt presented to ER w/numbness on the lt side of her face, lt arm & trunk; c/o hyperventilating;
29553	M	35	04/23/91	7	No	No	No	ARTHRALGIA	ARTHROSIS	INFECT	Rt knee tenderness followed by accumulation of fluid in bursa; W/2nd dose of vax Aspiration of rt knee bu
29561	F	30	04/24/91		No	No	No	JOINT DIS	FEVER	NAUSEA	pt vax hepta B. 3-4 hrs after 2nd dose pt developed stiffness in joints, temp 101F and nausea. Symp rem
29571	F	38	04/24/91	2	No	No	No	ARTHRALGIA	PAIN INJECT SITE		15jan90 pt vax hepta B. 17jan90 pt devel pain in the elbow and a soreness at the inject site.
29591	F	35	04/24/91	0	No	No	No	ASTHENIA	PAIN	RHINITIS	Administered first & second dose vax following second dose legs felt heavy & ached fr the mid-thigh dow
29612	F	35	04/26/91	5	No	No	No	PARESTHESIA	VASC DIS PERIPH		25jun89 pt vax hepta B. pt devel. tingling from back of head to buttocks & in arms and legs. 31jul89 pt vax
29613	F	35	04/26/91	35	No	No	No	ARTHRALGIA	EDEMA PERIPH	PARESTHESIA	19may89 pt vax hepta B. pt ex arthralgia w/ edema and numbness of 3rd, 4th,& 5th proximal interphangeal
29615	M	42	04/26/91		No	No	No	MYALGIA	ASTHENIA	DIARRHEA	pt vax hepta B. pt ex myalgia, fatigue, diarrhea, h/a and a flu-like illness in1 24hrs of vax w/ his first dose
29617	M	49	04/26/91		No	No	No	ASTHENIA	DIARRHEA	HEADACHE	pt vax hepta B. pt ex fatigue, diarrhea, h/a, flu-like illness wit 24 hrs.
29622	F	40	04/30/91	0	Yes	Yes	No	ASTHENIA	VERTIGO	DIZZINESS	22jan90 pt vax hepta B. after 5 min pt ex weakness, vertigo, lightheadedness, nausea. pt presented to e
29653	F	31	05/01/91	6	No	No	No	ASTHENIA	MALAISE	ARTHROSIS	Following 1st dose of vax developed fatigue, malaise, & swelling of the joints of rt hand w/arthralgias, joint
29662	F	25	05/01/91	3	No	No	No	MYASTHENIA	PARESTHESIA	HYPERESTHESIA	Pt given 1st dose of vax 3days later developed muscle weakness, numbness & a burning sensation in her
29667	F	21	05/01/91	0	No	No	No	ARTHRALGIA	FEVER	NAUSEA	14jun89 pt vax hepta B. pt devel. arthralgia & temp 100 F on 14jun89 & nausea w/ emesis on 16jun89. 17
29672	F	37	05/01/91	1	No	No	No	ARTHRALGIA	FEVER	PAIN NECK	09feb90 pt ex joint pain esp. in neck, ankles, wrist, and fingers. pt devel temp o
29673	F	26	05/01/91		No	No	No	MYASTHENIA	MYALGIA	MOVEMENT DIS	20feb90 pt vax 2nd vax hepta B. 21feb90 pt ex severe weakness and myalgia in the left arm and was unal
29679	F	20	05/01/91		No	Yes	No	REACT AGGRAV	LE SYND		Pt vaccinated w/1st dose of vax w/o adverse experience; following 2nd dose rheumatoid arthritis flared up
29681	M	25	05/01/91	1	No	No	No	MYALGIA	FEVER	HEADACHE	36hrs post 3rd dose of vax experienced severe pain including myalgia, fever & h/a;
29687	F	19	05/01/91	0	No	No	No	MYALGIA	PARESTHESIA		W/in 1 hrs post 2nd vax developed muscle aching in arm of inject w/tingling in fingers; Rec'd 1st dose of
29688	F	35	05/01/91	0	No	No	No	MYALGIA	PARESTHESIA		W/in 1 hrs of 2nd vax pt developed muscle aches in arm of inject & numbness of hand; Pt rec'd 1st dose
29697	M	41	05/01/91	0	No	No	No	NECK RIGID	HEADACHE	PARALYSIS FACIAL	Pt developed stiff neck, h/a & ill-sided Bell's Palsy; Rec'd 2nd dose on 23MAR90 experienced same sx;
29700	F	40	05/01/91	1	No	No	No	ARTHRITIS	ASTHENIA	MALAISE	1 day post vax pt experienced worsening of her arthritis & profound fatigue & malaise; Rec'd 2nd dose of
29712	F	32	05/02/91	60	No	No	No	PARESTHESIA	MYASTHENIA	GAIT ABNORM	Jul89 pt vax 2nd hepta B. pt ex paresthesia in extremities and weakness in her gait. MD made presumpt
29713	F	65	05/02/91		No	No	No	ARTHRALGIA	MALAISE	HEADACHE	26oct89 pt vax hepta B. pt ex some joint pain and malaise, and stated that she felt generally unhealthy
29719	M	32	05/02/91	1	No	No	No	ARTHRALGIA	MYALGIA	FEVER	27mar90 pt vax hepta B. next day pt vax w/ measles, mumps and rubella virus; vax live due to a measles e
29720	F	42	05/02/91	21	No	No	No	ARTHRALGIA	PAIN		07mar90 pt vax hepta B. 28mar90 pt devel pain in shoulder and left arm between shoulder and elbow. pt
29725	F		05/02/91		No	No	No	PARALYSIS FACIAL			pt vax 2nd hepta B. 2 days later pt ex 5th and 7th nerve paralysis characterized by unilateral motor and s
29730			05/02/91		No	No	No	ARTHRALGIA			pt devel severe arthralgia following 1st vax of hepta B, no other doses had been admin
29752	M	60	05/02/91	30	No	No	No	ARTHRALGIA	GI DIS	DEPRESSION	15sep88 pt vax 2nd hepta b> 15oct88 pt ex worsening pain in rts first CMC and MCP joints of both hands
29888	M	52	04/17/91	1	Yes	No	No	MYASTHENIA	RASH	PRURITUS	Rxn to recombivax admin June/July/Dec 1991 Initially weakness in lt deltoid & shoulder blade area,,July9
30033	F	38	04/25/91	15	No	No	No	VISION ABNORM	NEURITIS OPTIC		Lt eye dec vision about 12Feb91; appr/w eye MD 5Mar91. 12Mar91 DX /w ocular neuritis.
30083	M	39	04/29/91		No	No	No	ARTHRALGIA			2yrs s/p/vax series completed empl/vax found to be negative for Anti-HBs- waning immunity, Lt shoulder jo
30460	F	23	05/17/91	1	No	No	No	MYALGIA			Employee describes significant myalgias in calfs & legs X 2 days.The sx resolved spontaneously.No feve
30509	F	47	05/17/91	0	No	No	No	ARTHRALGIA	SWEAT	CHILLS	W/in 20min of vax, experienced arthralgia rec'd. 2nd dose w/in 20min experienced cold sweats, chills, mo
30509	F		05/17/91		No	No	No	ASTHENIA	NEURITIS PERIPH		Experienced fatigue following adm of 1st two doses of Hepatitis B vaccine; 1 month following 3rd dose, pt
30513	M	53	05/17/91	0	No	No	No	PARESTHESIA	NEUROPATHY	NEURITIS PERIPH	Pt adm 1st dose of vax ID experienced numbness in his wrist; Rec'd 2nd does & experienced a more pro
30520	F	31	05/17/91	1	No	No	No	ARTHRALGIA	FEVER	CHILLS	04may90 pt vax hepta B. next day pt devel joint pain and fever, chill, abdo cramps. fever remitted sponta
30525	M	46	05/17/91	0	No	No	No	ARTHRITIS	PARESTHESIA	SYNOVITIS	10may90 pt vax hepta B. w/i few hrs pt devel arthrxs which described as synovitis and stocking paresthe
30528	F		05/17/91	5	No	No	No	ARTHRITIS	RASH PETECH	EDEMA PERIPH	11oct89 pt vax 2nd hepta B. 16oct89 pt devel arthritis, 4 days later pt devel petechial rash on legs. 27no
30534	F	24	05/22/91	11	No	No	No	JOINT DIS	PAIN INJECT SITE	PAIN	Pt rec'd 2nd dose of vax 30JUL89 & developed morning stiffness in the lt shoulder in which vaccination o
30541			05/22/91		No	No	No	NEURITIS PERIPH			Pt developed peripheral neuropathy following vax w/Heb B;
30550	F	21	05/22/91	0	No	No	No	ARTHRALGIA	DIARRHEA		1hr post vax pt developed severe arthralgia; 2 hrs later she developed diarrhea;
30568	F	34	05/23/91	64	Yes	No	No	MYALGIA	VOMIT	PAIN ABDO	13dec88 pt vax 2nd hepta B. 16dec89 pt ex fever, aching,nausea, vomiting, upper right quad abdo pain,
30571	F	27	05/23/91		Yes	No	No	ARTHRALGIA	MYALGIA		14may90 pt vax hepta B. pt devel arthralgia and myalgia. concomitant med included sudafed, actifed, fo
30572	F	39	05/23/91	0	No	No	No	PARESTHESIA	PAIN	NAUSEA	08jun90 pt vax hepta b> 4 hrs later pt ex tingling, tenderness and shrp pains from hip to knee of lateral as
30577	M	32	05/23/91		No	No	No	ARTHRALGIA	PAIN		25jan90 pt vax hepta B. pt ex joint pain in fingers of both hands that persisted for 2 weeks. 20feb90 2nd v
30578	F	42	05/23/91	0	No	No	No	ARTHRALGIA	NAUSEA	EDEMA	28mar90 pt vax hepta b. pt ex joint aching, and nausea which remitted wit few days; abnb aches to cocu
30585	F	29	05/28/91		Yes	No	No	PARESTHESIA	PAIN		13apr90 and 04may90 pt vax hepta B. each time pt ex numbness and pain in the left side of face, lt inclu
30643	F		05/21/91		No	No	No	PARALYSIS			13jun89 pt vax hepta B. pt ex complete paralysis of arm.
30644	M	54	05/21/91	1	No	No	No	REACT AGGRAV			30jun90 pt vax hepta B. played golf 18 hrs after vax and ex reactivation of eye lid herpes simplex on 01ju

VAERS ID	SEX	AGE	DATE	ONSET DAYS	ER	HOSP	DIED	COSTART 1	COSTART 2	COSTART 3	REPORTED TEXT
347	F	47	05/21/91		No	No	No	MYASTHENIA	PAIN CHEST		03may90 pt vax hepta B next day pt devel weakness in left extremity w/i 2 weeks weakness resolved. 04J
30665	F	31	05/22/91	24	Yes	No	No	PARESTHESIA			08dec88 pt vax hepta B pt ex numbness in left arm. 05jan89 2nd vax in june 89 pt ex numbness in shoulder
30723	F	28	05/24/91	31	No	Yes	No	SCLEROSIS MULT	PARESTHESIA	VISUAL FIELD DEFECT	"Several wks' p/vax pt was hospitalized due to visual disturbances & muscle weakness. Dx multiple sclerosis
30764	F	45	06/04/91	24	No	No	No	ARTHRALGIA			08jan89, feb-89 and aug-89 pt vax hepta B. In feb-89 and mar-89 pt devel proximal interphyngeal joint pain
30765	M	37	06/04/91	0	No	No	No	MYALGIA	PAIN INJECT SITE	ARTHRALGIA	nov-88 and dec-88 pt vax hepta B aft each vax pt devel flulike sx. may-89 pt 3rd vax pt ex myalgia, and ar
30773	F	50	06/06/91	0	No	No	No	REACT AGGRAV			apr90 pt vax hepta B. 7 days aft vax pt devel alopecia. may90 pt vax 2nd hepat B alopecia worsened to "a
30778	M	60	06/06/91	1	No	No	No	PARESTHESIA	PARALYSIS		02aug90 pt vax hepta b. 24hrs aft vax pt devel numbness and tingling of rt leg. 48hrs aft vax pt unable to "m
30779	F	46	06/06/91	6	No	No	No	VISION ABNORM	PAIN	FEVER	19jul90 pt vax hepta B. 25jul90 pt ex visual disorder desc. as obstructing lines which lasted for one hr. pt ex
30782	F	49	06/06/91	0	Yes	No	No	ASTHENIA	PAIN CHEST	PAIN	04may90 pt vax hepta B. pt devel excessive fatigue. 04jun90 pt vax 2nd hepta b. 15jun90 pt devel excessive
30906	M	23	06/04/91	16	Yes	Yes	No	ARTHRALGIA	MYASTHENIA	RASH MAC PAP	Pt developed joint pain, muscle pain & weakness x 1wk; severe weakness in legs followed by facial & trunk
30965	F	40	06/06/91	0	No	No	No	ASTHENIA	VASODILAT	ANOREXIA	Felt very warm, took temp was normal, felt fatigued, c/o fatigue, loss appetite, dizziness;
30967	F	25	06/06/91	1	No	No	No	PARESTHESIA	ARTHRALGIA		Numbness in joints, arms & aching for 3 days.
30979	F	20	06/06/91		No	No	No	MYALGIA	PAIN EAR		pt vax hepta B. pt ex general achiness, and earache. visited w/ 2nd dose w/o adverse reaction
30981	F	58	06/05/91	0	No	No	No	ASTHENIA	HEADACHE	PAIN ABDO	pt vax hepta B. w/i 24 hrs pt ex fatigue, weakness, h/a, malaise. w/i 24 -48 hrs pt ex fleeting nausea in mor
30983	F	45	06/05/91		No	No	No	ARTHRALGIA	ARTHRITIS		pt vax hepta B. pt devel arthritis and arthralgia. pt vax 2nd hepta B. and ex same sx.
30985			06/05/91		No	No	No	ARTHRALGIA			pt vax hepta B, pt devel arthralgia which persisted for 4-5 months
30987	M	60	06/05/91	1	No	No	No	PARESTHESIA	PARALYSIS		02aug90 pt vax hepta B. 24hrs later pt devel numbness and tingling in rt leg. by 05aug90 pt was unable to "
31023	F	8	06/07/91		No	No	No	ARTHRITIS			pt vax hepta B. pt ex arthritis which resolved spontaneously in 3 weeks.
31054	F		06/10/91		No	No	No	GUILLAIN BARRE SYND			pt vax'd w/ 3 doses of Hepatitis B vaccine in approx OCT90 following vax developed Guillain Barre synd
31059	F	63	06/10/91	14	No	No	No	PARALYSIS FACIAL			pt vax'd w/ 1st dose hepatitis B and developed rt facial nerve palsy.
31074	F	42	06/10/91		No	No	No	ASTHENIA	DIZZINESS	NAUSEA	pt vax'd w/3 doses hepatitis B vac & experienced after each dose tiredness, light-headedness, weakness, & "
31078	F	45	06/10/91	0	No	No	No	PARESTHESIA			pt. vax'd w/1st dose of hepatitis B vac., 2hrs p/vax developed numbness of left side face.
31152	M	45	06/12/91	92	No	Yes	No	MYALGIA	GUILLAIN BARRE SYND		Mar90 pt vax w/ 1st hepta B w/o adverse effect. Apr90 vax w/ 2nd hepta B. Jun90 pt devel muscle weakness
31154	M	42	06/12/91	176	No	No	No	PARESTHESIA	ARTHRALGIA	MYALGIA	15Jul90 pt vax w/ hepat B. w/i 48h ex skin tingling, joint pains in all knees and myalgia in thighs. All 2
160	F	37	06/12/91		No	No	No	JOINT DIS	HYPERTONIA	PAIN	14Oct88 pt vax w/ hepta B, p/ 1 month pt ex morning stiffness, pain + swelling of neck, shoulders, elbows "
31161	M	47	06/12/91		No	No	No	ARTHRALGIA	FEVER	EDEMA	Pt vax w/ 2nd hepta B; 2 days later devel polyarticular arthralgia + fever 103F, swelling of hands, feet, + kne
31165	M	35	06/14/91	138	No	No	No	PARALYSIS FACIAL	INFECT		Pt rec'd 1st & 2nd dose vax 20DEC89 & 19JAN90 resp; On 7MAY90 pt exp loss of control of rt side of face
31166	F	42	06/14/91	0	No	No	No	ARTHRALGIA	HYPESTHESIA	PARESTHESIA	p/1st vax devel soreness of lt arm & shoulder joint, w/numbness & tingling of lt hand. 6JUL90 given 2nd dose
31168	F	35	06/14/91	31	No	No	No	ARTHRITIS			MD reported pt rec'd 1st dose of vax w/out adverse event; 2nd dose of vax in MAR90. Wks post vax exp pol
31176	F	56	06/14/91	121	No	No	No	ARTHRITIS	ARTHRALGIA	ARTHROSIS	Pt rec'd 1st & 2nd dose of vax DEC86 & JAN87 resp; APR87 pt developed generalized osteoarthritis w/pain
31177	F	54	06/14/91	90	No	No	No	ARTHRITIS	PAIN	PAIN BACK	Pt given 1st dose of vax DEC85, 2nd dose of vax JAN87; in approx MAR87 exp arthritis in lt hip, lt knee, rt "
31185	F	47	06/13/91	7	Yes	No	No	ASTHENIA	PAIN	PARESTHESIA	12apr90 pt vax 2nd hepta B. 19apr90 pt ex weakness and pain of left upper extremity, w/ pain and tingling "
31190	M	47	06/13/91		No	No	No	ARTHRALGIA			15aug90 pt vax hepta B. pt ex joint soreness.
31193	M		06/13/91	6	No	No	No	ASTHENIA	MALAISE	PAIN ABDO	05sep90 pt vax hepta B. 11sep90 pt ex fatigue, malaise, abdo cramps, rash, itching, myalgia and fever. sx "
31194	M		06/13/91	7	No	No	No	ARTHRALGIA	HEADACHE	NAUSEA	12sep90 pt vax 3rd hepta b. pt ex arthralgia, h/a, n, diarrhea, and weakness. sx resolved
31201	F	35	06/24/91		No	No	No	PARESTHESIA	FEVER	VOMIT	pt. vax'd w/ 1st dose of hepatitis B vac. & exp. paresthesia of left buttocks, thigh, & vagina w/ fever, emesis & "
31236	F	40	06/14/91		No	No	No	ARTHRALGIA			Pt vax w/ hepta B; 4 days later devel arthralgia, which resolved over next few days. nurse attnb pt exp to hig
31245	M	46	06/18/91	87	No	Yes	No	NEUROPATHY	ASTHENIA		06Mar and 10Apr90 pt vax w/ hepta B. Jun90 pt devel unspecified neurologic sx. dx of Guillain Barre Syndr
31247	F	38	06/18/91	0	No	No	No	ARTHRALGIA	MYALGIA	PALPITAT	Mar90 pt vax w/ hepta B. pt exp arthralgias in shoulders and spreading to elbows and wrists over next severa
31305	F		06/20/91		No	No	No	ASTHENIA	NAUSEA	SGOT INC	04Oct90 pt vax w/ hepta B; devel fatigue + nausea which persisted until 19Oct90. SGOT values elevated
31315	M	20	06/21/91		No	No	No	PARESTHESIA	CONJUNCTIVITIS		pt. vax'd w/ 1st dose of hepatitis B & exp. tingling in arm. vax'd w/ 2nd dose and exp. tingling in arm and dev
31318	F	30	06/21/91	19	Yes	No	No	ASTHENIA	PHARYNGITIS	LYMPHADENO	pt. recv'd 3rd dose hepatitis B vac & later exp. weakness, sore throat swollen lymph glands, T102, & rash cove
31321	F		06/21/91		No	No	No	ASTHENIA	NAUSEA		pt. recvd 1st hepatitis B vac & exp. tiredness, weakness in legs & nausea.
31330	M	73	06/21/91	13	No	No	No	ARTHRITIS	PAIN	GAIT ABNORM	pt. recovering fr. auto accident recvd a dose of hepatitis B vac & exp. arthritic pain in knees & exp trouble w
31747	M	68	06/27/91	1	No	No	No	ASTHENIA	LIVER FUNC ABNORM		Very tired, weak, fatigue easily which has improved, onset p/3rd vax, abn liver function tests which so far pe
31783	F	52	07/01/91	10	No	No	No	REACT AGGRAV			22Aug89 pt vax w/ 2nd hepta B, exp transitory arthralgia involving wrists, elbows, and left ankle + persistent
31786	M		07/01/91	3	No	No	No	ASTHENIA	ARTHRALGIA	INSOMNIA	08Nov90 pt vax w/ hepa B. 10Nov90 participated in 10.4m run. 11Nov90 exp syndrome characterized by fa
31816	F	51	07/02/91	2	No	No	No	ASTHENIA	SOMNOLENCE	PAIN NECK	1MAY91 1St inject of series, 3MAY91 slept all day- very very tired. Continued tiredness w/addition of lt neck
31844	M	26	07/02/91	2	No	No	No	MYALGIA	ASTHENIA	VASODILAT	Myalgias, fatigue, flushing, eye puffy;
1860	F	34	07/03/91	8	No	No	No	MYALGIA	DIARRHEA	MYOSITIS	8 days following vax pt exp pharyngitis & diarrhea, 16 days following vax exp erythematous rash on chest, ab
31879	F		07/03/91	4	No	No	No	ARTHRITIS			Pt given 1st dose of vax on approx 28OCT90 subsequently, pt exp arthritis, As of 28NOV90 the sx had resolv
31928	M	32	07/08/91		No	No	No	ASTHENIA	RASH VESIC BULL	PRURITUS	pt recvd 2 doses of Hep B vax dialysis formulation 1ml instead of Hep B vax 1ml on 03OCT90 & 03NOV90 " P

VAERS ID	SEX	AGE	DATE	ONSET DAYS	ER	HOSP	DIED	COSTART 1	COSTART 2	CASTART 3	REPORTED TEXT
931	F	41	07/08/91	187	No	No	No	PARALYSIS FACIAL			Pt recvd 3rd dose of Hep B 18DEC90 & 22DEC90 devel Bell's Palsy. Pt recvd 1st & 2nd doses 18JUN90
31934			07/08/91		No	No	No	ARTHRITIS			pt recvd dose of Hep B vax & devel arthritis.
31938	M		07/08/91	7	No	No	No	ARTHRITIS	PRURITUS	URTICARIA	pt recvd dose of Hep B vax 18JUN87 On 25JUN87 exam revealed synovitis in ankles, 'sore' fingers & depr
31945	F	46	07/08/91	0	No	No	No	VISION ABNORM	DIZZINESS		pt recvd 1st dose of Hep B vax 23JUN89 & later exp visual problems & dizziness
31946	F	30	07/08/91	0	No	No	No	ASTHENIA	CONFUS	HEADACHE	pt recvd 2nd dose of Hep B vax 12JUL89 & exp weakness,confusion & hva w/ mopon sickness On 14AUG
31953	M	43	07/05/91	0	No	No	No	ASTHENIA	MYALGIA	NAUSEA	Fatigue, myalgia, nausea, skin rash; rash began 7hrs postop remainder of sx began 24hrs post & lasted 4
32050	F	46	07/10/91	4	No	No	No	NECK RIGID	HYPESTHESIA	HEADACHE	Pt recvd 1st dose of Hep B vax 27JUN89 as a result of needle stick. On 01JUL89 devel stiff neck, numbne
32055	F	42	07/08/91	1	No	No	No	ASTHENIA	AMBLYOPIA	DIZZINESS	Pt recvd 1st dose of vax 21MAY90 & exp weakness,blurred peripheral vision,postural hypotension,dizzines
32074	F	35	07/25/91		No	No	No	ARTHRALGIA	MYALGIA		Pt vax w/ hepta B; devel diffuse arthralgias & myalgias. Persisted for 1 month and are subsiding.
32097	F	41	07/26/91		No	No	No	ARTHRALGIA	ASTHENIA	MYALGIA	Pt vax w/3rd hepta B; exp severe joint pain, fatigue, myalgia, still having problems, & inc lymphadenopathy
32102	F	29	07/26/91	1	No	No	No	PARESTHESIA			11Dec90 pt vax w/ hepta B; 12Dec90 exp rt arm going asleep for aprox. 2 sec, twice a day. Continued un
32107	F	33	07/09/91	3	No	No	No	VISION ABNORM	HEADACHE	NAUSEA	29Aug89 pt vax w/ hepta B; over next 2 weeks exp vision difficulty as if looking through gas vapors, hva, na
32113	F	47	07/09/91	0	No	No	No	MYALGIA	HEADACHE	ARTHRALGIA	10Oct89 pt vax w/ double dose of hepta B; devel muscle aches, severe hva, arthralgia. Missed 5 days of w
32123	F	50	07/10/91	7	No	No	No	MYALGIA	ASTHENIA	RASH	Oct89 pt vax w/ hepta B; 08Oct89 devel severe myalgia + fatigue + rash. PT tx w/ steroids. MD felt that re
32124	F	34	07/10/91		No	Yes	No	MYALGIA	LAB TEST ABNORM		05Jun89 pt given L-tryptophan w+ ex muscle aches. 04Aug89 pt vax w/ 3rd hepta B; sx worsened + was h
32129	F	37	07/10/91	5	No	No	No	ASTHENIA	EXTRASYSTOLES VENT	CARDIOVASC DIS	27OCT89 pt vax w/hepta B; 01NOV89 felt weak, tired, sick, & had PVC's assoc w/mitral valve prolapse. Sx
32133	F	40	07/10/91		No	No	No	ARTHRITIS			Pt vax w/ 2nd hepta B. One month later devel bilateral capsulitis. Tx w/ anti-inflammatory therapy, possibly
32141	F	25	07/12/91		No	No	No	PARALYSIS FACIAL			Pt recvd 1st dose of Hep B vax & later devel Bell's Palsy. Tx w/unspecified steroids.
32146	F	48	07/12/91	0	No	No	No	ASTHENIA	ARTHRALGIA		Pt recvd 1st dose of Hep B vax 28NOV89 & exp fatigue & awakened in morning w/ disseminated arthralgia
32156	F	34	07/12/91	2	No	No	No	ASTHENIA	NAUSEA	SOMNOLENCE	Pt recvd 1st dose of Hep B vax 06DEC89 & exp nausea,weakness & lethargy Pt recvd 2nd vax 05JAN90
32196	F	30	07/11/91	10	No	No	No	ARTHRALGIA	PAIN	PAIN BACK	Pt recvd vax 15FEB91; On 25FEB91 exp severe arthralgias; tx w/meds; approx 2 wks later exp severe ankle
32215	F	41	07/19/91	1	Yes	No	No	ARTHRALGIA	MALAISE		Pt recvd 1st dose of hep B vax 22JAN91 & exp diffuse arthralgia & malaise. Tx w/ meds MD feels events re
32232	F	37	07/22/91		No	No	No	ARTHRALGIA			Pt recvd 2 hep B vax on SEP90 & OCT90 & exp arthritic pain for 3 days.
32251	F	41	07/15/91		No	No	No	NEURITIS OPTIC	ANA	NEURITIS RETROBULBAR	Pt recvd 3rd dose of Hep B vax & devel optic neuritis.
380	F	39	07/16/91	0	No	No	No	MYALGIA	HEADACHE	PAIN NECK	Pt vax w/ 2nd hepta B on 04Dec90; Later pt exp aching all over, hva, neck ache. 9 hrs later pt exp vomiting
32386	F	37	07/17/91	2	No	No	No	ARTHRALGIA	ARTHROSIS	DYSPEPSIA	05Nov90 pt vax w/ hepta B; exp transient joint pain. 14Dec90 vax w/ 2nd dose, devel severe joint pain in an
32388	M	26	07/17/91	0	No	No	No	MYASTHENIA			04Feb90 pt vax w/ hepta B; exp muscle weakness in both legs. This was a 2nd dose in a series of 3 dose
32468	F	41	07/19/91	4	No	No	No	ARTHRALGIA	EDEMA	EDEMA FACE	27Dec90 pt vax w/ hepta B; 31Dec90 exp arthralgia & swelling of hands & face. No tx.
32470	F		07/23/91		No	Yes	No	ARTHRALGIA	ERYTHEMA NOD		Aug90 pt vax w/ 2nd hepta B; devel severe arthralgia. Tx w/ nsaid, solu-cortef, colchicine. Skin biopsy inc
32485	F	49	07/23/91	14	No	No	No	PARESTHESIA	PAIN	EDEMA PERIPH	07Feb91 pt vax w/ hepta B; exp left arm paresthesia which rotated to right arm. Pt recv CAT scan & MRI le
32486	F		07/23/91	379	No	No	No	PARESTHESIA	ALLERG REACT	DYSPHAGIA	16JAN91 pt vax w/ hepta B; exp trigeminal paresthesia left cheek roof of mouth. Recv CAT scan & MRI
32765	M	38	07/29/91	0	No	No	No	ARTHRITIS	MYALGIA	MYASTHENIA	Pt recvd 1st dose vax w/o problem.PY 2nd vax 02JUL90 felt arthritis like sx in shoulders & knee.PY 3rd vax n
32771	F	37	07/24/91	14	No	Yes	No	ARTHRALGIA	ERYTHEMA NOD		Pt recvd 2 doses of Hepatitis B vax; 2wks following 2nd dose devel severe arthralgia & dx w/erythema nodo
32942	F	36	07/31/91	365	No	No	No	NEURALGIA	PAIN	PAIN BACK	Pt recvd 1st dose on vax 9MAY90. Thxr day inject arm itching all day; Retolved 9MAY90; nausea, stomach
32943	M	72	07/31/91	31	No	No	No	VISION ABNORM			Pt recvd 1st dose of vax 10APR90 & devel star burst effect on lt eye, seen by ophthalmologist w/vision impri
32951	F	49	07/31/91	1	No	No	No	ARTHRALGIA	MYALGIA	FEVER	Day following vax pt had onset of athralgia, myalgia, temp 100, pr2nd immun developed polyarthritis. HBSAg
32954	F	60	07/31/91		No	No	No	ARTHRITIS	ARTHRALGIA	PAIN	Pt recvd 1st dose of Engerix-B IM/deltoid 19DEC89, w/in 2 wk period pt1st dose exp flare up of arthritis & n
33063	F	38	08/02/91	375	No	No	No	ARTHRALGIA	PRURITUS	RASH MAC PAP	8 days post vax pt exp arthralgia, mainly knees, lasting several days; 10 days post vax pt exp severe itching
33064	M	29	08/02/91	113	No	Yes	No	PARALYSIS	NEUROPATHY	PARESTHESIA	3 to 4 months post vax pt exp distal polyneuropathy w/paresthesia, pain & tremor; pt hospitalized from 31MA
33078	F	57	08/02/91	15	Yes	No	No	PARESTHESIA	TWITCH	ARTHRALGIA	11Sep89 pt vax w/Recombivax, next Engerix B 17OCT89; later exp joint pains lasting 6 weeks; fever, rt upper
33086	F	41	08/02/91	1	Yes	No	No	MYELITIS	NEURITIS	PARESTHESIA	pt recvd 1st vax 24JUL90; next day exp cervical myelitis, inflam sp cord effected all extremities; neuritis; sse
33087	F	30	08/02/91		Yes	No	No	MYALGIA	NEUROPATHY	MYOSITIS	Pt exp aching in shoulders, hands, hips & fingers 4 mo prsecerving 2nd dose vss, DX w/either polyneuropat
33211	F	65	08/08/91	7	Yes	No	No	ARTHRALGIA	PAIN NECK	PAIN BACK	Wrist, shoulder, knee, pain sore neck, back pain;
33221	F	53	08/08/91	3	No	No	No	MYALGIA	EDEMA	VASODILAT	Aching, red, swollen joints, hot to touch & dec temp.
33277	F	59	08/07/91	2	No	No	No	ASTHENIA	NAUSEA	DIZZINESS	2 days pvax pt began feeling very tired, had nausea, dizziness, & face was flushed while body was cold.
33407	M		08/12/91	0	Yes	No	No	ARTHRALGIA	REACT AGGRAV	ARTHRITIS	Pt recvd 3 doses of Hep B vax in OCT1983, NOV1983, & MAR1984, respectively; Since the 3rd vax pt exp s
33643	F	50	08/14/91	0	No	No	No	PARESTHESIA	TREMOR	DIZZINESS	24MAR91 pt 3rd vax; exp arm felt funny, hand was shaking, lightheaded, n, weak, & pale, felt hot & had chil
33648	F	30	08/14/91	14	No	No	No	ARTHRITIS	ARTHRALGIA	ARTHROSIS	15FEB91 pt vax; 01MAR91 exp onset of joint pain in knees, ankles, back & neck. Tx w/ Prednisone, ASA, ir
33649	F	37	08/14/91		No	No	No	NEURITIS OPTIC	AMBLYOPIA	ANEURYSM INTRACRAN	Pt vax & 2 weeks later exp optic neuritis.
33693	F	44	08/15/91		No	No	No	NEURITIS OPTIC			Pt recvd Hep B vax series in 1987, & recvd booster dose in MAR90, was revaxed in SEP90 & devel optic ne
33709	F	33	08/16/91	0	No	No	No	ARTHRITIS	HEADACHE	CHILLS	Pt recv 1st & 2nd dose on 22Jan & 22Feb91. 22Feb devel n/a for 2 days. 24Feb91 exp chills, fever, dizzir
33783	M	38	08/20/91		No	No	No	MYALGIA	FLU SYND	JAUNDICE	Pt recvd 1st dose of Engerix-B & exp 3 day episode of flu-like synd w/jaundice & body aches. The exact dat

VAERS ID	SEX	AGE	DATE	ONSET_TO_DAYS	ER	HOSP	DIED	COSTART 1	COSTART 2	COSTART 3	REPORTED TEXT
33784	F		08/20/91	1	No	No	No	MYALGIA	ULCER MOUTH		7MAR91 recvd Engerix-B & on 8MAR91 exp general achiness & a sore on lip ('like a fever blister'); No thr
33787	F	65	08/20/91	4	No	No	No	NECK RIGID	PAIN	ASTHENIA	Pt recvd 1st dose of Erroenix-B vax & exp stiffness in neck rt side 4-5 devs post vax. Pain in it upper arm e
33797	F	32	08/20/91	18	No	No	No	ASTHENIA	INFECT		12Oct90 pt vax 2nd dose, exp tiredness. Pt undergoing testing for Epstein-Barr. Results positive.
33818	M	62	08/20/91	90	No	No	No	REACT AGGRAV	REACT UNEVAL		Pt recvd 3 doses of Engerix-B, 3rd dose given 21NOV90; 19FEB91 was hospitalized for acute bronchitis; p
33817	F	32	08/20/91	1	No	No	No	REACT AGGRAV	FEVER	ARTHRALGIA	Pt recvd 1st dose of Engerix-B vax 17SEP90 & exp exacerbation of Lupus the following day 18SEP90. Af
33819	F	43	08/20/91	0	No	No	No	PARESTHESIA	MYALGIA	ARTHRALGIA	Pt recvd 1st dose of vax on 4MAR91 & exp immediate numbness & tingling in both arms & hands; c/o gen
34115	M	47	09/04/91		No	No	No	ASTHENIA	PHARYNGITIS	ASTHMA	01Feb, 01Mar, 17Apr91 pt vax, exp immense fatigue after 1st dose, mod to severe reaction after 2nd dose
34134	F	33	09/27/91	13	No	Yes	No	GUILLAIN-BARRE SYND	SERUM SICK	PERICARDITIS	Allergic to Hep vax, appears like rheumatoid arthritis, conjunctivitis, dehydrated, emotional trauma encepn
34152	F	47	09/03/91	8	No	No	No	ASTHENIA	ARTHRALGIA	PAIN	Pt recvd Engerix-B on 21MAR91 & 22APR91. 1 wk p/1st dose of vax, pt exp joint stiffness, aches & malai
34153	F	45	09/03/91		Yes	No	No	ARTHRALGIA	PAIN	HYPERTONIA	Pt recvd 1st dose of Engerix-B 15MAR91 & exp arthralgias. MD visit required; tx ASA, MD did not think ev
34275	F	47	09/03/91	0	No	No	No	ASTHENIA	NO DRUG EFFECT		Pt recvd 3 doses of series of Engerix-B & exp moderate fatigue 3-4 hrs p/each dose lasting 24-72 hrs. HE
34277	F	79	09/03/91	0	No	No	No	ARTHRALGIA	JOINT DIS		21MAY91 pt vax; exp temporomandibular joint pain on rt side 2 hrs after vax & temporomandibular joint pa
34920	F		09/19/91		No	No	No	ARTHRALGIA	EDEMA	ARTHRITIS	Pt exp ren 24 to 48 hrs p/this first inject; arthralgia & swelling of joints of hands; tx Motrin.
34960	F	60	09/26/91	0	Yes	Yes	No	ARTHRALGIA	MALAISE	ARTHROSIS	Pt recvd 3 doses of Recomb vax 1 to 2 yrs prior to report & did not seroconvert (WAES #91090418), pt gi
35050	F	47	10/01/91	2	Yes	No	No	PARESTHESIA	LOH INC	SGPT INC	Pt c/o 'numbness/fullness under rt rib cage'; pt (employee) went to family MD. Onset of sx occurred approx
35058	M	40	10/01/91		Yes	Yes	No	MYELITIS			Pt recvd 2nd dose of Hep B & two wks following vax, pt exp transverse myelitis;
35125	F	30	10/04/91	14	No	No	No	ARTHRALGIA			Pt recvd Engerix-B vax on 25FEB91 & exp arthralgias 2 wks later; Was treated w/Pred & seeing a specialist
35133	F		10/04/91		No	No	No	ARTHRITIS PYOGEN	FEVER	ARTHRALGIA	Pt recvd 4 doses of Engerix-B, given 4th dose MAY & 'HBIG' was given for post-exposure prophylaxis. Pt
35329			10/11/91		No	No	No	ARTHRALGIA			2 nurses exp arthralgias following the Hepatitis B vax;
35337	F	62	10/21/91		No	No	No	ASTHENIA	PLEURAL DIS		Pt recd 2 vaxs (1cc); 1st dose, either May or June, was uneventful; p/2nd dose, either June or July, 'deve
35341	F	19	10/21/91	0	No	No	No	NEURITIS	HYPESTHESIA	MYASTHENIA	Pt recd 2 doses vax (1cc) 18FEB91 & 18MAR91; p/2nd dose devd numbness & weakness of left arm; sym
35343			10/21/91	0	No	No	No	MYALGIA	HYSN INJECT SITE	MALAISE	3JUN91, 5hrs p/vax, exprd muscle aches & pains esp ankles, wrists, & hands; c/o feeling sick & achy; too
35392	F	30	10/14/91	0	No	No	No	ASTHENIA	HYPERTONIA	HEADACHE	Pt recvd first dose of vax 21MAY91 for Hep vax & immediately felt strange, pt reported weakness, muscle
35430	F	50	10/16/91	0	No	No	No	NECK RIGID	EDEMA INJECT SITE	SKIN DISCOLOR	Pt recvd 1st Engerix-B vax 28JUN91 & 2 hrs p/receiving the inject pt noticed stiffness & side of neck; Pt ex
35440	F	40	10/16/91	1	Yes	No	No	ARTHRALGIA	MYASTHENIA		Pt recvd vax 1st & 2nd dose of Hep B vax (brand unspecified) & recvd 3rd, Engerix-B on 19MAY91; w/in 2
35565	F	26	10/22/91	0	No	No	No	PARESTHESIA			Pt recvd dose of Engerix-B on 27JUN91 @ 12 noon booster dose, 2 hrs later 2PM exp tingling @ inject sit
35581	F	23	10/22/91	0	No	No	No	MYALGIA	ASTHENIA	HEADACHE	Pt recvd 1st dose of Engerix-B vax on 1JUL91 & 2nd dose 8AUG91 for Hep B prevention; 2 hrs p/2nd dos
35841	F	39	10/30/91		Yes	Yes	No	MYALGIA	ALLERG REACT	DYSPNEA	Pt recvd 1st vax & 'felt bad'. Given 2nd vax, devel OM & a ruptured ear drum & hospitalized 4 or 5 days; p
35926	F		11/05/91		No	No	No	NEURITIS OPTIC	BLIND		Pt recvd Hep B vax p/being splashed w/blood from a pt; devel optic neuritis; @ time of report, extent of los
35963	F		11/20/91		No	No	No	MYALGIA	ASTHENIA	REACT AGGRAV	Recvd Hep B vax AUG88 immediately p/muscle ache, weakness, fatigue;
36139	F	26	11/27/91	1	No	No	No	ASTHENIA	NEURALGIA		Subsequent to vax, pt devel tiredness, 31JUL91 pt devel trigeminal neuralgia; p/2 days, tiredness resolved
36184		34	11/13/91	0	No	No	No	PARESTHESIA	DYSPEPSIA	TACHYCARDIA	Pt recvd 2nd dose of Heptavax & exp numbness of extremities, nervous stomach, rapid pulse, flutery heart
36343	F	47	11/18/91	0	Yes	No	No	ASTHENIA	DIZZINESS	PALPITAT	W/in 10 minutes of inject felt weak, lightheaded, dizzy, had heart palpitations, tachycardia, diaphoresis, cl
36458	F	40	11/20/91	1	Yes	Yes	No	ARTHROSIS	ARTHRALGIA	FEVER	26SEP91 pt awoke w/swollen, painful joints; few hrs later pt exp sore throat, n/v, chest, pain & fever; @ ER
36555	F	28	11/22/91	1	No	No	No	ASTHENIA	HEADACHE	MYALGIA	3OCT91 tried n/v, muscleache; 4OCT91 severe fatigue, flushing, chills n/v, diarrhea, muscle ache, cold s
36792	F	44	05/29/92	1	Yes	No	No	ARTHRITIS	PAIN	ARTHRALGIA	Pt recvd booster dose of Engerix-B 12FEB92 & c/o w/in 12 hrs exp arthritic pain, muscles & joints really ha
36800	F	47	06/29/92	2	No	No	No	PARESTHESIA	HEPATOMEGALY	SGPT INC	Pt recvd 3 doses of Engerix-B & approx 2 days pos dose #3 pt c/o numbness & fullness under rt ribs, wen
36857			06/30/92		No	No	No	MYALGIA			Pt recvd 1 dose of Engerix-B & exp muscle ache & pain.
36881	M	33	06/30/92		Yes	No	No	ARTHRALGIA	MYALGIA	PAIN	p/receiving 2nd dose of Engerix-B vax aches & pains in knees, legs & fingers; pt exp same sx w/1st dose b
36903	F		07/06/92		No	No	No	ASTHENIA	FLU SYND	FEVER	Pt recvd 2 doses of Engerix-B following a puncture wound; pt exp extreme fatigue, flu-like sx, t100.6 fever c
37766	F	22	08/14/92		Yes	No	No	REACT AGGRAV			pt recvd 2 doses of Engerix-B & devel urinary yeast infection; 1st yeast infect never entirely went away &
37790	F	49	12/06/91	3	No	No	No	MYALGIA	HEADACHE	NECK RIGID	72 hrs p/2nd dose myalgia, severe n/v & mild c/o 'nuchal rigidity', bilateral calf pain & weakness.
37921	M	26	12/17/91	0	Yes	No	No	PARESTHESIA	DYSPNEA	VERTIGO	Pt recvd vax 7NOV91 8AM, returned to work noted numbness/tingling in hands by 10AM; noted inc paresth
38138	M	29	12/27/91		No	Yes	No	ARTHROSIS	ANEMIA HYPOCHROM	ESR INC	On 09OCT91 3 mos p/recving 2nd dose of vax, pt was hospitalized for polyarthropathy; tx: Indomethacin; pt
38194	F		01/03/92		No	Yes	No	PARESTHESIA	PAIN	SCLEROSIS MULT	Pt recvd 1st dose of Engerix-B FEB91 & some day later felt paresthesias in one foot & 'bad pain to waist' 3
38226	F	49	01/07/92	56	No	No	No	MYALGIA	NO DRUG EFFECT		Pt recvd 3 doses of Engerix-B 11SEP90, 11OCT90, & 2APR91; tested for Anti-HBS on 20JUL91 & found i
38238	F	22	01/08/92	1	Yes	No	No	ARTHRALGIA	RASH	LYMPHADENO	Pt recvd Engerix-B on 9JAN91 & 9JUN91 & w/in a day of both vax pt devel joint pain, a rash on face & swe
38249	F	22	01/08/92	14	Yes	No	No	ARTHRALGIA	EDEMA FACE	PAIN BONE	Pt recvd 1st Engerix-B vax 25JUL91 & 2 days later pt exp pain in elbow & wrists; 2 wks later exp aching in
38254	F	34	01/08/92	0	No	No	No	ARTHRALGIA	HEADACHE	SOMNOLENCE	Pt recvd 1st Engerix-B vax 28MAR91 & devel mild joint pain, n/v & lethergy for the first day; 29APR91 given
38262	F	49	01/08/92		No	No	No	PARESTHESIA			Pt recvd 1 dose of Engerix-B & subsequently devel paresthesia; event is reported to have resolved w/o treat
38268	F	43	01/08/92	0	No	No	No	ASTHENIA	VOMIT		28APR91 pt recvd Engerix-B & devel weakness & vomiting which lasted 24 hrs p/inject;
38304	M	46	01/08/92		No	No	No	PARESTHESIA			Pt recvd 3 doses of Engerix-B 8JAN91 & 5FEB91, & 8JUL91 & AUG91? pt exp paresthesia in arms, hand

VAERS ID	SEX	AGE	DATE	ONSET DAYS	ER	HOSP	DIED	COSTART 1	COSTART 2	CASTART 3	REPORTED TEXT
357	F		01/15/92	3	Yes	No	No	PARESTHESIA	HYPOKINESIA	ASTHENIA	Pt recvd 1st dose of Engerix-B & exp eye twitch & stomach pain x 3 wks; p/dose 2 of vax exp muscle twitc
38396	F	51	01/17/92	58	Yes	No	No	ARTHRALGIA	MYALGIA	MALAISE	Pt recvd 3 doses of Engerix-B 4MAY90, 8JUN90 & 2JUL90; Find 2 doses were uneventful; on 29AUG90 p
38406	F	45	01/17/92	7	No	No	No	PARESTHESIA			Pt recvd 1 dose of Engerix-B on 25SEP91 & 1wk p/1st dose pt exp tingling primarily on L arm which radiate
38470	F	31	01/30/92	138	Yes	No	No	NEUROPATHY	PAIN BONE	ARTHRALGIA	Pt recvd 2 doses of Engerix-B FEB & 5MAR91; 11JUL91 pt exp rt arm & leg neuropathy & lang bone & pa
38515	F		01/31/92	10	Yes	No	No	NEURITIS OPTIC	AMBLYOPIA		Pt recvd 3 doses of Engerix-B APR91, 1MAY91 & OCT91 & 10 days p/2nd dose exp optic neuritis & blurr
38550	M	37	02/03/92	0	Yes	No	No	ARTHRITIS	VASCULITIS	PAIN	Pt recvd 3 doses Engerix-B approx JAN91, FEB91 & AUG91; no rxn noted p/2 doses; p/3rd 4OCT91 pt ex
38553	F		02/03/92		No	No	No	PARESTHESIA			Pt was given Engerix-B p/1st dose of vax given pt exp tingling in fingers (exact time of event is unk); no b
38578	F	42	02/07/92	2	Yes	No	No	ARTHRALGIA	JOINT DIS	PAIN	22JUL91 pt recvd 1 dose of Engerix-B devel vague knee discom/sft wkn 24 hrs 2 days the following sx de
38589	F	40	02/07/92	0	No	No	No	MYALGIA	NAUSEA	HEADACHE	Pt recvd 3 doses of Engerix-B 22JAN91, 21FEB91, 22JUL91 & on 22JUL91 exp severe sore arm, nausea
38647			02/10/92		No	No	No	VISION ABNORM	PAIN INJECT SITE		Pt recvd 1 dose of Engerix-B (dates of administration unk) & 28OCT91 exp visual disturbance & pain on in
38652	F		02/10/92		No	No	No	MYALGIA	PAIN	HEADACHE	Muscle pain, pain, severe fva;
38704	F	29	02/11/92	1	No	No	No	ARTHRALGIA	ARTHROSIS		Pt recvd 1st Engerix-B vax on 18OCT91 & w/in a few days to 1 wk exp joint pain w/rch is persistng; vax w
38707	F	25	02/11/92	0	No	No	No	PARESTHESIA	NO DRUG EFFECT		Pt recvd a series of 3 inject of Engerix-B 16NOV91 3D rem following 3rd dose c/o arm feeling dead or not
38708	F	40	02/11/92	0	Yes	No	No	ARTHRALGIA	PARESTHESIA	NEUROPATHY	Pt recvd 2 doses Engerix-B 12SEP91 & 13NOV91; 1st dose uneventful; 7 hrs p/2nd vax pt devel pain in ar
38838	M	61	01/21/92	2	Yes	No	No	NEURITIS PERIPH	PAIN	PARESTHESIA	Pain & tingling in all extremities, difficulty walking sx aggravated by exercise; areas involved were both har
38846	F	33	02/11/92		No	No	No	ASTHENIA	DIZZINESS	HEADACHE	Pt recvd 2nd dose of Engerix-B JUN91 & 1 wk later became fatigued x 3 wks & was dizzy w/hrs; these sx
38848	F	32	02/11/92		No	No	No	ASTHENIA	DIZZINESS	NAUSEA	Pt recvd 2 doses of Engerix-B on 8MAY91 & 5JUN91 & pt called reporter on 8JUL91 c/o of prolonged fat
38853	M		02/11/92	10	Yes	No	No	ASTHENIA	FEVER	SYNCOPE	21JUN91 pt recvd 2nd dose of Engerix-B vax about 10 days p/2nd dose pt exp general weakness, fever, "
39009	F	60	01/29/92	4	Yes	Yes	No	NEURITIS	GUILLAIN BARRE SYND	HYPERTONIA	6JAN92 pt recvd dose of Engerix-B & 10JAN92 devel neuritis & sxs consistent w/GBS; pt hospitalized for
39322	M	34	02/06/92	0	No	No	No	MYALGIA	ARTHRALGIA	MYASTHENIA	3-4 hrs p/shot exp some soreness in R arm, inc pain in shoulder joint & upper arm muscles x 4 days; work
39361	F	36	02/12/92	8	Yes	Yes	No	ASTHENIA	CSF ABNORM	HYSN INJECT SITE	Pt recvd 1st dose of Engerix-B 22JAN92 & same day exp swelling @ inject site, fever, fvs; Also LP was d
39446	F	54	02/17/92	1	Yes	No	No	ASTHENIA	FEVER	ARTHRALGIA	Pt recvd a shot of Hep B JUL91 & the next day devel extreme fatigue, fever, joint pain; Later devel diarrha
39563	M	42	02/21/92	4	No	Yes	No	ARTHRITIS	ASTHMA	ESR INC	On 28MAY91 pt recvd 2nd dose of Engerix-B & 2 days later devel edema, pain in rt hand, arthralgia pain
39778	F	19	03/03/92		No	Yes	No	SCLEROSIS MULT	BLIND	NEUROPATHY	p/2nd dose 2SEP91 pt devel acute MS, 2 wks later bilateral visual blurring MD felt visual loss & myopia; hc
39794	F	37	03/05/92		No	No	No	ARTHRALGIA			Pt recvd 3 doses of Hep B, time of 3rd dose was MAY89; pt exp arthralgia;
39795	F		03/05/92		No	No	No	ARTHRALGIA			Pt recvd 3 doses of Hep B (recomb) vax in MAY89 & pt exp arthralgia; @ time of report sx persisted;
39798	F	33	03/05/92	1	No	No	No	NECK RIGID	HEADACHE	MYALGIA	Pt recvd 1st dose of Hep B vax (Recomb) on 4DEC90; w/in 24-48 hrs of receiving the vax pt devel a sever
39806	M		03/05/92		Ne	No	No	MYALGIA			Pt exp myalgia following vax w/Recomb; no further details were provided;
39809	F	46	03/05/92		No	No	No	REACT AGGRAV			Pt recvd 1st dose of recomb in AUG90 recvd 2nd dose & exp joint pains & sx of arthritis in several joints
39810	F	27	03/06/92	2	No	No	No	ARTHRALGIA	EDEMA PERIPH	PAIN	Pt recvd 2nd dose of Hep B vax on 16DEC90 & devel generalized arthralgia including swelling of the anke
39874	F	40	03/06/92	2	No	No	No	PARESTHESIA			Pt recvd 1st dose of Recomb on 8NOV90 w/o adverse exp; Pt recvd 2nd dose 8DEC90 & devel numbness
39843	M	35	03/05/92	33	No	No	No	ARTHRITIS	PAIN		Pt recvd 1st dose Recomb on 9JAN91 & on 11FEB91 pt exp arthritic pain in rt arm & shoulder, pts pain w
39844	M	36	03/06/92	3	No	No	No	REACT AGGRAV			Pt recvd 1st dose of Recomb on 25JAN91 & 3 days p/vax devel cold sores around mouth; pt did recvd 2n
39845	F	59	03/06/92	14	No	No	No	MYALGIA	PAIN	MYOSITIS	Pt recvd 1st dose of vax Recomb on 25SEP89 & on approx 9OCT89 pt devel severe aching & pain in the
39846			03/06/92		No	No	No	ARTHRALGIA			Pt recvd vax w/Recomb & exp arthralgia.
39857	F		03/12/92	0	Yes	No	No	NEUROPATHY	MYASTHENIA	ATAXIA	Pt recvd vax w/Hep B (recombinant) on 29JAN92; same day pt exp neurologic sx including muscle weakn
40178	F	65	03/23/92	0	No	No	No	ASTHENIA	HEADACHE	FEVER	Fatigue/weakness; fva; fever, nausea & diarrhea; sweating; achiness; sensation of warmth; light headedn
40194	M	51	03/24/92	385	No	No	No	REACT AGGRAV	ATROPHY MUSCLE	PAIN	In JAN1990 pt recvd 2nd dose of Hep B & subsequently, cervicobrachialgia worsened; MD felt pt exp wea
40206	F	39	03/24/92	3	No	No	No	ARTHRALGIA	HEADACHE	MYALGIA	On the evening of 22FEB pt exp joint pain, fva, body aches; These intensified & on 24FEB had inc temp
40234	M	35	04/01/92	21	No	No	No	ARTHRITIS			Pt recvd vax 9JAN91 & 3 wks p/vax dx as having rotator cuff inflammation in the opposite arm to that in wh
40235	F	43	04/07/92	0	No	No	No	ASTHENIA			Pt recvd 1st dose of vax on 24JAN91 & for 1 wk following vax pts arm was not paralyzed, but felt heavy &
40245	F	31	04/08/92	27	No	No	No	PARESTHESIA	SALIVA INC	INFECT	Pt recvd 2nd dose of vax 30DEC87 & 26JAN88 devel rt facial numbness & drooling; pt was taken to ER &
40246	F	54	04/08/92	2	No	Yes	No	MYALGIA	CHILLS	HYPERNATREM	Pt recvd 1st dose Hep B vax 27FEB91 & on 01MAR91 awoke feeling achy w/chills; afternoon pt devel diar
40247	M	56	04/08/92	1	No	No	No	ASTHENIA	DYSPEPSIA	NAUSEA	Pt recvd 1st dose of Hep B vax on 29DEC91; On 1JAN92 pt exp extreme fatigue, upset stomach & nause
40250	F	39	04/08/92	1	No	No	No	PARESTHESIA	PAIN BACK	PAIN	Pt recvd 3 doses of Hep B vax 15JAN90, 18FEB90, 02AUG90 & following 3rd dose exp "tingling sensation
40252	F	44	04/06/92	0	No	No	No	ASTHENIA	HEADACHE	MALAISE	Pt recvd 1st dose of HepB on 8MAR91 & a few hrs p/vax exp severe weakness, fva, malaise, flushing, ITC
40258	F	36	04/06/92		No	No	No	MYALGIA			Pt recvd 2 doses of Hep B vax who advarse rxn; pt recvd 3rd dose to ver ID instead of IM; subsequently
40260	F	40	04/08/92		No	No	No	ARTHRALGIA	FEVER	RASH	Pt recvd 2 doses of Hep B vax who adverse rxn; Pt recvd 3rd dose of vax ID instead of IM; Pt subsequent
40261	F	57	04/08/92	1	Yes	No	No	PARESTHESIA	MYASTHENIA		Pt recvd 1st dose of Hep B on 8MAR91 & on 7MAR91 devel facial paresthesia & muscle weakness in arm
40264	F	46	04/08/92	0	No	No	No	PARESTHESIA	VASODILAT	DYSPNEA	Pt recvd 3 dose of Hep B vax & 3 minutes p/inject pt exp numbness in extremities, hot flashes & SOB; tx D
40325	M	59	04/16/92	0	No	No	No	ASTHENIA	FEVER	SOMNOLENCE	Pt recvd 1st dose Hep B vax 5FEB91 & that evening pt devel asthama, fever, somnolence, & sweating; pt
40327	F	40	04/16/92	0	No	No	No	REACT AGGRAV			Pt recvd 1st dose of Hep B vax in APR91; approx 1/2 hr p/vax pt exp a mild asthma attack which reinitiated

VAERS #C	SEX	AGE	DATE	ONSET DAYS	ER	HOSP	DIED	COSTART 1	COSTART 2	CASTART 3	REPORTED TEXT
329	F	33	04/16/92	2	Yes	No	No	MYASTHENIA	MYALGIA	MALAISE	Pt recvd booster dose of Hep B vax on 9FEB91-Pt had recvd 2 prev series of Hep B in 1983 & 1987. & on
40332	F	51	04/16/92	14	No	No	No	ASTHENIA	ARTHRALGIA	HEADACHE	Pt recvd 3 doses Hep B vax 13SEP90, 18OCT90, 29MAR91 & 2 wksp/3rd dose pt devel weakness, arthral
40334			04/16/92	0	No	No	No	ARTHRALGIA			Pt recvd 1st dose of Hep B approx JAN91, 1 wk later, pt devel arthralgia of the ankles,
40352	F		04/16/92	10	Yes	No	No	ARTHROSIS	ARTHRALGIA	SCLERODERMA	Pt recvd Hep B vax & exp angioedema.
40358			04/16/92		No	No	No	ASTHENIA			Pt exp fatigue following vax w/Hep B vax; pt recovered;
40368	F	30	04/17/92	0	No	No	No	MYALGIA	VASODILAT	EDEMA	Pt recvd 2 doses of Hep B vax on 2APR91 & 17APR91. On the evening of 2nd dose pts arm became sore
40374	F	27	04/17/92	2	No	No	No	ARTHRALGIA	JOINT DIS	PAIN NECK	Pt recvd 1st dose Hep B vax on 19APR91 & 2 days later exp pain & stiffness in knees. Over the next 3 day
40411	F	41	04/17/92		No	No	No	ARTHRALGIA	MALAISE		Pt recvd 1st dose of Hep B vax on 3MAR91 & exp arthralgia & severe malaise;
40412	F	20	04/17/92	32	No	No	No	ARTHRALGIA	PAIN NECK		Pt recvd 1st dose of Hep B vax on 10APR91 & on 12MAY91 pt devel pain in knee & over the next 5 days,
40419	F	33	04/17/92	1	Yes	No	No	ARTHRALGIA	SERUM SICK	ASTHENIA	Pt recvd 1st dose Hep B vax 7FEB91 w/no noted problems. On 15MAR91 pt recvd 2nd dose of vax & 16MA
40425	F	49	04/17/92	1	No	No	No	ARTHRALGIA			Pt recvd 1st dose of Hep B vax on 21MAY91 & approx 24 hrs post vax pt exp bilateral hip pain that inc in s
40436	F	37	04/21/92	2	Yes	No	No	REACT AGGRAV	NECK RIGID	PAIN	Pt recvd 2nd dose of Hep B vax on 14MAY91 & 2 days p/vax the nature & intensity of hip changed; pt exp
40449	F	38	04/21/92	0	Yes	No	No	PARESTHESIA	PAIN	PAIN NECK	Pt 1st dose of Hep B vax on 9JUL90 & immediately pt devel arm numbness & pain; 2 to 3 hrs p/vax the pai
40450	M	40	04/21/92		No	No	No	REACT AGGRAV	ASTHMA		Pt recvd 1st dose of Hep B vax on 25APR91 & on 9MAY91 pt noted a worsening of rash as far as severity
40455	M	37	05/11/92	1	No	No	No	MYALGIA	FEVER	MALAISE	Pt recvd 3rd dose of Hep B vax (Recomb) on 15JUN91. Approx 3 hrs following 3rd dose, devel lechriness, t
40466	F	20	05/12/92	0	No	No	No	ASTHENIA	VOMIT	MYALGIA	Pt recvd Hep B vax 7MAY91 & immediately following the 1st dose, pt exp massive fatigue, vomiting, achime
40480	F	45	05/18/92		No	No	No	ASTHENIA	FEVER		Pt recvd full series of Hep B vax approx 1982; In JUN91 the pt found to have a neg Hep A & B titer HWAE?
40481	F	21	05/19/92	5	No	No	No	ASTHENIA	VOMIT	FEVER	Pt recvd 1st dose of Hep B vax on 7MAY91; approx 5 days later pt exp massive fatigue, vomiting, HOT & h
40492	F	24	05/19/92	5	No	No	No	PARESTHESIA	PAIN	HYSN INJECT SITE	Pt recvd 1st dose of Hep B vax on 7OCT91 & on 12OCT91 devel paresthesia, pain & dermatomal type rash @
40495	F	48	05/19/92	1	No	No	No	MYALGIA	PRURITUS	HYSN INJECT SITE	Pt recvd 3 doses of Hep B vax on 20FEB91, 26MAR91, & 6SEP91 & on 7SEP91 pt exp itchiness & itchin
40498			05/19/92		No	No	No	ARTHRALGIA	PAIN	MYASTHENIA	Pt exp arthralgia, pain, muscle weakness, & inc WBC count following vax w/Hep B;
40504			05/20/92		No	No	No	NEURITIS OPTIC			Pt was vaxed w/Hep B following vax pt devel optic neuritis;
40557	M	48	03/27/92	7	Yes	No	No	PARESTHESIA	ASTHENIA		Numbness of hands, feet, & lower legs started w/fingers about 1 wk p/vax moved to toes, bottom of feet & t
40563	F	47	03/30/92	0	No	No	No	ASTHENIA	SOMNOLENCE	VASODILAT	Became very tired & drowsy in one hr, p/3 hrs extremely drowsy & slept x 14 hrs awakened x 3 during time
3619	F	30	05/20/92		No	No	No	ASTHENIA			Pt recvd 1st dose of Hep B vax & subsequently exp fatigue.
40622	M	27	05/20/92	7	No	No	No	ARTHROSIS	ARTHRALGIA	BONE DIS	Pt recvd 1st dose of Hep B vax 13AUG91. Approx 1 wk later pt devel swelling & discomfort of rt ankle. WD
40624	F	28	05/20/92		No	No	No	PARESTHESIA			Pt recvd 3rd dose of HEp B vax on 16JUL91 & exp paresthesia in upper extremities & rt lower extremity.
40629	M	22	05/20/92	0	No	No	No	PARESTHESIA			Pt recvd 2nd dose of Hep B vax on 18SEP91 & 2 hrs p/vax pt exp paresthesia which lasted 6 hrs.
40637	F	33	05/21/92	1	No	No	No	ASTHENIA	ANOREXIA	FEVER	Pt recvd 1st dose of Hep B vax on 27JUN91, the following day pt exp fatigue, anoresia, & devel fever of 99
40638	F	28	05/21/92	1	No	No	No	ASTHENIA	ARTHRALGIA	FEVER	Pt recvd 2nd dose of Hep B vax on 12JUN91 & the following evening pt exp weakness, joint pain, & sever la
40639	M	32	05/21/92	2	No	No	No	ASTHENIA	ARTHRALGIA	FEVER	Pt recvd 2nd dose of Hep B vax on 12JUN91 & 2 days following vax pt exp weakness, joint pain, & devel a
40651	F	40	05/21/92	0	No	No	No	ARTHROSIS	ARTHRALGIA		Pt recvd 1st dose of Hep B vax in APR91 & devel joint pain; MAY91 recvd 2nd dose of vax & devel swelling
40652	F	22	05/21/92	30	No	No	No	ARTHRITIS			Pt recvd 1st dose of Hep B vax in SEP91 & 2 wks p/vax devel polyarthritis which persisted for 3 days. pt lat
40659	F	57	05/22/92	0	No	No	No	MYALGIA	FEVER	NAUSEA	Pt recvd 2nd dose of vax 21OCT91 & following vax applied ice packs to arm, 3 hrs later arm became very s
40660	F	31	05/22/92	0	No	No	No	PARESTHESIA	MYALGIA	ASTHENIA	Pt recvd 1st & 2nd dose Hep B vax 18SEP91 & 23OCT91 & immediately following 2nd vax pt exp numbness
40670	M	44	05/22/92		No	No	No	ARTHRALGIA	MYALGIA		Pt recvd 2nd dose of Hep B vax in MAY91 & devel arthralgia & myalgia recurred to a more severe degree.
40677	M	43	05/22/92	0	Yes	No	No	ASTHENIA	HYPERTENS	PARESTHESIA	Pt recvd 2nd dose of Hep B vax MAY1991 & following vax pt suddenly became weak & blood pressure shot
40695	F		05/26/92	577	No	No	No	MYALGIA			Pt recvd 3rd dose of Hep B vax in SEP89 approx APR91 pt devel sx of fibromyalgia; No further details were
40696			05/26/92		No	No	No	MYALGIA			Pt exp sx similar to pts who were dx w/fibromyalgia; details of these sx @ time of report were unk. No further
40697			05/26/92		No	No	No	MYALGIA			Pt exp sx similar to pts who were dx w/fibromyalgia; details of these sx @ time o of the report were unk. No
40698			05/26/92		No	No	No	MYALGIA			Pt exp sx similar to pts who were dx w/fibromyalgia; details of these sx @ time of the report were unk. no fu
40699			05/26/92		No	No	No	MYALGIA			Pt exp sx similar to pts who were dx w/fibromyalgia; details of these sx @ time of the report were unk. No fu
40700			05/26/92		No	No	No	MYALGIA			Pt exp sx similar to pts who were dx w/fibromyalgia; details of these sx @ time of the report were unk.
40701			05/26/92		No	No	No	MYALGIA			Pt exp sx similar to pts who were dx w/fibromyalgia; details of these sx @ time of the report were unk.
40702			05/26/92		No	No	No	MYALGIA			Pt exp sx similar to pts who were dx w/fibromyalgia; details of these sx @ time of the report were unk.
40703			05/26/92		No	No	No	MYALGIA			Pt exp sx similar to pts who were dx w/fibromyalgia; details of these sx @ time of the report were unk.
40704			05/26/92		No	No	No	MYALGIA			Pt exp sx similar to pts who were dx w/fibromyalgia; details of these sx @ the time of the report were unk.
40705	F		05/26/92		No	No	No	MYALGIA	ASTHENIA		Pt exp long-term myalgia & fatigue following vax w/Hep B;
40715	F	28	05/26/92	2	Yes	No	No	ARTHRALGIA	COUGH INC	ANOREXIA	Pt recvd 1st dose of Hep B vax in MAY 1991 w/no adverse rxn. On 12JUN91 pt recvd 2nd dose of Hep B va
1724	F	35	05/26/92		Yes	No	No	ARTHRALGIA			Pt recvd 2 doses of Hep B vax on 11SEP89 & 13OCT89 following vax pt devel arthralgia, which persisted 2
40735	F	31	05/26/92		No	No	No	MYALGIA	ASTHENIA	NAUSEA	Pt recvd 3 doses of Hep B vax & following 3rd dose pt exp sore arm, fatigue, nausea & hiv; sx subsided p/v
40745	M	40	05/26/92	14	No	No	No	REACT AGGRAV			Pt recvd 2 doses of Hep B vax on 13MAR91 & 15APR91 approx 2 to 3 wks following 2nd worsening of arthr

VAERS ID	SEX	AGE	DATE	ONSET DAYS	ER	HOSP	DIED	COSTART 1	COSTART 2	CASTART 3	REPORTED TEXT
750	M	53	05/28/92	14	No	No	No	ASTHENIA	ARTHRALGIA	MYALGIA	Pt recvd 2 doses of Hep B vax 23MAY91 & 20JUN91 & on 4JUL91, 2 wks following 2nd vax exp upper boc
40751	M	42	05/28/92	2	Yes	No	No	PARESTHESIA	DIZZINESS	VERTIGO	Pt recvd 1st dose of Hep B vax on 28JUN91 & exp numbness & tingling on rt side of face & rt arm w/assoc
40760	F	36	05/28/92	38	Yes	No	No	PARESTHESIA	MYASTHENIA	EDEMA FACE	Pt recvd Hep B vax on 18JUN91 & on 26JUN91 pt devel numbness & tingling down rt arm to fingers, dec
40771	F	45	05/28/92	15	Yes	No	No	ARTHRALGIA	JOINT DIS		Pt recvd 2 doses of Hep B vax on 13JUN90 & 17JUL90 approx AUG90 exp bilateral wrist pain, w/pain & he
40772	F	26	05/28/92	0	Yes	No	No	PARESTHESIA	PAIN NECK	NECK RIGID	Pt recvd 2 doses of Hep B vax on 19JUN90 & 23JUL90 & 1 hr following 2nd vax pt exp numbness & tingin
40781	M	44	05/28/92	3	No	No	No	ASTHENIA	PAIN	PAIN CHEST	Pt vax with 1st dose 30Jul91 On 2Aug91 exp fatigue & weakness. On 7Aug91 exp pain on one side of fac
40782	F	24	05/28/92	1	No	No	No	ASTHENIA	MALAISE		Pt vax w/ 2nd dose of Hep B on 13Jul91 the next day following vax devel weakness & malaise. At time of th
40783	M	40	04/01/92	53	No	Yes	No	PARESTHESIA	MYASTHENIA	NEUROPATHY	Dysesthesia of lt neck & shoulder followed by paresthesia & weakness (proximal & distal(lt arm & lt hand
40826	F	46	06/08/92	8	Yes	No	No	ARTHRITIS	ARTHRALGIA	MYALGIA	Pt recvd 2 doses of Hep B vax 20JUN91 & 18JUL91 & on 26JUL91 devel diffuse arthritic complaints, arthr
40840	F	35	06/08/92	1	Yes	No	No	MYALGIA	MALAISE	ASTHENIA	Pt recvd 1st dose of Hep B vax & the next day devel achiness, malaise, fatigue, h/a & stated just didn't fee
40860	F	40	06/08/92		No	No	No	MYALGIA	ARTHRALGIA		Pt recvd Hep B vax on 20JUN91 & recvd 2nd dose 18JUL91 & exp generalized muscle & joint pain, No fur
40861	F	19	06/09/92	1	No	No	No	NECK RIGID			Pt recvd 1st dose of Hep B vax on 30AUG91 & following vax, pt exp a stiff neck for the next 3 days. On 8O
40863	F	50	06/09/92	14	No	No	No	ARTHRALGIA			Pt recvd Hep B vax 2AUG91 & on 16AUG91 exp sharp bilateral pain in joints of hands & fingers; pain pers
40867	M	46	06/09/92		No	No	No	ARTHRITIS	LYMPHADENO		Pt recvd 2 doses of Hep B vax 25JUN91 & 24JUL91 & following 2nd dose devel severe arthritic sx & lymph
40870	F	40	06/09/92		No	No	No	NEUROPATHY			Pt recvd 3 doses of Hep B & devel lumbosacral plexopathy, No further details were provided.
40878	M	47	06/09/92	393	No	No	No	NEUROPATHY			Pt recvd 1st dose of Hep B vax on 18APR91 & mid MAY91 devel myeloradiculopathy; 14JUN91 vaxed w/2
40881	F	44	06/09/92		No	No	No	REACT AGGRAV	MYALGIA	INJECT SITE REACT	Pt recvd 1st dose of Hep B vax on 20NOV91 & exp a flare-up of shingles sore arm/local rxn & a systemic
40884	F	31	06/09/92	1	No	No	No	ARTHRALGIA	ASTHENIA	RHINITIS	Pt recvd 1st dose of Hep B vax on 26NOV91 & 18 hrs following the vax w/Hep B vax pt exp severe joint pa
40888	F	55	06/10/92		No	No	No	REACT AGGRAV	NO DRUG EFFECT		Pt recvd 3 doses of Hep B vax 4JAN91, 10FEB91, & 5AUG91 & following each dose of vax pt had an exac
40891	F	39	06/10/92	0	No	No	No	ASTHENIA	MALAISE	DIARRHEA	Pt recvd 3 dose of Hep B vax on 27NOV91 & by dinner time, pt exp fatigue, malaise & devel diarrhea The
40894	M	25	06/10/92	2	No	No	No	PARALYSIS FACIAL			Pt recvd 1st & 2nd dose of Hep B vax on 19OCT91 & 23NOV91 & 2 days following the 2nd vax pt devel Be
40897	F		06/11/92		No	No	No	MYALGIA	EDEMA INJECT SITE	URTICARIA	Pt recvd 2nd dose of Hep B vax & exp soreness & devel local swelling & hives, No further details were prov
40899	M	23	06/11/92		Yes	No	No	MYALGIA	CHILLS	PAIN ABDO	Pt recvd 2nd dose Hep B vax 19NOV91 & exp dizziness, achiness, chills, rt upper quad pain, nausea & fev
40901			06/11/92		No	No	No	MYALGIA			Pt devel muscle weakness following vax w/Hep B; No further details were provided;
902			06/11/92		No	No	No	NEUROPATHY			Pt recvd Hep B vax on 3JUL91; pt subsequently exp nerve problems, No further details were provided.
41042	F		06/05/92		No	No	No	ARTHRALGIA	ARTHROSIS		Pt reported that they were admin hep B vax in 1988. 3 wks p/ recving the 3rd dose devel pain & swelling
41057			06/05/92		No	No	No	ASTHENIA	LIVER FUNC ABNORM		Pt recvd Hep B vax following vax pt exp fatigue, weakness & elevated liver enzymes; lab eval revealed no
41064	M	36	06/08/92		No	No	No	ASTHENIA	SPLENOMEGALY	LIVER FUNC ABNORM	Pt recvd 2nd dose Hep B 26AUG87 & MD stated vax was Engerix-B & 1 mo p/vax devel fatigue, splenomeg
41076	M	12	04/09/92	1	Yes	Yes	No	REACT AGGRAV	INJURY ACCID		Pt recvd 1st dose of Hep B in OCT91 w/no adverse rxn; On 27NOV91 pt recvd 2nd dose of vax & on 28NC
[illegible]	F	73	04/29/92	0	No	No	No	ASTHENIA	TREMOR		Weakness, shakiness & tremor 30minutes following inject, (cont)
[illegible]	M	32	04/30/92	1	Yes	No	No	ASTHENIA	FEVER	MYALGIA	Fatigue, aching, fever, sweating, [illegible]
41497	F	48	05/01/92	3	No	No	No	MYALGIA	CHILLS	ASTHENIA	9AM started w/aching all over, chilling, feeling tired, t101 all day 6APR92; took APAP; 7APR92 t99 7 felt b
41670	F	44	05/07/92	0	No	No	No	MYALGIA	ASTHENIA		pt continues to c/o residual aching & weakness;
41674	F	24	05/07/92	13	Yes	Yes	No	ASTHENIA	MYASTHENIA	NEURITIS	Pt recvd 3 doses of vax; 9MAR92 was adm to hosp c/o generalized weakness w/involvement of lt leg, had
41678	M	28	05/07/92	2	No	No	No	ARTHRALGIA	NAUSEA	VOMIT	Acute onset of achy joints, nausea, vomiting, bilateral flank pain, h/a, & t103,
41845	M	41	05/12/92	7	No	No	No	NEURITIS	MYASTHENIA	PAIN	Brachial plexus neuritis, rt shoulder; muscular weakness in rt shoulder w/pain/soreness; sx are gradually r
41902	F	39	05/15/92	0	Yes	No	No	PARESTHESIA	URTICARIA	PRURITUS	Immediately p/ recving vax pt felt 'tingling' sensation down arm to elbow then broke out in hives under arm
41903	F	50	05/15/92	2	Yes	No	No	ASTHENIA	MYALGIA	HEADACHE	Intense fatigue, myalgias, h/a of acute onset 2 days p/ recving the 2nd HepB vax.No rxn from the 1st. Grac
42153	F	21	05/29/92	57	No	Yes	No	ARTHRITIS			5Nov91 approx 2 mos p/ recving a 2nd dose of vaccine pt devel polyarthritis involving the shoulder,neck, h
42394			06/11/92		No	No	No	ASTHENIA			Pt recvd 1st dose of Hep V vax & felt fatigued; hepatitis serology was ordered, pt had core antigen,
42397	F	42	06/12/92	1	Yes	No	No	MYALGIA	HYSN INJECT SITE	RASH	3Jan92 recvd 1 dose vax & 4JAN92 arm ached; 5JAN92 devel local erythema below inject site & down elb
42467	F	38	06/05/92	0	No	No	No	PARESTHESIA	PAIN INJECT SITE	TWITCH	2 hrs p/inject numbness rt 2nd & 3rd fingers & poss rt forearm numbness; @ time of inject noted burning-
42506	F	27	06/12/92	1	No	No	No	ASTHENIA	VASODILAT	RASH	9JAN92 pt recvd Engerix-B & 10JAN92 felt very fatigued, felt like hot flashes, forehead, cheeks & chest ha
42525	F	45	06/16/92		No	No	No	MYALGIA	NAUSEA	SOMNOLENCE	Pt recvd 2nd dose of Engerix-B 17MAY91 & reporter indicated that due to exposure a titer was taken p/2nd
42541	F		06/15/92		No	No	No	PARESTHESIA	DIZZINESS	NAUSEA	Pt recvd 2nd doses of Hep B vax 14JAN92 & exp numbness in hand & arm, lightheadness, nausea & hear
42544	F	30	06/15/92	2	No	No	No	REACT AGGRAV			Pt recvd Engerix-B vax 30AUG90 & 1OCT90 & 5 months later was hesitant about receiving 3rd inject beca
42615	F	29	06/10/92	1	Yes	No	No	PARESTHESIA	EDEMA TONGUE	NAUSEA	c/o lt arm numbness; lt side facial numbness, tongue thickness, N/V; onset 2AM 28MAY92; 28MAY 1100A
42709	F	34	06/17/92	0	No	No	No	NEURALGIA	NEUROPATHY	ASTHENIA	Pt recvd 3 doses Engerix-B vax 7MAY91, 26JUL91, & 10JAN92 & 1/2 hr later exp pain in rt hand (in gangl
42809	F	40	06/18/92	0	No	No	No	MYALGIA	PHARYNGITIS	LUNG DIS	Pt recvd a very sore, achey arm for several day p/sore throat, congested chest & nasal passages for sever
2917	F	44	06/22/92	0	No	No	No	ARTHRALGIA	ASTHENIA	FEVER	Joint aches, extreme fatigue x 3 wks; raised red bumps on chin lasted 1 mo; fever 101 x 48-72 hrs;
42949	M	44	06/23/92	30	No	No	No	ARTHRALGIA	BONE FRACT SPONTAN	VISION ABNORM	Pt recvd vax 1Oct91 30Oct91 devel joint pain primarily in the hands & feet. 6mos later diagnosed w/ stress
43024	F		06/25/92	42	No	No	No	MYELITIS			Pt recvd 2 doses of Engerix-B 19SEP91 & 20OCT91 & 20DEC91 pt exp transverse myelitis which reported

VAERS ID	SEX	AGE	DATE	ONSET DAYS	ER	HOSP	DIED	COSTART 1	COSTART 2	COSTART 3	REPORTED TEXT
329	M	50	06/26/92	14	No	No	No	ARTHRALGIA	HYPOKINESIA		Pt devel arthralgia of neck & shoulders approx 27JAN92, rotation of neck dec to one half nl; tz peaked in se
43041			06/29/92		No	No	No	GUILLAIN BARRE SYND			Pt devel GBS p/ vaccination
43043	F	59	06/29/92		No	No	No	ASTHENIA			Pt recvd Engerix B on 27Jan92 for prevention of hepatitis B infection. Pt devel extreme fatigue lasting 12-14
43044			06/29/92		No	No	No	PARESTHESIA	PARALYSIS		Reporter did not have any information regarding this adverse event. Reporter indicated that he heard a pt ex
43121	F	32	06/24/92	0	Yes	No	No	MYALGIA	HEADACHE	DIARRHEA	c/o body aches, hrs on & off x 3 days; diarrhea x 4-5 days now gone, flu like sx relieved w/APAP which has
43325	F	32	07/06/92		No	Yes	No	ASTHENIA	ARTHRALGIA	SGPT INC	Pt recvd 1st dose of vax 27APR92 & exp unc asthenia. 15MAY92 devel diffused arthyalgias, elevated SGPT a
43356	F	43	07/06/92	2	Yes	No	No	ARTHRALGIA	ARTHROSIS	FEVER	Arthralgia w/joint swelling & fever beginning 4/5-12 hrs p/vax;
43374	F	35	07/06/92	21	No	No	No	ASTHENIA	MYALGIA	ARTHRALGIA	On 28FEB92 pt exp fatigue, muscle & joint aches & pains w/generalized nausea, dec appetite, shaking, chi
43398	F	20	07/14/92		No	Yes	No	PARESTHESIA	CSF ABNORM	GLOBULIN INC GAMMA	Pt recvd 2nd dose vax 25JUL91 & on 27JUL91 devel paresthesia of feet; hospitalized & lab eval revealed ch
43431	F	57	07/14/92	0	No	No	No	MYALGIA	PAIN	EDEMA	had sorianess in lt hand & wrist that PM p/shots 13APR92. 14APR92 had pain, swelling & extreme soriness
43451	F	42	07/16/92		Yes	No	No	PARESTHESIA	HEADACHE	PAIN BACK	pt recvd 1 dose of Engerix-B & exp paresthesia, onset 1 wk to 10 days, sx persist, hrs onset immed dur stor
43514	F	46	07/17/92	30	No	No	No	ARTHRITIS			approx 4 wks p/vax pt devel flare of arthritis, shoulders, wrists, hands, rt knee, prior to that had only AM hard
43544	F	26	07/17/92	0	Yes	No	No	MYALGIA	HYPERTONIA	EDEMA TONGUE	some muscle aches 2 hrs post inject; jaw complaint 4 hrs post inject, jaw stiffness & thick tongue, SOB; no e
43585	F	81	07/20/92	2	Yes	No	No	ARTHROSIS	MYALGIA	HYPOKINESIA	severe swelling rt & lt knees, pain in muscles, pain so severe unable to walk;
43674	F	45	07/21/92	2	Yes	No	No	PARALYSIS FACIAL	NECK RIGID	HYPESTHESIA	4MAY92 pt recvd vax 5MAY92 noted stiffness in back of neck on lt side; pt noted numbness of upper lip pro
43625	F	51	07/23/92	14	No	Yes	No	MYASTHENIA	ATAXIA	VISION ABNORM	on 15JUN92 2 wks p/2nd dose of vax pt had lower body weakness & balance was off; lost lt eye field vision;
43677	F	20	07/28/92	0	Yes	No	No	REACT AGGRAV	PARESTHESIA		pt recvd Hep B vax & w/in 1/2 hour to 45 mins exp hypertension & tingling up through arm; tx w/OPH in ER;
43698	M	54	07/28/92	0	Yes	Yes	No	ARTHRALGIA	FEVER	URIN FREQUENCY	Same noc p/inject pt had joint pain, fever & frequent urination-cont intermittant joint pain; 7APR92 severe ch
43725	F	74	07/29/92	1	Yes	No	No	ARTHRITIS	REACT AGGRAV	ARTHRALGIA	pt reports incr in severity of arthritis sx (joint pain) 1 days p/vax; seen by MD 15JUN92; tx w/pain med; MD a
43797	F	49	07/30/92	24	Yes	No	No	ARTHROSIS	ARTHRALGIA	FEVER	pt recvd 1 dose of Engerix-B vax about 2 1/2 wks following dose exp joint swelling, joint pain & fever; hospita
43819	F	46	07/30/92	3	Yes	No	No	MYALGIA	PAIN	PAIN ABDO	13MAR92 had Hep B vax & started aching w/severe leg & stomach pains; rash all over looked like had fanta
43898	F	33	08/04/92	14	Yes	Yes	No	ARTHRALGIA	PAIN	PARESTHESIA	Pt recvd Recombivax HB 6FEB92 & 2nd dose 9MAR92; pt hospitalized early MAR92. On 4MAY92 pt seen b
43917	F	33	08/05/92	21	No	No	No	NEURITIS OPTIC			dx w/optic neuritis 3 wks p/vax;
43924	M	67	08/06/92	0	Yes	No	No	NEUROPATHY	ATROPHY MUSCLE	ARTHRALGIA	Pt recvd Hep B vax on 29NOV88 & devel frontal h/a, 1105, severe joint pain, myalgia, trapezius spasm, unabl
426	F	23	08/06/92	0	Yes	Yes	No	SCLEROSIS MULT			Pt recvd Engerix-B vax & devel classical sx of MS; Reporter indicated event is permanently disabling; 17JUL
43985	F	34	08/17/92	12	Yes	No	No	ASTHENIA	MYALGIA	ARTHRALGIA	17FEB92 recvd Engerix-B & 28FEB92 devel fatigue, muscle & joint ache, nausea, dec appetite, shaking & c
44001	F	45	08/18/92		No	No	No	MYASTHENIA	ARTHRALGIA	HEADACHE	Pt recvd 3 doses of Engerix-B & @ the end of JAN92 reported had been suffering muscle weakness, joint p
44002	F	43	08/18/92	1	No	No	No	ARTHRALGIA	NEURITIS	PAIN EYE	18NOV92 pt recvd 1 dose of Engerix-B. 19NOV91 c/o joint pain, neuritis in legs & eyes hurt; vax was discon
44031	M		08/19/92		No	No	No	ARTHRITIS			Pt completed the Engerix-B about a yr ago, p/2nd dose of vax pt exp arthritis sx which disappeared p/3 mont
44035	F	48	08/19/92		No	No	No	MYALGIA			Pt recvd 1st dose of Engerix-B 12FEB92 & 1 wk p/1st dose pt exp muscle ache in lt wrist, radiated to whole
44046	F	23	08/20/92	0	Yes	No	No	PARESTHESIA			Pt recvd 2 doses of Engerix-B & 12MAR92 @ bedtime pt exp numbness all over body; legs numb; pt feels sl
44122	F	28	08/13/92	1	No	Yes	No	NEUROPATHY	PARESTHESIA		acute transient neuropathy beginning 24 hrs p/vax w/numbness in toes gradually spreading to feet & lower li
44238	M	51	08/15/92	0	No	No	No	ARTHRALGIA			pt devel arthralgia of the shoulder & elbow in the evening of the day vax recvd;
44241	F	30	08/20/92	1	No	No	No	NECK RIGID	EDEMA INJECT SITE	HYSN INJECT SITE	12DEC91 pt recvd 2nd dose of Hep B vax & 13DEC91 pt devel neck stiffness; 14DEC91 devel local swelling
44280	F		08/20/92		No	No	No	ARTHROSIS	PAIN		Pt recvd 1st dose of Engerix-B vax 20OCT91 & the following day 21OCT91 exp arthritic sx; swollen joints in t
44287			08/20/92		Yes	No	No	ARTHRALGIA			Pt recvd 2 doses of Engerix-B & exp severe arthralgia following both injects, following 2nd inject sx describe
44292			08/20/92		No	No	No	ARTHRALGIA			pt recvd 2 doses of Engerix-B vax & exp arthralgia following both injects; no bc was given;
44307	F	41	08/21/92	0	No	No	No	ASTHENIA	HEADACHE	PAIN NECK	Pt recvd vax 1030AM 22JUN92 & @ 11AM same day was tired & weak; 330PM h/a started-lt side of head &
44445	F	43	08/27/92	0	No	No	No	PARESTHESIA	ASTHENIA		Pt recvd vax 15NOV91 & w/in 4 minutes of inject devel tingling of lt arm, leg & bottom of foot; pt also extra bre
44447	M	52	08/27/92		No	No	No	PARESTHESIA			Pt recvd vax 15NOV91 & immed tingling sensation of lt arm, resolved w/in 3 hrs w/o tx;
44448			08/27/92		No	No	No	ARTHRALGIA			Pt recvd 2 doses of Engerix-B vax & exp arthralgia following both injects;
44449			08/27/92		No	No	No	ARTHRALGIA			Pt recvd 2 doses of Engerix-B & exp severe arthralgia following both injects;
44455	F	38	08/27/92	2	No	No	No	ARTHROSIS	ARTHRALGIA	MYALGIA	pt recvd 2 doses of Engerix-B approx 29OCT91 & 29NOV91 & 3DEC91 pt exp systemic swelling of joints, an
44467	F	53	08/25/92	0	Yes	No	No	ASTHENIA	SOMNOLENCE	MYALGIA	Pt recvd Hep B vax & following 1st dose became fatigued & very sick; MAR92 recvd 2nd dose of vax & again
44495	M	38	08/25/92	3	No	No	No	ARTHRALGIA	PAIN		pt recvd vax on 20JUL02 & pt states 3-4 days later noted severe knee pain w/pain & tenderness from knees
44509	F	42	08/26/92	35	Yes	No	No	PARESTHESIA	NEURITIS	HYPERESTHESIA	Severe upper arm & shoulder pain bilateral brachial plexitus; hyperesthesia, swelling of fingers & ankles; incr
44517	F	47	08/26/92		No	No	No	ARTHRALGIA	PAIN		Bilateral knee, shoulder, hand & foot pain;
44605	F	34	09/01/92	0	Yes	Yes	No	PARESTHESIA	PAIN CHEST	DYSPNEA	Pt recvd 2 doses of Engerix-B & 7AUG92 w/in 10-20 minutes of dose 2 had tingling rt arm, severe heart palp
1808	F	32	09/01/92	0	Yes	No	No	PARESTHESIA	ECG ABNORM	ASTHENIA	Pt recvd 2 doses of Engerix-B vax & had tingling rt arm & leg down rt side, dusky color, tingling spread to lt s
44646	F	40	09/02/92	1	Yes	No	No	ARTHRALGIA	ARTHROSIS	VASODILAT	25JUN 1 day post vax pt exp painful joints w/swelling, some redness & heat felt, eg, feet, ankles, elbows, knee
44657	F	51	09/02/92	4	No	No	No	PARESTHESIA	HEADACHE	VASODILAT	numbness & tingling of face & head, h/a & body flushing starting 3 days p/vax & lasted 3 days off & on for m
44679	F	31	09/04/92	10	No	No	No	ARTHRALGIA	URTICARIA	PETECHIA	arthralgia, hives, petechia, dizziness, urticaria, insomnia; joint pain fr elbow & knees down; reported on 17Al

Mr. MICA. Judy Converse, you are recognized.

Ms. CONVERSE. Thank you for the opportunity to testify. I regret having a reason to speak here today and have no other reason to do so except for the sake of truth. I live in Massachusetts. I wish to state also that I hold a master's degree in public health and I am a registered dietician, I was trained to accept and encourage immunization and was in no way inclined against immunizing my son Benjamin. He is 2½ now.

I would like to say there is no history of autism or seizure disorder in my family or my husband's family. If Ben were here in front of you today, he would seem completely normal, but I will try to explain a little bit about his disability which he struggles with every day. He was born full term, normal in every way. Vaginal birth with no interventions or drugs. His Apgar scores were 9 and 10, which means that all of his reflexes were perfect and present.

Before discharge, he was immunized with Recombivax HB against hepatitis B. Neither I nor my husband recall receiving informed consents for this vaccine, nor do we recall seeing him get the shot, but it is in his immunization record. No signed informed consent specific to this hepatitis B vaccine was present in the copy of Ben's medical record which we recently requested.

His fourth night in this world was his first at home. And about 5 hours after arriving home, he had his first seizure. Frantic calls to maternity and pediatric staff fell on deaf ears. The extent of the medical advice we received was to put him on our clothes dryer and turn it on.

No one mentioned the vaccine. No one expressed concern that he was turning blue, that he couldn't stop screaming or that he appeared to be having tremors or full-body spasms. Ben had 3 more seizures, losing consciousness in the next 8 days, as well as many episodes of arching his spine rigidly without losing consciousness.

He vomited forcefully every day, had a recurring mild fever, eczema, was unable to remain asleep, had diarrhea and cried constantly, but no one thought any of this was out of the ordinary. I was told these thing are normal for a breast fed infant which, of course, I knew was not true. He was only 12 days old.

The third time he passed out, he did not resume consciousness. He was cyanotic. At the emergency room he was tested for several diagnoses and all were negative or inconclusive. He was observed overnight, and after nearly losing him, we were sent home the next day with a shrug.

No one mentioned the vaccine. No one expressed interest or concern for the events of the previous week and no one advised us in any way about what appeared to be seizures and a struggle for his life.

Ben's medical record even states in a gross understatement that his first days of life prior to this admission were uneventful. The same doctor who wrote this note privately admonished me for agreeing with the attending pediatricians to spare Ben the trauma of another spinal tap.

Convinced Ben had meningitis, he said, "It is people like you who cause lifelong mental retardation." Ben's discharge note states only that he had apnea, despite having tested negative for it. We en-

tered the hospital looking for answers but left with none. He worsened with the second immunization for hepatitis B at age 4 weeks.

This was when I realized he had been given the shot at birth and that was probably causing his problem. I asked for a delay for Ben's other immunizations at 2 months and was refused. I knew that accepted pediatric practice dictates that a sick child should not be immunized, but the doctor refused. When I persisted, he told me we could either immunize Ben on schedule, which we had to do because it was the law, or we could call DSS.

With this threat, Ben was immunized and all of his symptoms worsened. At 4 months he was immunized again. At 6 months, I refused further shots and switched doctors. He was seen by neurologists and developmental specialists, but no one could explain why he was too floppy to attempt normal developmental tasks, couldn't sleep, suckled poorly, kept vomiting, why eczema persisted, despite being breast fed, why he passed out in shock when he heard Velcro, plastic bags, or aluminum foil.

By age 10 months, he could not pull himself to sitting or crawling and could not roll over. We sought help from the Early Intervention Program, and Ben qualified for services based on his motor delays. For the first time, a formal acknowledgment of his delays was drafted. Reflexes which were normal at birth had disintegrated and protective responses inexplicably delayed.

Ben had two or three seizures a week during his early infancy and early toddlerhood. The events of these seizures never vary and Ben had one as recently as 2 months ago. He cries hard with one breath which seems to empty his lungs; and he is then silent, mouth open, not breathing and struggling for air.

Excuse me. As he suffocates, he turns red, blue, and then purple. His extremities become blue, his limbs flail as if he is drowning. Often on his left side Ben will have a flapping tremor of his hand while his arm, neck, and shoulder are rigidly flexed.

As his asphyxiation is complete, he is gray. His eyes lose their luster, his pupils dilate and his eyes roll back in his head and then he is unconscious. He usually regains consciousness quickly once his muscles are relaxed and he can breathe again, but these episodes are traumatic, exhausting, and frightening for Ben. They invariably occur in response to a stimulus he cannot manage, whether it is auditory anxiety related or from a fall or bump.

Even though Ben had seizures like this when he was just a few days old, we were told they were breath-holding spells which he consciously contrived in response to our overprotectiveness. The doctors told us we were causing Ben's seizures, odd behaviors, and delays by bad parenting.

I was told I over-nursed him by one neurologist, and asked why I needed something to be wrong with my son by a pediatric developmental specialist. I believe this is a grossly ignorant assessment of what may be grand mal seizure episodes.

Ben also appears to have petit mal seizures in which he rolls his eyes back in his head and grimaces, pierces the air above his head with his left hand, elbow locked, and hand quivering. Ben was diagnosed with autism recently and sensory integrative disorder last fall.

He cannot reliably sense, organize, or prioritize information that he receives about anything in the world. He cannot be placed in group daycare. He is terrified of his own peers. These few examples don't describe how profoundly disabled he is now.

I would especially like to state that our pediatric providers were very unsupportive, and I do believe my son would have died if I followed their advice. We have had very little guidance from them through this journey. His current physician agrees not to immunize him and has supported our refusals, but she has not reported his reaction and discouraged me from doing so.

She told me we would be harassed by the Massachusetts State Department of Public Health and forced to prove damage from each vaccine with invasive blood tests. When we asked for a medical waiver, she gave us only a vague philosophical one.

She acknowledged to me that the hepatitis vaccine is an unnecessary affront to an infant's well-being and she refuses to give the younger two or her three children this vaccine because it is of no benefit.

I have no doubt in my mind that this vaccine damaged my son, not just because he was normal at birth, full term with a family history void of these problems, but because the progression of events after the shot are in keeping with criteria for a hepatitis B vaccine adverse event listed by the Vaccine Injury Compensation Program.

The fact that the pediatric community failed to recognize his reaction in no way exonerates them or the vaccine industry. It simply means that thousands of healthy newborns will slip through the cracks with severe reactions and be untreated and unacknowledged.

After reading data on hepatitis B in the United States, as a person trained in public health sciences, it is plain to me that a program to vaccinate newborns is of no worth to anyone except those who sell vaccines. The immunity it imparts wears off before a child is old enough to have sex with an infected partner or use contaminated needles, which are the foremost modes of transmission. Therefore, it is my opinion that there is no benefit and only risk for newborns receiving this vaccine. Thank you.

[The prepared statement of Ms. Converse follows:]

Statement of Judy Lafler Converse

My name is Judy Lafler Converse. I live on Cape Cod in Massachusetts. I regret having a reason to speak here today. I have no other reason to do so except for the sake of truth, and to spare other families the trauma and loss we have endured.

I also wish to preface my comments by stating that I hold a master's degree in public health and am a registered dietitian. I was trained to accept and encourage immunization and was in no way inclined against immunizing my son, whose name is Benjamin. He is now two and a half years old. There is no history of autism or seizure disorder in either my family or my husband's family. If Ben were here in front of you today, he would seem completely normal, but his appearance belies the struggle he faces every day.

Ben was born full term and normal in every way. His birth was vaginal and without interventions or drugs. His Apgar scores were 9 and 10. All his reflexes were recorded as normal. He was very peaceful. Before discharge, Ben was immunized with Recombivax HB against hepatitis B virus. Neither I nor my husband recall receiving informed consent for this vaccine, nor do we recall seeing Ben get the shot, but it is recorded in his immunization record. No signed informed consent specific to the hepatitis B vaccine was present in the copy of Ben's medical record which we recently requested. Ben's fourth night in this world was his first at home, and we arrived there at about 5 PM. Five hours later, he had his first seizure. Frantic calls to the maternity staff and pediatrician on call fell on deaf ears. The extent of the medical advice we received was to put him on our clothes dryer and turn it on. No one mentioned the vaccine. No one expressed concern that Ben was turning blue, that he couldn't stop screaming, or that he appeared to be having tremors and full body spasms.

Ben had three more seizures, losing consciousness, in the next 8 days, as well as several episodes of arching screaming without losing consciousness. He was vomiting forcefully every day, had a recurring mild fever and eczema, was unable to remain asleep, soaked several diapers a day with glossy mucous and diarrhea, and cried constantly. No one thought any of this was out of the

ordinary. I was told these things were normal for a breast fed infant. He was only 12 days old. The third time he passed out, he did not resume consciousness. His breathing was slow and shallow and he was cyanotic. At the emergency room, Ben was tested for several diagnoses and all were negative or inconclusive. He was observed overnight. After nearly losing him, we were sent home the next day with a shrug. No one knew what was wrong, no one mentioned the vaccine, no one expressed interest or concern for the events of the previous week, and no one advised us in any way about what appeared to be seizures and a struggle for Ben's life. Ben's medical record even states, in a gross understatement, that his first days of life prior to this admission via the emergency room were "uneventful". The same doctor who wrote this note privately admonished me for agreeing with the attending pediatricians to spare Ben the trauma of another spinal tap. Convinced Ben had meningitis, he said, "it's people like you who cause lifelong mental retardation." Ben's discharge note states only that he had "apnea", despite having tested negative for it. We entered the hospital hoping for answers, but we left with absolutely none.

Ben worsened with the second hepatitis B immunization at 4 weeks. It was at this moment that I realized he'd been given the shot at birth and that this may be causing his problems. At two months I asked Ben's pediatrician to postpone his immunizations. I asked only for a delay so that Ben could continue recuperating. I knew that accepted pediatric practice dictates that a sick child should not be immunized. The doctor refused my request. When I persisted, he told me we could either immunize Ben on schedule, which we had to do because it was the law, or we could call DSS. With this threat, Ben was immunized. All of his symptoms worsened. At four months, Ben was immunized again. At six months, I refused further shots and switched doctors.

Ben was seen by neurologists and developmental specialists, but no one could explain why he was too floppy to attempt normal developmental tasks, was unable to sleep day or night, suckled poorly, kept vomiting, why eczema persisted despite being breast fed, or why he passed out in shock when he heard Velcro, plastic bags, or aluminum foil. By age 10 months, Ben could not pull himself to sitting, could not crawl, and had difficulty rolling over. We sought help from the Early Intervention Program and Ben qualified for

services based on his gross motor delays. For the first time a formal acknowledgment of his delays was drafted. Reflexes which were normal at birth had disintegrated and his protective responses were inexplicably delayed. A developmental therapist taught him to crawl.

Once he walked, he fell on his head constantly, and toppled backwards when sitting down. He had no skill or strength to go from standing to sitting, but would fall like a tree, without throwing out his arms to protect himself. He became extremely fearful of bumps to his head and soon the slightest touch there, or just the anticipation of being bumped, would produce a seizure. He would have two or three seizures a week during his infancy and early toddlerhood. The events of these seizures never vary, and Ben had one as recently as two months ago. Ben cries hard with one breath, which seems to empty his lungs. He then is silent, mouth open, not breathing, and struggling for air. As he suffocates, he turns red, then blue, then purple; his extremities become blue; his limbs flail about as if he is drowning. Often, on his left side, Ben will have a flapping tremor of his hand while his arm, neck and shoulder are rigidly flexed. As his asphyxiation is complete, he is gray, his eyes lose their luster and open, seeing nothing; his pupils dilate; his eyes roll back into his head and he then is unconscious. He usually regains consciousness quickly once his muscles are relaxed and he can breathe again, but these episodes are traumatic, exhausting, and frightening for Ben. He is sad and scared in the aftermath. They invariably occur in response to a stimulus he can not manage, whether it is auditory, anxiety-related, or from a fall or bump. Even though Ben had seizures like this when he was just a few days old, we were told they were breath holding spells which he consciously contrived in response to our over protectiveness. The doctors withdrew and not only became unsupportive, but blaming: They essentially told us we were causing Ben's seizures, odd behaviors, and developmental delays by bad parenting. I was told I "overnursed" him by one neurologist and asked "why I needed something to be wrong with my son" by a pediatric developmental specialist. I believe this is a grossly ignorant assessment of what may be grand-mal seizure episodes. Ben also appeared to have petit mal seizures in which he would roll back his eyes and grimace, or suddenly pierce the air above his head with his left hand, elbow locked and hand quivering. These occurred randomly; he

would endure the brief spasm then go back to whatever he was doing.

What are our lives like now? Ben was diagnosed with sensory integrative disorder last fall. Last week we learned he is on the autism spectrum as well with a diagnosis of pervasive developmental disorder. This means he can't reliably sense, organize, or prioritize the information his brain receives about anything - gravity, balance, sound, light, emotion, anything. He learned to walk without sensing when he was falling down. He can't tolerate change, being touched without notice first, the feel of food in his mouth, or even the presence of his own peers, whose random squeals and movements terrify him. He can't be placed in group day care and has extreme separation anxiety. These few examples don't begin to describe how profoundly limited Ben is physically, developmentally and socially. Though Ben is extremely bright and verbal, we don't know if Ben will be able to attend school since he can't function in the bright, noisy environment of a schoolroom.

In many ways we are lucky. It is my belief that my nutrition training served me well. I took steps immediately upon suspecting vaccine damage that I believe saved Ben from dying or lapsing into profound autism. Because of this very early and diligent dietary intervention, plus intensive efforts in occupational therapy, Ben has had the opportunity to recover some functioning. With more relentless effort, we fervently hope he will be able to function like other kids. But my husband and I have lost friends, work, income, and nearly lost our marriage as we struggled against the medical providers who were supposed to be helping. Our pediatric providers were so blind, so biased against the possibility that a vaccine could be damaging that, I believe, my son would have died if not for our persistent refusal to follow their advice.

We have had little pediatric guidance or support throughout this journey. Though Ben's current physician agrees not to immunize him and has supported all referrals we have requested for treatment and evaluation, she has not reported his reaction and discouraged me from doing so. She told me we would be harassed by the state department of health and forced to prove damage from each vaccine with invasive blood tests. When we asked for a medical waiver

she gave us only a vague philosophical one. She acknowledged to me that the hepatitis vaccine is an unnecessary affront to an infant's well being and that she refuses to give the younger two of her three children this vaccine, because it is of no benefit.

I have absolutely no doubt in my mind that the hepatitis B vaccine damaged my son and caused his developmental disorders. Not just because he was normal at birth, full term, with a family history void of such problems, and with no other events to precipitate such an array of symptoms, but because the progression of events after the shot is in keeping with criteria for a hepatitis B vaccine adverse event as listed by the Vaccine Injury Compensation Program. This is true with one exception: It took longer than four hours for my son to have his first seizure. All symptoms of anaphylaxis were present but had a slower onset and persisted for months. In my mind this fact in no way exonerates the vaccine industry or those that make vaccine policy. It simply means that thousands of healthy newborns can slip through the cracks with severe reactions unacknowledged and untreated; thousands will die, have delays, or become autistic and their pediatric providers will be just as uninformed as ours were.

One final comment as an individual trained in public health sciences: After regarding data on hepatitis B in the US, it is plain to me that a program to vaccinate newborns is of no worth to anyone except those who sell vaccines. The immunity it imparts wears off before a child is old enough to have sex with an infected partner or use contaminated needles, which are the foremost modes of transmission. There is no benefit, and only risk, for newborns receiving this vaccine.

Mr. MICA. Thank you for your testimony. We now recognize Ms. Kirschner and Lindsay Kirschner at this time.

Ms. MARILYN KIRSCHNER. I thank you for having us here today. I am here with my daughter Lindsay, maintaining a commitment to pave the way so that other parents can make an informed choice in regard to the hepatitis B vaccine. Lindsay is representative of all of the children who fall under the mandate.

Six months before the vaccine, we had an idyllic life, reveling in the joy of Lindsay's bat mitzvah, perfect in every way. Lindsay received the hepatitis B vaccine 2 days before entering high school.

The next day she seemed flu-like. The day after that, so dizzy she couldn't stand up without holding the walls. The following day she passed out. So our life goes since August 1997.

Lindsay has had syncopal and pre-syncopal episodes. Her ability to stand was compromised for almost 6 months due to unremitting dizziness. Following our doctor's advice, unknown the vaccine was the culprit, Lindsay had the series of three. It was on the third shot Lindsay became so violently ill within 2 hours that I knew the vaccine was the catalyst of her illness.

At 16, Lindsay should be having fun with friends, dating and driving. Instead, her days are filled with doctor visits, 15 specialists, MRIs, CAT scans, spinal taps, ER visits, and hospital admissions. Lindsay is plagued on a daily basis with headaches of a severe kind, joint pain, seizures, nausea, hair loss, dizziness, gastroesophogal reflux, and extreme fatigue.

She has been diagnosed with an Acquired Dysautonomia and is unable to hold food down with frequent retching and vomiting. She takes a minimum of 10 medications daily; and if she misses one, her ability to stand is in serious jeopardy for up to a month.

We have traveled to specialists in four States and will be traveling to doctors in two more States before July. Unfortunately, Lindsay is not isolated in her journey. After WPLG Miami health reporter Kristi Krueger broke Lindsay's story, the first one to air in the country, I heard from dozens of people who have themselves been, or have family members, affected by this vaccine.

Please join me in viewing some clips from the Emmy Award-winning broadcast that brought national attention to this issue.

Mr. MICA. Maybe while they are trying to get that working——

Ms. MARILYN KIRSCHNER. I will finish my testimony.

Family life as we knew it has been destroyed. This illness is an emotional and an extreme financial drain, as I am hardly able to work, depending on my family to support us and feeling like a beggar for our survival.

As a single parent, this vaccine has ripped out a part of our lives that can't be replaced. Lindsay, my former National Junior Honor Society president in 8th grade, is now on a 504 disability plan, missing 70 days of 9th grade and pushing beyond that in this, her 10th grade year. What about her future, college, a career?

Will my son David ever forgive me for being so unavailable last year when he was a senior now that he is 3,000 miles away in L.A.? The joy of his scholarship offers and prom departure all took a back seat to Lindsay's illness. Or the fact that he is spending his birthday on a plane so we could be at this hearing after just returning Sunday from his first year at USC. What about Lindsay's

puppy, Frisbee, and bird, Boca, who are boarded almost as much as they are at home?

What about our shattered lives, barely a fragment left of what used to be? Tragedy is not supposed to be the American way. Lindsay, nor anyone, should have to live like this because scientific studies weren't done to determine if this vaccine was safe to give to every child. My daughter shouldn't have to suffer like this because government officials and drug company executives didn't do their jobs. Thank you.

[The prepared statement of Ms. Marilyn Kirschner follows:]

I am here today with my daughter, Lindsay, maintaining a commitment to pave the way so that other parents can make an informed choice in regards to the Hepatitis B vaccine. Lindsay is representative of all the children who fall under the mandate. Six months before the vaccine we had an idyllic life, reveling in the joy of Lindsay's Bat Mitzvah, perfect in every way.

Lindsay received the Hepatitis B vaccine two days before entering High School. The next day she seemed flu-like, the day after that so dizzy she couldn't stand-up without holding the walls. The following day she passed out. So our life goes, since August 1997. Lindsay has had syncopal & pre-syncopal episodes, her ability to stand was compromised for almost six months due to unremitting dizziness. Following our Drs. advice, unknown the vaccine was the culprit, Lindsay had the series of three. It was on the third shot Lindsay became so violently ill within two hours, that I knew the vaccine was the catalyst of her illness.

At 16, Lindsay should be having fun with friends, dating, & driving. Instead her days are filled with Dr. visits (15 specialists), MRI'S, CAT SCANS, SPINAL TAPS, ER VISITS, & Hospital admissions. Lindsay is plagued on a daily basis with HEADACHES (of a severe kind), JOINT PAIN, SEIZURES, NAUSEA, HAIR LOSS, DIZZINESS, GASTROESOPHOGAL REFLUX, & Extreme Fatigue. She has been diagnosed with an acquired Dysautonomia & is unable to hold food down with frequent retching, & vomiting. She takes a minimum of 10 doses of medication daily.

We have traveled to specialists in four States, and will be travelling to two more States before July.

Unfortunately, Lindsay is not isolated in her journey. After WPLG(MIAMI) HEALTH REPORTER, Kristi Krueger, broke Lindsay's story (the 1st one to air in the country), I heard from droves of people who have been or have family members affected by this vaccine. ~~(video)~~ PLEASE JOIN ME IN VIEWING SOME CLIPS FROM THE EMMY AWARD WINNING broadcast that BROUGHT NATIONAL ATTENTION TO THIS ISSUE. (VIC

Family life as we knew it has been destroyed. This illness is an emotional & extreme financial drain... as I am hardly able to work, depending on my family to support us, and often feeling like a beggar for our survival.

As a single parent this vaccine has ripped a part of our lives that can't be replaced. Lindsay, my former National Junior Honor Society President in 8th grade, is now on a 504 Disability Plan.... missing 70 days of 9th grade, and pushing beyond that in this her 10th grade year. What about her future? College? A Career? Will my son David ever forgive me for being so unavailable last year when he was a senior, now that he's 3,000 miles away in LA. The joy of his scholarship offers, & prom departure all took a backseat to Lindsay's illness. Or the fact that he's spending his birthday on a plane so we could be at this hearing just after returning Sunday from his 1st year at USC. What about Lindsay's puppy Frisbee, who is boarded almost as much as he's at home?

What about our shattered lives, barely a fragment left of what use to be? Tragedy is not supposed to be the American way. Lindsay, nor anyone should ever have to live like this because of the greed of the manufacturer.

Mr. MICA. Thank you for your testimony, and now we will recognize Lindsay Kirschner.

Ms. LINDSAY KIRSCHNER. Thank you. I would just like you to imagine having a life like the one that follows. Your day starts at 2 a.m., when your body starts jerking uncontrollably and a burning smell fills the air. After your body relaxes, you drift back to sleep only to be awakened a short hour later overcome by nausea.

You reach for the bowl that is always on the side of your bed because you've had this feeling before, and you know it is not going to be pretty. Maybe you get another 2 or 3 hours of sleep, but a soothing voice awakens you at 6:15 because it is time to get ready for school.

You feel a killer headache approaching on the ride and you dread the thought of sitting in classrooms for the next 6½ hours while fighting constant dizziness and nausea.

When you try to take your Algebra II tests, you realize that you have forgotten the formulas to use, even though you wrote them more than 25 times in your homework last night.

As the day passes, you look at other kids and long to be normal like them. And maybe for 10 minutes in between constant aches and pains, you manage to forget your problems and feel like you do belong. But then a sudden sharp pain in your arm or the urge to vomit reminds you how different you truly are.

Let's face it. You haven't made it through one full week of school in your 10th grade year of high school. You struggle to keep your head up throughout the remainder of the day and are relieved when the dismissal bell finally rings.

When you get home, forget watching Rosie or MTV. Your eyes are already closing, and so you fall into the comfort of your bed and stay there for the next couple hours. If you manage to wake up in time to do all of your homework, then you struggle to finish it because sitting at the computer brings constant dizziness.

Later, when you start retching, you instantly regret eating the food you had for dinner, whether it be nachos or pasta, and you vow never to eat it again, no matter how delicious it tastes.

Although you are anxious to get more sleep, the thought of nighttime evokes anxiety because as you lie in bed, you know that in just a few short hours, the painful cycle will begin again and your struggle will continue.

To most of you, this would just be a bad dream. But it is the reality I have faced for the past 2 years; and no matter how hard I pinch myself, it won't go away. Thank you.

Mr. MICA. Thank you for your testimony.

[The prepared statement of Ms. Lindsay Kirschner follows:]

Lindsay Kirschner

Imagine having a life like the one that follows: Your day starts at 2 AM when your body starts jerking uncontrollably and a burning smell fills the air. After your body relaxes, you drift back to sleep only to be awakened a short hour later overcome by nausea. You reach for the bowl that's always on the side of your bed because you've had this feeling before and you know it's not gonna be pretty. Maybe you get another 2 or 3 hours of sleep, but a soothing voice awakens you at 6:15 because it's time to get ready for school. You feel a killer headache coming approaching on the ride to school, and you dread the thought of sitting in classrooms for the next 6 and a 1/2 hours while fighting constant dizziness and nausea. When you try to take your Algebra 2 test, you realize that you've forgotten the formulas to use, even though you wrote them more than 25 times in your homework last night. As the day passes, you look at the other kids and long to be normal like them. And maybe for 10 minutes in between constant aches and pains, you manage to forget your problems and feel like you DO belong. But then a sudden sharp pain in your arm, or the urge to vomit reminds you just how different you truly are. Let's face it, you haven't made it through one full week of school in this, your 10th grade year of high school. You struggle to keep your head up throughout the remainder of the school day and are relieved when the dismissal bell finally rings.

When you get home, forget watching Rosie or MTV, your eyes are already closing, and so you fall into the comfort of your bed and stay there for the next couple hours. If you manage to wake up in time to do all of your homework, then you struggle to finish it because sitting at the computer brings on constant dizziness. When you start wretching, you instantly regret eating the food you had for dinner, whether it be nachos or pasta, and you vow never to eat it again, no matter how delicious it tastes. Although you are anxious to get more sleep, the thought of

night-time evokes anxiety because as you lie in bed, you know that in just a few short hours, the painful cycle will begin again, and your struggle will continue.

To most of you, this would just be a bad dream, but it is the reality I have faced for the past 2 years... and no matter how hard I pinch myself, it won't go away.

THANK YOU

Doctors, nurses, hospital visits,
it wasn't supposed to be like this.
My life was shattered like a broken mirror,
sometimes the pain is too hard to bear.
These pieces don't fit into my puzzle because they seem to be jagged,
why do I always feel so worn and ragged?
I wish this ordeal would just come to an end,
the pain, the tears, the loss of friends.
All I want is for my broken spirit to mend.
I've realized though that my journey has only just begun,
but I miss the days of happiness when life was fun.

Brother ___ Kirschner

My sister Lindsay is my best friend. Nothing about our life as a family is normal. It is so sad for me to watch what has happened to her over the past two years. I want all the good times back, when I could take her out with me, or like the other kids who have their siblings visit at college. The pressure is tremendous on me at school, with the constant worry of how my mom can handle this alone... and the phone calls from my sister crying in the hospital with all the poking and prodding. I'm so afraid that her dreams for the future will be shattered by the reality of her illness.

Mr. MICA. I don't know if we can get this to restart there. These are clips that you have provided, Mrs. Kirschner.

[Video shown.]

Mr. MICA. I would like to thank both of you for your testimony and recognize at this time Barbara Hahn. Barbara, you are recognized. Welcome.

Ms. HAHN. Thank you. I would like to thank also Congressman Mica for allowing me to be here to testify today. My name is Barbara Hahn. I am from the greater Cincinnati area north of Kentucky. Up until several months ago, I was employed as an interpreter for the deaf which takes a lot of concentration, and also I am a chaplain.

In June 1995 I was diagnosed with hepatitis B. That was about a week before my 25th wedding anniversary. My doctor told my husband and I that I had a sexually transmitted disease and that he should be tested and vaccinated.

What the doctor failed to tell me at the time was that hepatitis B could be spread in many other ways. I had complete trust in my husband and thank God he had faith and trust in me. So the suggestion of sexual promiscuity did not harm our marriage in any way.

Within a week, we were informed that my husband tested negative as did my children who have all been vaccinated since this ordeal began. Incidentally, none of them have had any adverse reaction to the vaccination.

Shortly after my diagnosis of hepatitis B, an employee of the Cincinnati public schools where I formerly worked informed me that it was the belief that a student I had worked with had hepatitis B. This employee and the child's nurse had gotten themselves vaccinated.

I was furious because no one had bothered to tell me about the vaccine, and I had worked very closely with this child as an interpreter. I had even gone to gym class, a place where children are frequently hurt, with this student. However, I have since been informed that this child did not have hepatitis and had only been vaccinated for protection since this student was in a high-risk group, being that he had multiple disabilities.

This story caused a great deal of pain to the student's family, and I deeply regret if they were hurt in any way by my checking out this rumor. I was eventually told by the representative of the Cincinnati school occupational safety department that I probably contacted hepatitis from a dentist since this is thought to be one of the easiest places that we can pick up the virus.

I never pursued this possibility any further because my doctor told me in June 1995, at that same time that I was diagnosed, that I already had cirrhosis of the liver which meant that I probably had had the virus for years. I tried for years to find out how I got this virus.

Had it been from my mother who died of liver cancer as a result of breast cancer? Did I get it from grade school or dental work surgeries? Did I get it from one of the hospitals or clinics where I happened to be an interpreter? Did I get it from a child who ran into me on the playground or from the little girl who was upset and bit me while I was working at the Cincinnati public schools?

Recently, the immigration policies have brought an increasing number of foreign students into our school systems, and the incidents of hepatitis are much higher in other countries. Is that how I got this disease? I am part of the 40 percent of hepatitis B patients who will never, repeat, never know how we got this chronic, possibly terminal, disease.

I would wish to see no one else go through this. While the possibility of a liver transplant looms in the future, at present I suffer from what is called portal hypertension, which is related to cirrhosis, and chronic fatigue. Portal hypertension means that I wake up every once in a while feeling nauseous and throw up great amounts of blood and end up in the ICU.

It's through repeating bandings of 3 to 6 month intervals that they are controlled. That's where they put a tube down my throat and try to tie off these little bulges before they rupture. I am constantly nauseous, constantly fatigued. Sometimes I get confused about what I'm going to say, and I have not been able to fully enjoy my grandchildren.

The only thing that I can be sure of, is I did not get hepatitis B from sexual contact, drug use, or tattoos. However, I have now arrived at a place in my life—I accept the fact that I will never know the path of my transmission. I no longer search for that answer.

Now I focus on how the virus can be stopped from spreading. Hopefully, someday our schools will be as worried about hepatitis as they are with other vaccines. I was required to be tested for several things before becoming employed by the school, but no one ever asked me to be tested for hepatitis.

Now, ask yourself how easy it would be for your children to contract the disease while playing basketball, soccer, baseball, or track. What about the fights in the school lunch lines? Or what about the little girls and boys who trade pierced earrings back and forth perhaps unknowingly infected with hepatitis B since it is a silent disease that we don't know about for years.

I don't mean to frighten anyone here with the ease of contacting hepatitis, but statistics show that it's easier spread than AIDS, as others will no doubt testify to.

In closing, I make one personal point. I know by being here today I have added another brick to my wall of isolation because of the fear some people have of contracting my disease. I also know that many people will not believe that I have only had one intimate partner in my life for 29 years, but my husband does. And you know, that's really all that matters to us.

Oh, yes, there is one more thing. The best thing my doctor did tell me is I needed to get my kids and my grandchildren vaccinated, and I did. So you cannot even imagine the joy when several weeks ago, I received in the mail my son's blood donor card. Actually, he received it. I took it. And he is now an eligible blood donor.

Why am I happy? This means that I have successfully prevented my son from contracting this terrible disease and he is safe. So all I'm asking of this committee is to consider and help me to protect other children the same way I am trying to protect my own, through vaccination. Thank you.

Mr. MICA. Thank you for your testimony and I will recognize Karen with PKIDS.

Ms. KAREN. Chairman Mica and members of the committee, I appreciate the opportunity to speak today. I am here today to talk about my family. I won't add to the list of statistics related to the immunization issues. I would like to personalize them to bring them to a level that you can relate to from the heart, rather than from a business, political, or clinical standpoint.

My husband and I have three young children. Unfortunately, I can't bring them with me, but these are the three children. One of us became infected with hepatitis B and is now a carrier. One of our twins is the face of this virus. Although he has no apparent symptoms yet, his liver is dying.

This is an invisible process until the end. Biopsies at ages 3 and 4 confirmed that he already had cirrhosis, and as you have heard from other people on the panel that's quite unusual. It usually takes decades, but at age 3 he already had cirrhosis, which is permanent scarring of the liver.

He did not respond to a 7-month course of Interferon, which is a form of chemotherapy, and no other treatment has been available for him. He has had cirrhosis long enough now that he must be monitored frequently for liver failure and cancer.

There is a four letter F word which we try to shield our children from, and it's something they shouldn't know anything about at such a young age, and that word is fear: fear of social repercussions, fear of financial ruin, fear of sickness, death, and loss.

You may have noticed that I have not provided our family name, and that's because I can't. The first thing hepatitis B families learn, usually after rejection by friends and family, is to go to extreme lengths to protect their children's privacy.

We cannot risk exposing our children's plight on news programs such as 20/20 to help inform others of the dangers of this disease. We desperately want to reach out for comfort when we learn our child has an incurable illness, but we can't. Local hospitals offer support groups for parents of children with diseases such as cancer, but not hepatitis.

We, therefore, formed a nonprofit group, PKIDS, or Parents of Kids with Infectious Diseases. PKIDS is determined not only to help families with infected children but also to educate the public about viruses including hepatitis.

My work with PKIDS enables me to accomplish my personal goal of ensuring that other families are prepared to deal with the complicated issues related to living with an infectious disease. Parents feel an overwhelming need to warn day care workers, teachers, Sunday school teachers, playmates and their parents of the extra care that needs to be taken if our child scrapes his knee, bites or is bitten, or has a bloody nose.

We want to tell everyone to get shots, yet we agonize over the negative consequences of telling. Will our child be treated fairly? Will he be ostracized on the playground? Will our kids be singled out as the kids at school that everyone needs to avoid? Will information given to the school nurse in confidence wind up as the topic of conversation at a PTA meeting?

There are discrimination and disability laws that guarantee my child a public education, but there are no laws to protect his heart. My husband and I attended a school parent meeting and during casual conversation, a mom mentioned that she had visited the school superintendent because she had heard there was a child in the district with hepatitis B. She wanted the superintendent to identify that child so that she could isolate her child from him.

My husband and I sat there paralyzed in silence waiting for everyone to look at us. And all I could think of was if you wanted to protect your child, get the shots; have him get the shots.

We supervise our child's play. We watch his soccer games. We coach his soccer games. We are there as much as possible in order to protect other people's children. But it's obviously impossible to continue this vigilance as the children grow older.

When a neighbor tried to put a bandage on our child's bleeding cut, I pushed her away; and she thinks I am overprotective. But what she doesn't realize is that I was protecting her. No one else should have to live with this virus because it's preventable.

We worry about our ability to provide the best medical care for our child. His Interferon treatment cost well over $20,000 and only a portion was covered by insurance. We are self-employed and we watched our health insurance premiums triple over a 3-year period. Those premiums now exceed our mortgage payment.

We wonder if we will ever be able to afford college or retirement for our children. If no cure or control is found for hepatitis B in the very near future, our son will most likely need a transplant, a liver transplant. We have been warned that transplant and post-transplant care could ruin us financially.

At worst, it's only a temporary solution for him, as the virus could eventually take the new liver as well. I call this virus IT, capital I, capital T. Those of you familiar with Stephen King's Master will understand why. IT invades our lives, our thoughts, our spiritual beliefs no matter what defenses we erect.

I watch my happy children playing, and IT reminds me that we will soon have to tell my son that he has a serious illness. Whenever he doesn't feel well, I wonder if this is IT. How long will IT allow him to play the sports he loves? How will IT affect his school performance? Hepatitis statistics make it very difficult for us to be optimistic.

You can all look at your children and fantasize about their senior proms, their weddings, and their careers, but I cannot. My son is a leader, he is clever, he is creative, he is charming, and he is very protective of his brothers and they look up to him. I fear the effect IT will have on his brothers, and I worry about how they will deal with this illness or worse.

I fear that I will watch my child die, the worst possible thing that can happen to a parent. No other family should ever have to experience this pain because three shots can prevent IT. Hepatitis B is transmitted primarily through blood and sexual contact with infected persons.

My child can infect yours by sharing tooth brushes at camp. He is losing his baby teeth and when children lose their teeth their gums bleed. And kids share things. A toothbrush is one of the

things they share. He can infect your children through biting or leaving blood residues on a hard surface.

He has frequent nosebleeds as a result of the virus. It affects his clotting factor, and the virus lives on hard surfaces such as tables for up to a week. He doesn't even have to be there and another person can become infected or through sports as mentioned by other people.

There are infected kids out there with no symptoms. They are not reported, no one knows they have it. They have not been diagnosed yet. Infected children and young adults will be socializing with and dating your children. It is clear to me that those who oppose immunizing our children are well informed about things such as vaccine composition and side effects.

However, I beg you to educate yourselves about the hepatitis virus and disease progression as well because only then will you be able to make a truly informed decision regarding immunizations and help us to protect our children. Thank you.

Mr. MICA. Thank you for your testimony.

[The prepared statement of Ms. Karen follows:]

INTRO

My name is [redacted]* and I'm a PKIDS Mom. My entire family has been devastated by the Hepatitis B virus as it has afflicted both my husband and son. I am testifying today to stress the dire necessity of having all school-age children - your children - immunized against this dreaded, but preventable disease. With Hepatitis B spreading at epidemic proportions, it's very possible that your child could be playing with an affected child (like my son). My hope is that all children will be immunized so that they and their families won't ever have to experience the nightmare that we are going through.

*Please do not use my last name for privacy issues.

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May 26.1999

I'm a PKIDS Mom. I am very fortunate to have a loving, devoted spouse and three wonderful sons -ages 13, 11, and 7. I would guess that we're a pretty typical family in that we work very hard as well as play very hard (especially during baseball season!) and maintain a ferociously hectic schedule. Where we're not typical, however, is that both my husband as well as my oldest son have Hepatitis B. My husband was infected by me, a registered nurse, who contracted hepatitis (and later converted) while working in ICU - talk about an occupational hazard! That was the beginning of a nightmare that would haunt us for the rest of our lives. To this day we haven't a clue as to how - or when - our son was exposed. The doctor's we saw back then did not feel any need to get the boys tested, informing me that kids weren't being tested for hepatitis, even though we were considered a "high risk" family. They saw three healthy, young boys and reminded their paranoid mother that "this was not a casually transmitted disease." Of course, I wanted to believe them. The boys were all immunized when my youngest was just an infant. Unfortunately, I'd find out later that it wasn't soon enough.

Several years ago, my husband's liver showed evidence of cirrhosis and he was referred to a hepatologist for treatment. He recommended that our boys be tested for hepatitis B and we were horrified to learn that our oldest son had this dreaded disease also. It seemed that this nightmare would just not go away. "How and when did this happen?" we asked ourselves over and over. We can't recall any blood related issues between my husband and our son, assuming that's where our son's infection originated from. Maybe it came from the playground across the street.

Suffice it to say, our entire family has been affected by this. My husband failed a trial of Interferon - the boys watched and asked a lot of questions about the daily injections, my oldest wondering if this was something he was going to have to endure also. My husband has since been on Lamivudine and we're keeping our fingers crossed. He's had liver biopsies, ultrasounds, endoscopies, many blood tests and doctor's visits. He had an extensive work-up and is currently on the liver transplant list. Needless to say, this is a guy who used to get faint just walking into a hospital to visit someone.

Our son has also had a biopsy and several ultrasounds, as well as the "routine" lab tests and doctor's visits. He's a very well-adjusted teenager but at times even he asks, "Why me?" Is he going to be walking down that

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transplant road some day? I try not to go there. In the meantime, he has many friends (but only his closest ones know about his hepatitis) and is involved in just about everything - he's an excellent student, is active in scouts, and puts his heart and soul (and liver) into various sports. He's just a great all-around kid - who looks and acts like your kids - but he's dealing with stuff a normal 13-year-old shouldn't have to. It breaks our hearts. He played one season of football (and was quite a good linebacker) before we knew he had hepatitis. After that, he was told that football was probably one sport he should avoid because of the contact involved. Heck, before we knew he had hepatitis, our son could have unknowingly infected your son or daughter. Needless to say, my husband and I have attended his baseball, volleyball, basketball and soccer games as well as track and cross-country meets. I sit in the audience praying not that his team wins but that he doesn't get injured. I feel that, rather than being able to comfort my son, my first concern would be to protect his caregiver; hopefully it would be me. He can't even scratch a mosquito bite without me freaking out. My son carries a small first-aid kit in his backpack just in case of injuries; he knows to handle them himself or to give gloves to anyone who might assist.

I worry and pray every day as our son leaves the house in the morning that God will protect him as well as those he encounters. I often think about his future - high school, college, career, marriage, grandchildren - rarely do I get through the whole list without getting horribly depressed regarding father and son. We don't know what the future holds for us and the uncertainty doesn't feel good. They say that good things always come out of the bad, and while we've always been faithful, we have become even more so, and that's a good thing. We're hoping for a cure and praying for a miracle. I believe that our family is in God's loving hands and I derive great comfort in that - some days it's all I've got. Every night, father and son bless each other's livers with holy water - they get comfort in that; some days it's all they've got.

I can't turn the clocks back for us but I'm here to protect and be an advocate for other children and urge you to encourage them

Mr. MICA. And we will recognize our last witness in this panel, Betty Fluck. You are recognized. Welcome.

Ms. FLUCK. I would like to thank you for allowing me to come before you today to share my experience with you. Never did I dream that I would have this opportunity. I am a diagnosed victim of the hepatitis B vaccine. My husband and I are not antivaccine. Each of our three boys has been vaccinated per health department guidelines. However, they will not have the hepatitis B vaccine.

On December 2, 1997, I took my second hepatitis B vaccine in the series of three. I was required to have the immunization for my job. I am a registered nurse and have been for 20 years. I had just started a new job as a public health nurse for the local health department in Kokomo, IN. Part of my job description was to give immunizations in the department's weekly clinic.

Roughly 12 hours after receiving my vaccine, I woke up in severe pain. I developed a 104 degree fever, nausea, vomiting, respiratory problems, a rash, severe head, neck and back pain, swollen joints, and I was unable to move my legs.

When the fever broke several hours later, I regained a small percentage of my leg strength, but the severe damage had already been done. I had to use a cane to move around. I had absolutely no energy, and I had constant joint and leg pain.

I was sleeping approximately 22 hours per day. I continued to run intermittent low-grade fevers. The first doctor that I went to said that I had a reaction to the hepatitis B vaccine but was unable to help. I went from doctor to doctor looking for help.

I ended up at Indiana University Medical Center in Indianapolis. I first saw a doctor who was very kind and told me that he had read about some of the problems with the vaccine. He promised to do some research into the vaccine's adverse reactions. He asked me to see one of his colleagues at IU Med Center, a rheumatologist.

This rheumatologist from IU was simply hostile to the idea that the hepatitis B vaccine could have caused my problems. He suggested that some of my problems could be caused by or attributed to a kidney stone. Please be aware that at this point, my fingers were so painful that I could not open a soda can.

I returned to the first doctor at IU Med Center 1 month later for a scheduled followup. This doctor, who had been encouraging and sympathetic 1 month ago, now refused to use the word vaccine and attributed some of my problems to the aging process.

Unhappy with both of these doctors, I requested a meeting with a patient advocate and the IU doctors. At this meeting the first doctor finally told me that I had a "political problem, not a medical one." My condition continued to deteriorate from cane to walker to knee braces.

Finally, in September 1998, I was put in full leg braces that run from my toes to my hips. With the use of the braces and forearm crutches, I have some mobility. Eight months after the initial injury, I was able to find an out of State doctor who was treating people for vaccine damage.

I must now see him every 3 months. The vaccine has caused nerve damage to my legs and hands. The medical name for my problem is chronic inflammatory demyelinating polyneuropathy

[IDP]. I also have multiple types of autoimmune disorders, and I now have an elevated rheumatoid arthritis factor.

I undergo weekly IV treatments that cost several thousand dollars per week. Although I have more energy now, there is no real prognosis for my condition. Immediately after I was injured, I contacted the pharmaceutical company asking them for help. They told me that they had never heard of this problem before.

I realized at that point that I was not that unique and decided to write to the FDA through the Freedom of Information Act. I requested any reports on file about adverse reactions to the hepatitis B vaccine for one particular company from 1991 to present.

Four months later, I received a box containing a 1,045-page report. On each page, there were summaries of approximately eight reactions. These 8,000-plus reactions ranged from mild to death. I made an appearance on ABC's 20/20 in January 1999, on their story about the hepatitis B vaccine.

Since that show was aired, I have received numerous calls from adult victims and parents of children who had been injured after taking the hepatitis B vaccine. One common theme among the victims is that their doctors told them it couldn't be the vaccine because it was perfectly safe.

I recently testified before the State senate committee in Indiana with the intent of removing the mandate for the hepatitis B vaccine for school entry. The proposed amendment was designed to give parents the choice to waive the vaccine for any reason.

On March 2, 1999, it passed the State senate by a vote of 45 to 4. However, the House sponsor of the original bill killed it rather than bring the bill up for debate. In Indiana, a doctor from the department of health told the Senate committee that one of the arguments for the vaccine was that it was the "first anti-cancer vaccine."

Fortunately, we were able to show that the "anti-cancer vaccine" theme was taken from the PATH website. PATH is an organization within the World Health Organization. PATH suggested that the "first anti-cancer vaccine" theme was a good marketing tool to bring about interest in a "boutique" vaccine.

I have minutes from the CDC study group meeting on the hepatitis B vaccine held in March 1997. The minutes of the meeting show that it would take at least a 60-day study to show the onset of MS. Clinical studies done by the two manufacturers were 4 and 5 days in length respectively.

It should be noted that the afternoon session of this meeting was chaired by Dr. Robert Sharrar of Merck. This group was to decide how to identify various types of adverse reactions, such as MS, and demyelinating disease and to plan meaningful studies.

When Dr. Sharrar appeared on ABC's 20/20 in January, he said that he honestly believed that hepatitis B vaccine had not caused any problems. Can an employee of a pharmaceutical company that manufactures the vaccine be objective in designing experiments to show fault in a product that generates close to $1 billion in sales for his company?

The form that people are given about the vaccine was written by the CDC. It does not address serious adverse reactions. When you

look at the vaccine insert provided by the manufacturer, several adverse reactions are noted.

I have since talked to many healthcare professionals who are also unaware of the potential adverse reactions listed on the vaccine insert. It makes me wonder why the pharmaceutical company representative that I talked with earlier, the one who was unaware of any adverse reactions, was unaware of what their own company's insert said.

A vaccine that still has so many unanswered questions should not be mandated for children. It just does not make sense. The right to decide if it's in the best interests of the child should be made by the parents. After all, it appears that for the most part, when a child is severely handicapped by this vaccine, the parents are on their own.

No one pushing the mandate is there for help or comfort. In an article on the hepatitis B vaccine that was printed in the Washington Post, a spokesperson for the CDC said that nothing unexpected had been observed in the way of adverse reactions.

At first, I thought they meant that their position was that no adverse reactions had occurred. Now, I really don't think it was denial. Despite over 20,000 reports to VAERS for the two manufacturers, nothing unexpected had occurred. I really believe that the number and type of injuries is no surprise for the CDC. Maybe the only surprise to the CDC is just how hard the victims are fighting back. Thank you.

Mr. MICA. Thank you for your testimony.

[The prepared statement of Ms. Fluck follows:]

Testimony of Betty D. Fluck
for
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy, & Human Resources
John L. Mica, Chairman

May 18, 1999

I would like to thank you for allowing me to come before you today to share my experience with you. Never did I dream that I would have this opportunity. I am a diagnosed victim of the Hepatitis B vaccine . My husband and I are not anti-vaccine. Each of our three boys has been vaccinated per Health Department Guidelines. However, they will not have the hepatitis B vaccine.

On December 2, 1997, I took my second Hepatitis B vaccine in the series of three. I was required to have the immunization for my job. I am a Registered Nurse and have been for twenty years. I had just started a new job as a Public Health Nurse for the local Health Department in Kokomo, Indiana. Part of my job description was to give immunizations in the department's weekly clinic.

Roughly twelve hours after receiving my vaccine, I woke up in severe pain. I developed a 104 F fever, nausea and vomiting, respiratory problems, a rash, severe head, neck and back pain, swollen joints and I was unable to move my legs. When the fever broke several hours later, I regained a small percentage of my leg strength, but the severe damage had already been done.

I had to use a cane to move around. I had absolutely no energy and I had constant joint and leg pain. I was sleeping approximately 22 hours per day. I continued to run intermittent low grade fever.

The first doctor that I went to said that I had a reaction to the Hepatitis B vaccine but was unable to help. I went from doctor to doctor looking for help. I ended up at Indiana University Medical Center in Indianapolis. I first saw a doctor who was very kind and told me that he had read about some of the problems with the vaccine.He promised to do some research into the vaccine adverse reactions. He asked me to see one of his colleagues at I.U. Med Center, a rheumatologist. This rheumatologist from I.U. was simply hostile to the idea that the Hepatitis B vaccine could have caused my problems. He suggested that some of my problems could be attributed to a kidney stone. Please be aware that at that point, my fingers were so painful that I could not open a soda can.

I returned to the first doctor at I.U. Med Center one month later for a scheduled follow up. This doctor who had been encouraging and sympathetic one month ago now refused to use the word vaccine and attributed some of my problems to the "aging process".

Unhappy with both of these doctors, I requested a meeting with a patient advocate and the I.U. doctors. At this meeting, the first doctor finally told me that I had a "political problem, not a medical one."

My condition continued to deteriorate from cane, to walker, to kneebraces. Finally in September, 1998, I was put in full leg braces that run from my toes to my hips. With the use of the braces and forearm crutches, I have some mobility.

Eight months after the initial injury, I was able to find an out of state doctor who was treating people for vaccine damage. I must now see him every three months.

The vaccine has caused nerve damage to my legs and hands. The medical name for my problem is Chronic Inflammatory Demylenating Polyneuropathy (CIDP). I also have multiple types of auto immune disorders, and I now have an elevated rheumatoid arthritis factor. I undergo weekly IV treatments that cost several thousand dollars per week. Although I have more energy now, there is no real prognosis for my condition.

Immediately after I was injured, I contacted the pharmaceutical company asking them for help. They told me that they had never heard of this problem before. I realized at that point that I was not that unique and decided to write to the FDA through the Freedom of Information Act. I requested any reports on file about adverse reactions to the Hepatitis B vaccine for one particular company from 1991 to present. Four months later I received a box containing a 1045 page report. On each page, there were summaries of approximately eight reactions . These 8000 + reactions ranged from mild to death.

I made an appearance on ABC's 20/20 in January, 1999 on their story about the Hepatitis B vaccine. Since that show was aired, I have received numerous calls from adult victims and parents of children who have been injured after taking the Hepatitis B vaccine. One common theme among the victims is that their doctors told them that it couldn't be the vaccine because it was perfectly safe.

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I have minutes from a CDC Study Group Meeting on the Hepatitis B vaccine held in March, 1997. The minutes of the meeting show that it would take at least a 60 day study to show the onset of MS. Clinical studies done by the two manufacturers were four and five days in length, respectively. It should be noted that the afternoon session of this meeting was chaired by Dr. Robert Sharrar of Merck. This group was to decide how to identify various types of adverse reactions such as MS and demylenating disease and to plan meaningful studies . When Dr. Sharrar appeared on ABC's 20/20 in January, he said that he honestly believed that the Hepatitis B vaccine had not caused any problems. Can an employee of a pharmaceutical company that manufactures the vaccine be objective in designing experiments to show fault in a product that generates close to a billion dollars in sales for his company?

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handicapped by this vaccine, the parents are on their own. No one pushing the mandate is there for help or comfort.

In an article on the Hepatitis B vaccine that was printed in the Washington Post, a spokesperson for the CDC, said that nothing unexpected had been observed in the way of adverse reactions. At first, I thought they meant that their position was that no adverse reactions had occurred. Now, I really don't think it was denial. Despite over 20,000 reports to VAERS for the two manufacturers, nothing unexpected had occurred. I really believe that the number and type of injuries is no surprise to the CDC. Maybe the only surprise for the CDC is just how hard the victims are fighting back.

Mr. MICA. I would like to thank all of our witnesses for their testimony this morning. I have a couple of questions, the first for Mr. Belkin. I believe you testified that you did not have any notice as to possible adverse reactions before the immunization?

Mr. BELKIN. Yes. We received no warning. Our pediatrician seemed to think this was like giving an Advil or Tylenol or something. No warning, no ''watch out, this is dangerous, this could cause convulsions.'' Nothing whatsoever in any way, shape, or form.

Mr. MICA. Of course you have experienced a tremendous personal tragedy. Based on what you know now, do you think there should be some warning or some signoff by parents, such as informed consent?

Mr. BELKIN. Yes, absolutely. And I think the doctors should be held responsible. The bureaucracy should be held responsible. Right now, I have taken about 40 other reports from other parents where the same kind of thing has happened—where they found about 10 other SIDS cases, and numerous other nurses that have the same kind of things as Betty.

In every single case the doctors have denied responsibility. No, it's not the vaccine. It's happened over and over. Convulsion, oh, it is not the vaccine. Second time around, convulsions. No responsibility. As well as disclosure and choice, the doctors should be held responsible for reporting adverse reactions so when a dangerous medicine is out there, it doesn't keep happening. That's my only goal in doing this.

Mr. MICA. Now, I know that they eliminated some factors for the cause of the death of your child. Was there a specific scientific or pathological forensic study that linked your child's death to this vaccination?

Mr. BELKIN. No, not yet. I intend to pursue that. I have not done that yet. I am going to take the autopsy results. I'm trying to find someone who knows and will not deny it. What I found is that the New York City medical examiner and every doctor, they call up Merck and Merck says, ''you are the first person that has ever called us, this has never happened before.'' So then they say, ''well, how can I say this child died from the vaccine?'' and it turns out there are 400-something other deaths in VAERS.

So what is happening is, from the top down they are denying that this is happening. And the people at the bottom, the pediatricians, the people that are doing the autopsy say ''well, they say it's safe; it couldn't be the vaccine.'' There has to be some disclosure from the top down to the bottom.

There is a huge body of evidence of brain swelling in causing encephalitis, which is basically the result which they are denying. So I still have to go forward with this to actually go to another neuropathologist, which I intend to do.

Mr. MICA. Thank you. Ms. Converse, your child had reactions and you stated to the doctor, the physician, that your child was having reactions. Were you warned in advance that the child might have adverse reactions?

Ms. CONVERSE. No.

Mr. MICA. Then, after you said that there were problems, you said that the doctor ignored those and went ahead with the vaccinations?

Ms. CONVERSE. Right. Because I knew that the pediatricians would be unsupportive if I mentioned that I suspected the vaccine, I never told them that.

Mr. MICA. You did not tell them.

Ms. CONVERSE. I simply explained his symptoms.

Mr. MICA. Each time your child was vaccinated, there were adverse reactions?

Ms. CONVERSE. Yes. But the most profound was with the hepatitis B.

Mr. MICA. Do you have professional or scientific evidence that the vaccine has been the cause of your child's condition?

Ms. CONVERSE. The evidence that I am using is that he fits all of the criteria that the Federal Government describes. We do not have a blood test which I have just learned that we can get to—Myelin Basic Protein. I just learned of that.

Mr. MICA. Have you taken advantage of or applied for compensation under the Vaccine Injury Compensation Program?

Ms. CONVERSE. No, not yet because of the discouraging comments that my pediatrician gave me in terms of basically coming out and saying that we have had a reaction. But my position on that is changing. I think the other reason why we haven't is we have been very overwhelmed in caring for our son.

Mr. MICA. In the reporting system that we have, the Vaccine Adverse Event Reporting System, do you know if your child has been included in that—either through doctors or your report?

Ms. CONVERSE. He has not.

Mr. MICA. What about your child, Mr. Belkin?

Mr. BELKIN. Yes.

Mr. MICA. Ms. Kirschner, were you warned in advance that your child might have an adverse reaction? How old was she when she had her shots?

Ms. KIRSCHNER. Lindsay was 14. I had no warning at all. In fact, on the appointment that she was vaccinated, the doctor didn't even see us. There was no consent form. Nothing. Even the day after we went back to him when she had flu-like symptoms, he told me she had the flu. I did not even make the connection that it was tied into the vaccine. When I called him every day because she was just getting worse and worse, he didn't know.

Mr. MICA. Thank you. Ms. Hahn, you contracted hepatitis B and you said that you didn't know how you contracted it. You have heard some of the stories today about individuals who had their child vaccinated under the mandatory program. After your condition was discovered, you had your family vaccinated. Was that the case?

Ms. HAHN. Yes, it was.

Mr. MICA. So they hadn't been vaccinated before. You didn't experience adverse reaction in your family. First of all, what do you think about the additional requirement for informed consent before these vaccines are given, particularly for the parent since of course, the child can't give intelligent consent to vaccination? And do you think we should have some other limits on vaccination?

Ms. HAHN. I can't speak for their situation. In mine, I had my doctors, who are with Group Health Associates of Cincinnati, and I have always been informed of every vaccination my children have received. We have had the same doctor all of their lives. My oldest is 27 and my youngest is 21. I have always been informed of the risk. My husband was even informed of the risk.

Mr. MICA. How old were your children when they were vaccinated?

Ms. HAHN. My youngest son was 16.

Mr. MICA. But if they had been vaccinated—one of the questions we will get into a little bit later is how long this vaccine is effective for. So they might have to be vaccinated again if they were 16 and had it done at birth?

Ms. HAHN. No one has ever informed me of that. I read a little bit on the Internet of some people suggesting it, so I can't answer. My doctors haven't seen any need. I believe before you would do that, from what I understand when I ask my doctor about that, is that you would do a simple blood test first to see if they needed to be, you know——

Mr. MICA. Finally, were they given any warning that there might be an adverse reaction or were you given any warning that your husband or children might have an adverse reaction to the vaccine?

Ms. HAHN. Yes. I also encouraged all of my family members, my grandchildren who are all under the age of 4, my sister, and my brother to be vaccinated. I don't know of one of my friends yet that has had a problem.

Mr. MICA. I have additional questions, but I will recognize Mr. Waxman.

Mr. WAXMAN. Thank you very much. Let me thank all of the witnesses and tell you how sorry I am to hear about the misfortunes all of you have suffered, some from the vaccine reaction, apparently from the vaccine reaction, and some from hepatitis itself. We are dealing with a difficult issue. We want to control this disease, but evidently there are, in some cases, horrible reactions to vaccines and we want to be sure that they are minimal and that everything is being done to prevent those adverse reactions.

Mr. Belkin, you showed us some charts that were pretty surprising. The question, of course, is one of causation, whether those lists of reactions were, in fact, caused by the vaccine itself. Have you conducted controlled research such as might be peer reviewed and published?

Mr. BELKIN. No, and I think that's exactly what should be done. You cannot go through—I encourage you to go through the VAERS reports and look at them yourself. I spoke at the New York City Rotary Club. I was invited to speak on this subject. A gentleman came up and refuted me and he said he had been sent by Merck.

He was the chairman of the American Academy of Pediatrics. It is a major thing when Merck sends the chairman of the local district of the American Academy of Pediatrics. I asked him what he thought about VAERS, and he said that it's garbage. I said, what would you do to improve it? He said, there is no money for that.

So what is happening is it is just going nowhere.

Mr. WAXMAN. Let me interrupt you, because we have to have research done. Any manufacturer of any kind of pharmaceutical prod-

uct has got to continually check, in my view, about adverse reaction reports. One of the concerns I have had is that the FDA is under such pressure to approve drugs, they get them approved, and we want to know before they are sending them out to be used widely that they check for all of the adverse reactions. And if they are out there and they learned about adverse reactions, they respond to it.

We are going to hear from somebody from the FDA in a minute. I'm making that as a general statement. But the charts that you held up have not been peer reviewed themselves. They are the list of statistics of people who have had adverse reactions; is that right?

Mr. BELKIN. That's correct.

Mr. WAXMAN. You haven't had anything peer reviewed or published in any scientific——

Mr. BELKIN. No, I haven't. That needs to be done.

Mr. WAXMAN. Do you have a dispute with the national statistics that show that a third of all hepatitis B cases occur in people who are not in high-risk groups?

Mr. BELKIN. Those studies are very interesting. Are they done on the basis of epidemiological study or are they done by questionnaires? That's the question. I think that the science really has not been done. I am not an expert on the subject, but from what I have heard, those little pie charts showing so many intravenous drug users, that's the result of questionnaires.

I'm not absolutely certain about that. I think this whole area needs to be looked at by independent scientists without ties to drug companies or the government.

Mr. WAXMAN. If you have people who are identified as high risk because of certain activities that they engage in, that's pretty clear. If you have people who never engage in those kinds of activities and whom you wouldn't consider high risk contract hepatitis B, we have to wonder why.

The report that I am referring to indicates a third of all of the hepatitis B cases occur in people who are not considered high risk. I am sure it is based on some questionnaire, because how would you know whether somebody is in a high risk group or not? But that doesn't invalidate the conclusion. The reason that I raise this is that it has got to be of concern to all of us that hepatitis B is a pretty awful disease.

It's not just limited to people who are high risk. If we can prevent this disease we ought to do so. The question is can we do it in a way without these costs?

I have a letter from a woman in Santa Monica, which is in my district. She says,

> I understand your committee is hearing from individuals concerned about the dangers of immunization against hepatitis B. As a school nurse, I would like to urge you to keep in mind the devastating effects of this liver infection against which the vaccine protects both individuals and society in general by lowering the pool of infected people. It's true that a few people do suffer adverse reactions to various immunizations. Nevertheless, although it may seem harsh to say so, the public health benefits of preventing disease by immunization outweigh the relatively low risk of harm to the rare susceptible person. In California, the State requires hepatitis B immunization of public school students in specific grades, but allows waivers for individuals with personal beliefs or medical conditions which render them unwilling or unable to be vaccinated. The availability of such waivers should allow your vac-

cine critics to decline personal vaccinations without depriving other individuals in society as a whole of this life-saving protection.

What do members of this panel think of that idea, allowing waivers?

Ms. CONVERSE. If I could respond to that, Mr. Waxman. I think it is very interesting to be here today because I am noticing that victims on both sides of this share a lot of problems, both the course of their illness—there is some cross-over, and there is cross-over in terms of isolation and lack of treatment.

What this is telling me is, clearly we don't understand the whole picture of transmission and why there is this chunk of people who we can't identify as to how this is being transmitted. And the second thing, it is very clear that we don't understand who reacts adversely and why.

My beef is that unless you profile criteria about who will react adversely and unless that is very much part of an informed consent—for instance, if you are of northern European extraction and you have a history of allergies in your family—I am making that up. I don't know what the criteria would be—that you should be informed that you may be adversely affected. That doesn't exist right now.

Mr. WAXMAN. Do you think we even know that information?

Ms. CONVERSE. No, we do not know that. My point being that you cannot mandate this universally for newborns until you know who may be adversely affected because you will damage thousands of people.

Mr. WAXMAN. We know with every immunization that we have there are going to be some rare cases where there is going to be an adverse reaction, sometimes horrible and even deadly.

Ms. CONVERSE. I think what is emerging with this one is a profile, if I might go out on a limb and say. I recently attended an autism parents support group on Cape Cod where I live, a small group, 10 parents. All of them had red hair. That is rare, and I think these are the kinds of things that might emerge that really should be looked into. That may be different from other vaccines.

Mr. WAXMAN. I hope we can find a profile and find a reason for adverse reactions. We need to have it done, however, through scientific methods.

Ms. CONVERSE. But until that's done you cannot make it a law that a newborn get this shot because it's criminal. You have no way of knowing——

Mr. WAXMAN. You have no way of knowing, except we do know that the overwhelming majority of people are not adversely affected and the disease is prevented. On that basis, most people want their children to be immunized from polio, diphtheria, whooping cough, and hepatitis B.

Every single one of those immunizations has an adverse reaction with some individuals. If we knew why some individuals react that way, we wouldn't have them take the vaccine. But as a society, we do require people to be vaccinated. In Santa Monica, CA, according to this letter that I received, they allow people to opt out if they have this concern or fear.

Ms. CONVERSE. If I could just interject one more comment and then I will stop. Our experience—I'm assertive, educated. I have a

public health background and very much accept immunization. I was persistent and tactful with our providers. I never told them I think the vaccine caused a problem because I knew that might be an inflammatory comment for them. They failed to recognize not just that it was a reaction, but that my son was even ill.

So this experience tells me that there will be many, many children who don't get reported. So when you say there are a few that have a problem, I think it's the tip of the iceberg.

Mr. WAXMAN. Did you ask your doctor about the possible risk of the hepatitis B vaccine or about any of the childhood vaccines that you put your child through?

Ms. CONVERSE. Yes, but we weren't aware that he was going to be given that shot at birth. It was not discussed at all.

Mr. WAXMAN. So you were aware that there is a possible risk?

Ms. CONVERSE. I was aware through my public health training.

Mr. WAXMAN. But you didn't talk to your doctor about it specifically?

Ms. CONVERSE. I wouldn't agree with that. Through my public health training, I was aware of other vaccines and the risks associated with them.

Mr. WAXMAN. My question is, did you talk about it with your doctor?

Ms. CONVERSE. Yes, absolutely.

Mr. WAXMAN. Why were you, as a public health person, afraid to tell your doctor that you thought your child was having an adverse reaction to the vaccine?

Ms. CONVERSE. Because my training taught me that these are very rare and there are a few sacrificial lambs for the good of the whole and that's just the way it goes. I wanted to encourage——

Mr. WAXMAN. I thank you very much for your——

Ms. CONVERSE. I wanted to encourage my provider to help us, and I did not want to discourage them by antagonizing them.

Mr. WAXMAN. I appreciate what you had to say, and I am sorry for all of the terrible things that you have gone through. Did you want to raise a comment? I think my time is up, but why don't you go ahead.

Ms. HAHN. Chairman Mica and Congressman Waxman, the subject of the questionnaire about hepatitis—and it only asked questions. I have had the same health maintenance provider for over 20 years. He and they are very aware of my medical conditions. I was told that I would have preventive care and they would know anything before it happened.

When I first became a little ill, or rather I was very ill—I lost 44 pounds—it was looked at first as just chronic diarrhea and stuff. Within a matter of a couple of weeks, hospitals. Then they were even telling me possibly cancer. They were going to remove my spleen for blockage. All of that got narrowed down after they did some tests.

Then the very last thing they looked at and they said, Chaplain Hahn, you have a sexually transmitted disease. I believe that was more for the safety of my husband. They wanted to make sure that this didn't go any further. So even the best of prevention, best of care, best of trying to take care, you don't know.

I worked with your children. I didn't know I had it for probably 20 years. The only way that I can prevent your children from getting it and trying to be the best at my universal precautions is for you to have your children vaccinated.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. MICA. Mr. Tierney.

Mr. TIERNEY. Thank you. I don't want to prolong this for any of you. I am really very sympathetic to all that you said, and I understand how difficult this must be for you. Particularly Lindsay, I want to say that your courage here today has been noted by everyone.

Rather than going to a more extensive question, because I think that you have all been excellent in your testimony and very informed, I only want to pursue one area. I think, Ms. Converse, you made the statement, if I am correct, that you thought the effects of the vaccine wear off within a certain period of time.

Ms. CONVERSE. That's my understanding.

Mr. TIERNEY. Could you expand on that a little bit and tell me where you get that information and that conclusion.

Ms. CONVERSE. I get that information from a Massachusetts Department of Public Health flyer on hepatitis B for parents, which says that your child will need a booster by the time they reach—I think it's either age 11 or 14.

Mr. TIERNEY. I was thinking that you had excluded the booster part of it, including that the booster was going to wear off.

Ms. CONVERSE. Correct.

Ms. FLUCK. Can I say something, please?

Mr. TIERNEY. Absolutely.

Ms. FLUCK. In regards to that question, my husband and I have done a lot of research since I have been stricken with this. We noted that in India where there is a very high rate of hepatitis B, that one of the hospitals there recommend boostering every 4 years for hepatitis B. That's a recommendation from a hospital in India where hepatitis B is very rampant.

But what I'm saying is, they don't say how long these immunities will last for. But some places where they do have a very high risk, they boost every 4 years.

Mr. TIERNEY. Are you saying that the entire Nation has a policy of boosting every 4 years or that single hospital?

Ms. FLUCK. In India, they do but that's their policy.

Mr. BELKIN. The Merck package insert says that the time is indeterminate. That's the way they define it on the package insert.

Mr. MICA. Thank you, Mr. Tierney. One last question, Ms. Fluck. Your particular affliction has been medically diagnosed and connected to the vaccination?

Ms. FLUCK. Yes, it has.

Mr. MICA. Have you filed a claim in the Vaccine Injury Compensation Program?

Ms. FLUCK. No, not as of yet. Again, part of the reason is, I guess, one of the things that happened, my husband made some calls to the CDC and he talked to Dr. Chen. Dr. Chen recommended that he talk to Dr. Evans. Dr. Evans called our house, and we had no idea who this gentleman was.

So my husband really didn't want to give him too much information. We found out eventually that he is among the people who decide who gets what, and if they get anything from the claims. He seemed very proud of the fact that they hadn't paid out anything to any of the victims of hepatitis B unless they had anaphylactic shock.

Over the phone, without any kind of information about me whatsoever, except for the fact that I can't walk, he told my husband, your wife did not have an adverse reaction to hepatitis B. That's what we are dealing with. I also told you in my testimony how I was told my problem is a political problem, not a medical problem. I have gone from doctor to doctor. It's like they are afraid to say anything.

Mr. MICA. Well, I would like to thank you and all of our panelists for your testimony today, for coming forward and providing our panel with your personal experience and recommendations as we move forward in our oversight capacity. So I thank each of you, and I will excuse you at this time.

Our second panel today——

Mr. WAXMAN. Mr. Chairman, just a word to Ms. Fluck. We are checking about the assertion about the vaccine compensation system. Don't be so trusting of a comment that you have heard. There is more data for the anaphylactic shock than any of the other adverse reactions, but the compensation system does look at other reactions. So I would urge you to pursue it if you feel there is a connection——

Ms. FLUCK. I am diagnosed. I have all the medical testing and immunological testing. But what I'm saying is, this doctor seemed awfully proud to say that they have never paid out anything to anybody unless they have had anaphylactic shock.

Mr. WAXMAN. You seem awfully willing to take what he has to say at face value, and you don't seem to be willing to take what others say at face value; and I think that you have had enough reason to be more independent-minded. I'm urging you to go ahead and pursue this vaccine compensation.

Mr. MICA. Thank you. Again, I appreciate your providing us with your personal experience—each and every one of you—and we will excuse you at this time.

I will now call our second panel, which consists of primarily government officials. Harold Margolis, who is the Chief of the Hepatitis Branch of the Centers for Disease Control. We also have Susan Ellenberg, Director of Biostatistics in Epidemiology Division of the Food and Drug Administration. If we could have them come forward.

I would like to call the meeting back to order here. Those who are leaving, please do so and others cease conversation so we could proceed. Dr. Margolis, you have someone with you. Is that individual going to testify?

Dr. MARGOLIS. No, he is not. I will introduce him. Dr. John Livengood from the National Immunization Program.

Mr. MICA. Thank you for identifying him. And as I mentioned to our other witnesses, this is an investigation and oversight panel under Government Reform. We do swear in our witnesses, so those

two who are going to testify please, if you are going to answer questions, I will swear you in.

[Witnesses sworn.]

Mr. MICA. And we have another witness or somebody who may be answering questions. Could you identify yourself? Dr. Ellenberg, could you identify the individual?

Dr. ELLENBERG. This is Dr. Marcel Salive who is Chief of the Epidemiology Branch in the FDA's Center for Biologics Evaluation and Research.

Mr. MICA. Thank you. Again, welcome each of you. If you have lengthy statements, we would like to make them part of the record. We do have a number of panelists today. If you have additional, information we will by unanimous consent make it part of the record within reason. So I would like to first recognize Susan Ellenberg, Director of Biostatistics and Epidemiology Division of the Food and Drug Administration. You are recognized and welcome.

STATEMENTS OF HAROLD MARGOLIS, CHIEF OF THE HEPATITIS BRANCH, CENTERS FOR DISEASE CONTROL; JOHN LIVENGOOD, NATIONAL IMMUNIZATION PROGRAM; AND SUSAN ELLENBERG, DIRECTOR OF BIOSTATISTICS AND EPIDEMIOLOGY DIVISION, FOOD AND DRUG ADMINISTRATION

Dr. ELLENBERG. Thank you, Mr. Chairman. Good morning. I appreciate the opportunity this morning to discuss the Vaccine Adverse Event Reporting System [VAERS], with you. My written testimony is more detailed, and I'm pleased that you are willing to include it.

Mr. MICA. Without objection that will be made part of the record.

Dr. ELLENBERG. Before I begin, I would like to say that as a parent I certainly have the greatest sympathy for those who have testified today in the previous panel. The job of the public health service is to investigate and hopefully prevent all of these kinds of problems. That's what we are dedicated to do.

Vaccines are among the most significant public health achievements of all time and have been responsible for saving millions of lives and preserving health worldwide. They are extremely safe.

Nevertheless, like all medical treatments, vaccines are not entirely risk free. Vaccines are unique in that they are administered to healthy individuals, often children, and in some instances are required by State law. While serious complications are extremely rare, they can occur.

Because of the virtually universal exposure of our population to vaccines, it is important to identify even those very rare adverse reactions. VAERS was initiated in 1990 as a joint program of the FDA and the CDC. It receives reports from vaccine manufacturers, health professionals, State and local public health clinics, and vaccinees themselves or their parents or guardians.

To encourage reporting of any possibly vaccine-induced adverse event, the criteria for reporting to VAERS are deliberately nonrestrictive. The system accepts and includes any report submitted, even when there is no obvious connection to vaccination other than timing. Such reporting systems are essential to the discovery of potential rare adverse consequences of medical product that may not become evident until millions of people have been exposed to them.

There are important limitations, however, as I will discuss later, but first a brief overview. VAERS receives 11,000 to 12,000 reports a year. About 15 percent of these reports describe a serious event. Most of the remaining 85 percent of the reports describe self-limited transient events such as injectionsite reactions, irritability, prolonged crying, and fever.

Currently, all reports of serious events and fatalities are followed up in detail by health professionals. Medical staff carefully monitor trends in adverse event reporting for vaccines. VAERS performs a critical function by generating signals of potential problems that may warrant further investigation.

This is especially valuable in assessing the safety of newly marketed vaccines. As an example, a review of reports of adverse events in infants following the hepatitis B vaccine was performed by FDA staff several years ago. This comprehensive review concluded that no new concerns had emerged in the first few years following the recommendation for universal infant immunization.

It's important to recognize that VAERS data alone are often inadequate for drawing firm conclusions or providing any basis for regulatory actions. Probably the most important reason is that it is unable to establish causality for most reports of serious adverse events, the issue that Mr. Waxman had alluded to.

Most of the types of serious problems reported to VAERS occur in unvaccinated, as well as in vaccinated, individuals. With 4 million babies born each year in the United States and virtually all being vaccinated beginning at birth or shortly thereafter, almost any adverse experience in a child will follow a vaccination, and some of these will by chance follow within a few days of the vaccination.

Thus, even if a vaccine was not the cause of certain rare medical problems, it is a certainty that some number of these problems will occur within a short interval following a vaccination. For this reason, the fact that an event, even a very serious event such as a death, happens to occur shortly after a vaccine has been administered cannot by itself lead to the conclusion that the event was caused by the vaccine.

When the review of VAERS data identifies a signal of a potential new vaccine associated event, this association, therefore, must be further investigated in more rigorously controlled studies before causal conclusions can be drawn.

VAERS data have contributed to our understanding of vaccine safety and vaccine risks. Several investigations of VAERS data have uncovered previously unrecognized problems that may occur rarely in vaccine recipients and examples of these are provided in the written testimony.

Sometimes VAERS findings which we routinely publish in medical journals may provide useful and reassuring information that new problems have not been identified after additional exposure with a vaccine, as previously noted.

I want to thank the committee and the chairman for this opportunity to discuss the VAERS system and will be happy to answer any questions.

[The prepared statement of Dr. Ellenberg follows:]

Statement of

Susan S. Ellenberg, Ph.D.

Director, Biostatistics & Epidemiology Division

Center for Biologics Evaluation and Research

Food and Drug Administration

Department of Health and Human Services

Before the

Subcommittee on Criminal Justice, Drug Policy

and Human Resources

Committee on Government Reform

U.S. House of Representatives

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Susan Ellenberg, Ph.D., Director of the Division of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to discuss the Vaccine Adverse Event Reporting System (VAERS), designed to receive and evaluate reports of adverse events following vaccinations. As requested by the Committee, I will provide an overview of the system and the evaluation and review of the information that is obtained through these reports.

THE IMPORTANCE OF VACCINE SAFETY

Vaccines are among the most significant public health interventions of all time, and have been responsible for saving millions of lives and preserving health worldwide. Nevertheless, like all other medical products, vaccines are not entirely risk-free. While serious complications are extremely rare, they can occur. Since there is virtually universal exposure of our population to vaccines, it is important to identify even these very rare adverse reactions. Vaccines are unique in that they are administered to healthy individuals, often children, and in some instances are required by State law. The very highest standards of safety in these products, therefore, are required.

The National Childhood Vaccine Injury Act

In recognition of the importance of vaccine safety, the National Childhood Vaccine Injury Act of 1986 (NCVIA), 42 U.S.C. § 300aa-1 et seq., as amended, requires each health care provider and vaccine manufacturer to report to the Department of Health and

Human Services (DHHS) specific adverse events listed in the Vaccine Injury Table following the administration of vaccines. 42 U.S.C. § 300aa-25. The Vaccine Injury Table is a table of vaccines and a list of injuries, disabilities, illnesses, conditions and deaths for which compensation may be provided under the NCVIA. 42 U.S.C. § 300aa-14. FDA has implemented regulations that clarify the broader responsibilities of vaccine manufacturers, who are required to report every adverse event of which they learn, regardless of the type of event (i.e., including those not in the Vaccine Injury Table). 21 C.F.R. § 600.80

The NCVIA led to the creation of a unified national system to collect, manage and evaluate these adverse event reports. This system, initiated in 1990 and jointly managed by FDA and the Centers for Disease Control and Prevention (CDC), is VAERS. VAERS receives reports from vaccine manufacturers, private practitioners, state and local public health clinics, and vaccinees themselves (or their parents or guardians). It is similar in intent and operation to surveillance systems for other types of FDA regulated products maintained by the FDA and to safety surveillance programs in other countries. VAERS accepts all reports of suspected adverse events after administration of any U.S. licensed vaccine.

POST-MARKETING SURVEILLANCE SYSTEMS

VAERS is a "passive" surveillance system. This means that it relies on health professionals, patients or guardians to submit reports of adverse reactions following vaccination. (An "active" surveillance system, in contrast, would follow all individuals

in a defined population to determine their responses to vaccination.) To encourage reporting of any possibly vaccine-induced adverse event, the criteria for reporting to VAERS are non-restrictive. In effect, the system accepts and includes any report submitted, no matter how tenuous the possible connection with vaccination might seem.

These types of systems are essential to the discovery of potential rare adverse consequences of medical products that may not become evident until millions of people have been exposed to them. While they are critical to FDA's post-marketing surveillance, there are important limitations to the interpretation of the data, however, as discussed below.

OVERVIEW OF VAERS ACTIVITIES

VAERS receives 11,000 to 12,000 reports per year. (This number does include some multiple reports of the same incident, most often these are of serious reports.) Approximately 15 percent of the reports describe a "serious" event, which is considered to be either fatal, life-threatening, or resulting in hospitalization or permanent disability. Most of the remaining reports describe self-limited, transient events such as injection site reactions, irritability, prolonged crying and fever.

All reports are entered into a computer database. Selected reports of serious events and all reports of fatalities are followed up individually by a health professional. Autopsy reports and other relevant medical records are sought and retrieved for review. Medical

staff carefully monitor individual reports and trends in adverse event reporting for vaccines, with particular attention to newly licensed vaccines.

VAERS data are available to the public through the National Technical Information Service and also through requests to FDA's Freedom of Information office. Patient identifiers are removed from all data provided to the public. General information and the VAERS form itself are available on the VAERS Internet website. The website address is: http://www.fda.gov/cber/vaers.html.

OBJECTIVES OF VAERS

Spontaneous report-based surveillance programs, such as VAERS, perform a critical function by generating signals of potential problems that may warrant further investigation. As such, VAERS is the "front line" of national vaccine safety surveillance. It is especially valuable in assessing the safety of newly marketed vaccines. Careful review of reports during the initial months following licensure can provide additional assurance about the safety of a new vaccine, uncover previously unexpected events which occur when a vaccine is used in a more diverse population than was studied in clinical trials or rapidly identify potential problems not observed pre-licensure. Such a review was conducted several years ago by FDA investigators for reports of adverse events in infants following hepatitis B vaccine. This comprehensive review concluded that no

serious events likely attributable to the vaccine had emerged in the first few years following the recommendation for universal infant immunization. [1]

Although VAERS has methodological limitations inherent in passive surveillance systems, VAERS is essential to the U.S. vaccine safety monitoring system. It is the only surveillance system which covers the entire U.S. population and includes the largest number of case reports of events temporally associated with vaccination in the U.S. It provides timely availability of data from a geographically diverse population, allowing rapid detection of possible new, unusual or rare adverse events. Such detection generates hypotheses that may then be tested in other databases.

Based on careful review, analysis and further investigation of spontaneous reports, FDA can initiate various actions: manufacturers' labeling or packaging change(s), conducting or requesting manufacturer-sponsored post-marketing epidemiological investigations (hypotheses testing in more rigorous databases); issuing a Safety Alert or "Dear Health Professional" letter, inspecting manufacturers' facilities/records, or working with a manufacturer regarding possible withdrawal of vaccine from the market (for safety or efficacy reasons). Keeping vaccine labeling/package inserts up-to-date is an ongoing, dynamic process that depends on new information gleaned from spontaneous adverse event reports as well as other sources. Dissemination of safety-related information to health care professionals and the public is an important health goal of post-marketing surveillance.

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[1] Niu MT, Davis D, Ellenberg SS, *Recombinant hepatitis B vaccination of neonates and infants: emerging safety data from the Vaccine Adverse Event Reporting System (VAERS)*, Pediatric Infectious Diseases

LIMITATIONS OF VAERS

While assessment of VAERS data is a critical first step in identifying potential new information about the safety of vaccines, it is important to recognize that VAERS data alone are often inadequate for drawing firm conclusions or providing a basis for regulatory actions. Many reports omit important data and/or contain obvious errors that may not be easily identifiable or correctable. Multiple vaccines are frequently administered simultaneously, according to currently recommended vaccine schedules, making it difficult or impossible to determine which (if any) of the vaccines administered was the possible cause of the event. The extent of under-reporting of events occurring after vaccination is unknown, and the number of individuals in subgroups of interest (for example, infants) receiving the vaccine during specific time intervals is not known, so that incidence rates cannot be calculated. In addition, because VAERS accepts and encourages reports of all temporal associations, regardless of the rationale for the vaccine being the cause of the outcome reported, there is also "over-reporting" since many events reported, and entered in the database, are most likely not attributable to vaccination.

Probably the most important limitation of VAERS, as it is for any passive reporting system, is its inability to establish causality for most reports it receives. Adverse events occurring in unvaccinated individuals are not reported, so there is no "control group" to study. Most of the types of serious adverse events reported to VAERS can occur in unvaccinated as well as vaccinated individuals. Without an unvaccinated group it is

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usually impossible to assess whether the number of reported events is different from the number that would have been observed in the absence of vaccination.

With virtually universal childhood immunization, beginning at birth or shortly thereafter, any adverse medical event in a child will "follow" vaccination, and some of these will coincidentally follow within a few days of a vaccination. Thus, even if a vaccine is not the cause of certain rare medical problems, it is a certainty that some number of these events will occur within a short interval following a vaccination. For this reason, the fact that an event—even a very serious event such as a death—occurs shortly after a vaccine has been administered cannot by itself lead to the conclusion that the event was caused by the vaccine.

An adverse event can be causally attributed to a vaccine more readily if:

1. The event conforms to a specific clinical syndrome whose association with vaccination has strong biologic plausibility (e.g., anaphylaxis).

2. A laboratory result confirms association (e.g., isolation of vaccine strain varicella vaccine from skin lesions of a patient with rash).

3. The event recurs on re-administration of vaccine ("positive rechallenge.").

4. A controlled clinical trial or well-designed epidemiological study shows greater risk of adverse events among vaccinated than unvaccinated (control) groups.

Because few of the serious adverse events reported to VAERS meet any of the first three criteria (one such example, however, is described below), and because clinical trials are almost always too small to provide useful information on rare events, methodological

more rigorous epidemiological studies must be conducted to assess causality for most serious adverse events that are investigated. A determination that the vaccine caused the post-vaccination event usually cannot be made on the basis of information acquired from individual VAERS reports.

VACCINATION AND SIDS

Sudden Infant Death Syndrome (SIDS) exemplifies the problem with interpreting VAERS data. About 150 deaths a year are reported to VAERS. Most of these are of infants under one year of age; of these, most are diagnosed as SIDS. The reported time from vaccination until death varies from a few hours to many weeks or even months. In most cases multiple vaccines are involved, consistent with recommended immunization schedules. Because SIDS occurs during the first year of life both in the absence and presence of vaccination, one cannot presume a causal connection if SIDS follows shortly after vaccination. In fact, one can predict that such events would occur, even in the absence of a causal connection, because virtually all infants (approximately four million live births per year in the U.S.) receive vaccines on multiple occasions during the first year of life and because SIDS occurs at the relatively high rate of somewhat less than one per thousand live births in the U.S.

In response to public concerns arising in the early 1980s about the safety of another vaccine, the DTP (diphtheria, tetanus, pertussis) vaccine, the National Institutes of Health's National Institute of Child Health and Human Development investigated the question of the association between SIDS and DTP in a large case-control study. This study did not support the hypothesis that DTP vaccine caused SIDS; it demonstrated a

lowered risk for SIDS in children receiving DTP vaccine. FDA continues to review each death, including all SIDS deaths, reported following administration of DTP vaccine.

MULTIPLE SCLEROSIS

Recent attention has been given to the possibility that vaccination with a hepatitis B vaccine increases the risk for developing multiple sclerosis (MS). While we cannot say with absolute certainly that the vaccine has never caused a case of MS, some temporal associations are expected because hepatitis B vaccine is administered to the same age groups where symptoms of MS first occur. Since 1990, VAERS has received 76 U.S. reports of MS following vaccination with hepatitis B vaccine. These reports are spread fairly evenly over the years. CDC has undertaken a further prospective study of the possible association between demyelinating disease (neurological diseases) and the hepatitis B vaccine.

VACCINE SAFETY DATALINK

As noted previously, when review of VAERS data identifies potential new vaccine-associated events, the hypothesis of causation must be further investigated in more rigorously controlled studies. Such studies can be performed by CDC's Vaccine Safety Datalink (VSD), a computerized medical record linkage system of patients enrolled in four health maintenance organizations, where causality may be more rigorously evaluated. FDA has worked with the VSD to address a variety of concerns, some of which have arisen from VAERS reports.

For example, FDA's review of adverse events reported in infants following receipt of hepatitis B vaccine, noted above, revealed an apparent difference between two brands of this vaccine with regard to reporting rate (i.e., the number of reports divided by number of doses distributed). Nothing in the product content or manufacturing processes provided a likely explanation for this difference. Because of the limitations of data in spontaneous reporting systems like VAERS, FDA believed it was essential to study this issue further to determine whether or not the difference was real. Data from VSD sites that had used both vaccines were reviewed. These data, which provided a true event rate in a defined population, showed similar rates of adverse events for both vaccine brands.

CONTRIBUTIONS OF VAERS DATA TO UNDERSTANDING VACCINE SAFETY

New Reactions

Several investigations of VAERS data have uncovered previously unrecognized problems that may occur rarely in vaccine recipients. FDA investigators noted occasional instances of life-threatening thrombocytopenias (low platelet counts) following the administration of MMR (measles, mumps, rubella) vaccine, a previously unappreciated level of severity of a known side effect. Other FDA investigators documented a series of cases in which hair loss followed immunizations (primarily hepatitis B vaccine), a rare effect not previously reported. Because some of these cases exhibited "positive rechallenge," as defined earlier, there is a greater level of confidence that these outcomes truly may have been caused by the vaccine. In another study, FDA staff identified a series of cases of severe injuries resulting from vaccination-induced fainting or syncope. These outcomes

did not appear related to any specific vaccine, but were most probably attributable to the act of vaccination itself.

Sometimes VAERS data may provide the useful and reassuring information that new problems have not been identified after additional experience with a vaccine, as in the previously noted report on hepatitis B vaccine in infants.

Trends in Reporting

VAERS data also have been used to compare reporting patterns over time and investigate changes in reporting rates that might be due to changes in vaccine practices. For example, CDC epidemiologists reviewed reports of fever, seizures, and hospitalizations following administration of a newly licensed combination of diphtheria, tetanus and acellular pertussis vaccine (DtaP). The rate of such reports was about one-third lower than the reporting rate following the standard DTP vaccine, consistent with—and confirming in the context of general practice—the safety findings of the pre-licensure clinical trials.

CONCLUSION

Vaccine safety is the subject of numerous initiatives within the Public Health Service, and FDA participates in a variety of cross-agency efforts in this area, including the vaccine Inter-Agency Group coordinated by the National Vaccine Program Office, the

Vaccine Safety Subcommittee of the National Vaccine Advisory Committee, and the Advisory Commission on Childhood Vaccines. FDA sends liaison members to other Public Health Service agency advisory groups.

FDA evaluates the risks and benefits, both known and potential, for all FDA regulated medical products. Hepatitis B vaccines have demonstrated clear and major benefits in reducing transmission of hepatitis B infections. Such infections have been known to cause serious liver disease and primary liver cancer. Thus at present, we have well documented benefits and little in the way of verified serious risks. The Agency will continue to monitor and investigate the serious adverse reports received on hepatitis B vaccines and all vaccines.

Vaccine safety is a high priority of FDA and the Agency considers all of its safety programs, including VAERS, as critical to carrying out the goal as stated in the NCVIA. 42 U.S.C. § 300aa-1. The goal is to achieve "optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." FDA continues to work towards this goal.

Thank you for this opportunity to discuss the VAERS system and its importance to vaccine safety.

Mr. MICA. Thank you. We will defer questions until after we have heard from Dr. Harold Margolis, Chief of the Hepatitis Branch of the Centers for Disease Control. You are recognized, sir.

Dr. MARGOLIS. Thank you, Mr. Chairman, and our written testimony is submitted for the record.

Mr. MICA. Without objection, that entire statement will be made part of the record.

Dr. MARGOLIS. I am here with Dr. John Livengood of the CDC's national immunization program. We are here to discuss the importance of the hepatitis B vaccination and the prevention of hepatitis B-related liver disease and cancer and the safety of the vaccine.

I am both a parent and a pediatrician. Nothing matters more to me than the health and safety of my children and the children of others. Based on my 20 years of work in the field, I have concluded, first, that hepatitis B is a serious risk to infants, children, and adults; second, we have a safe and effective vaccine for addressing that risk; and, third, it is our responsibility to protect the health of our children and future generations by using this vaccine.

Persons who become infected with hepatitis B either recover in several months or go on to have chronic infection. In the United States, one and a quarter million persons are chronically infected with hepatitis B and are at high risk of cirrhosis and liver cancer.

Hepatitis B is a silent killer destroying the liver in someone who thinks they are completely well. When first infected, two-thirds of adults and more than 90 percent of young children do not have symptoms of hepatitis. Studies have shown that each year 20,000 to 25,000 children have been infected with hepatitis B in the United States. These children acquire their infections in their households as well as in their community.

The importance of these childhood infections is illustrated in figure 1. If infected, 90 percent of infants and 30 to 60 percent of children less than 5 years of age, will remain chronically infected. Thus a large proportion of adults with chronic hepatitis B became infected as infants or young children.

If we do not prevent childhood infections, we cannot control hepatitis B in the United States. Hepatitis B immunization prevents greater than 90 percent of infections. Studies have shown that routine vaccination of infants and children eliminates transmission of chronic infection and reduces liver cancer. They have also shown that vaccinated persons retain long-term immunity.

The CDC vaccine recommendations are made with the advice of the Advisory Committee on Immunization Practices, or the ACIP. Hepatitis B immunization issues have been discussed at ACIP meetings on 20 occasions since 1986. In 1991, a comprehensive immunization strategy to stop transmission of hepatitis B infection in the United States was adopted by the ACIP and recommends, one, prevention of perinatal hepatitis B infection; two, routine hepatitis B vaccination of infants and adolescents; and, three, vaccination of high-risk adolescents and adults.

The decision to vaccinate a child protects that child and the community. Because hepatitis B produces a chronic infection, a decision not to vaccinate a child not only puts that child at risk of infection, but puts others in the community at risk as well.

The CDC is strongly committed to ensuring the safety of vaccination. Hepatitis B vaccines are among the safest we have. Since licensure, the safety of the vaccine has continued to be monitored. Several reviews have been done and have not shown a causal association between hepatitis B vaccination and a variety of severe, neurologic adverse events. In addition, ongoing studies are investigating whether other alleged adverse events are associated with vaccination, including multiple sclerosis.

As the FDA has discussed, case reports of serious adverse events following vaccination rarely provide a convincing link between the event and vaccination. Sudden infant death syndrome is such an example. Because almost 10 million doses of hepatitis B vaccine are administered to infants each year, some infants unfortunately will die shortly after vaccination by coincidence alone. Available scientific data do not support any causal role for vaccination in SIDS.

As shown in figure 2, 1992 was the first full year that the hepatitis B vaccine was recommended for routine infant immunization. Vaccine coverage was 8 percent, and there were 4,800 SIDS death that year.

In contrast, by 1996, when hepatitis B vaccination coverage had risen to 82 percent, there were only 3,000 SIDS deaths. These data are reassuring because if the hepatitis B vaccine was a major cause of SIDS, we would have expected an increase in cases, not a decrease.

In summary, hepatitis B causes 4,000 to 5,000 deaths a year in the United States. If exposed to the virus, infants and young children are most at risk of chronic infection and death as adults 20 to 40 years later. Fortunately, we have a safe and highly effective vaccine to prevent the transmission of this deadly virus and to prevent liver cancer. Immunization of infants, children and adults is supported by the American Academy of Pediatrics, the American Academy of Family Physicians, the American Medical Association, the American College of Obstetricians and Gynecologists, the Hepatitis Foundation International, and the American Liver Foundation, among others. Only by achieving high vaccination rates can we optimally protect Americans from this serious disease.

Thank you for your attention. Dr. Livingood and I will be happy to answer questions.

[The prepared statement of Dr. Margolis follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

TESTIMONY OF

HAROLD S. MARGOLIS, M.D.

CHIEF

HEPATITIS BRANCH

DIVISION OF VIRAL AND RICKETTSIAL DISEASES

NATIONAL CENTER FOR INFECTIOUS DISEASES

CENTERS FOR DISEASE CONTROL AND PREVENTION

BEFORE THE

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON CRIMINAL JUSTICE,

DRUG POLICY, AND HUMAN RESOURCES

MAY 18, 1999

Good morning, Mr. Chairman and members of the Subcommittee. I am Dr. Harold Margolis, Chief of the Hepatitis Branch at the National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am joined by Dr. John Livengood, Director, Epidemiology and Surveillance Division, National Immunization Program, CDC. We are here this morning to discuss the importance of hepatitis B vaccination in the prevention of acute and chronic liver disease and liver cancer caused by hepatitis B and the safety of hepatitis B vaccine.

Like you, I have deep sympathy for the parents who testified on the previous panel. Like many of my CDC and Food and Drug Administration (FDA) colleagues, I, too, am a parent. I am also a pediatrician. As both a parent and a pediatrician, nothing matters more to me than the health and safety of my children and the children of others. Thus, while I am here to offer expert testimony on hepatitis B vaccine, my scientific and public health expertise is broadened by my responsibilities as a parent and pediatrician. All perspectives lead me to the same conclusions: (1) that hepatitis B is a real and serious risk to infants and young children; (2) that we have a safe, effective, and proven vaccine for addressing that risk; and, (3) that as scientists, physicians, policy makers, and parents, it is our responsibility to protect the current and future health of our children by broadly using this vaccine.

Hepatitis B Disease

Hepatitis B is a serious disease that kills 4,000 to 5,000 Americans each year and 1 million people worldwide. Of the 4,165 liver transplants performed in the United States in 1997, 332 (8 percent) were for acute liver failure; sixteen percent of these cases of liver failure were caused by hepatitis B. Approximately 220 people (5 percent) receive a liver transplant each year so that they may survive their hepatitis B end-stage liver disease.

In addition to the deaths that occur from chronic liver disease, 150 to 200 people in the U.S. die each year from hepatitis B-related acute liver failure. A patient in acute liver failure is one of the sickest persons for whom a physician will ever have to provide care. The liver does many things, including making blood clotting factors, storing sugar as energy reserves, digesting food, and removing waste products from the blood. When a person's liver is severely damaged from

hepatitis B virus, all of these functions are lost. A person in acute liver failure bleeds into their skin and internal organs and from intravenous sites. Because of the build up of nitrogen wastes in the blood, the person becomes stuporous and eventually goes into coma.

Hepatitis B is caused by infection with the hepatitis B virus, abbreviated HBV. Persons with HBV infection have this virus circulating in their blood, much like hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Persons who become infected with HBV either recover from their infection in several months or they may remain chronically infected for most of their life. Persons with chronic HBV infection are at high risk of death from cirrhosis and liver cancer. In addition, they are likely to transmit their infection to other people. In the United States, 1.25 million persons are chronically infected with HBV.

Although HBV is a common infection, it often goes unnoticed. Only one-third of adults will have symptoms of hepatitis when they first become infected. More than 90 percent of young children who become infected will have no symptoms.

Chronic infection with HBV also often goes undetected for 20 to 40 years until the resulting liver disease makes the person ill. In essence, HBV is a silent, unnoticed killer destroying the liver or stimulating the development of liver cancer in someone who thinks they are completely well. The risk of chronic infection and death from cirrhosis and liver cancer is inversely related to the age when acutely infected. For children less than one year of age who become infected, 90 percent will remain chronically infected. A child less than 6 years of age who becomes infected has a 30 percent chance of remaining chronically infected. A teenager or adult who becomes infected with HBV has a 3 percent to 5 percent risk of chronic infection.

Persons who become chronically infected as adolescents or adults have a 15 percent chance of dying from liver disease. Persons who become chronically infected as young children or infants have a 25 percent chance of dying from hepatitis B-related cirrhosis or liver cancer. Thus, the

youngest who are most likely to get a silent acute infection, if exposed, are also most vulnerable to silent chronic infection and death.

Prevention of chronic infection is of utmost importance because once a person is infected, there are few treatment options, and all are very expensive. Antiviral treatment with interferon or lamivudine is effective in approximately 40 percent of patients with chronic HBV liver disease, and not all infected persons are candidates for treatment. For persons with advanced liver disease, liver transplantation is an option. However, availability of organs is limited, and an organ recipient must remain on immunity suppressing drugs for the rest of his or her life and must take hepatitis B immune globulin to prevent reinfection of the liver and recurrence of severe chronic liver disease. The treatment of liver cancer is not very encouraging, with the average survival following diagnosis being less than one year. It is important to note that while the incidence of most cancers is declining in the United States, the rate of liver cancer has been increasing over the past 10 years.

Although most people do not have symptoms of HBV infection, blood tests can accurately identify persons with either a chronic or resolved infection. A number of studies were carried out prior to widespread use of hepatitis B vaccine in the United States to determine the burden or magnitude of this disease. National studies conducted by CDC have shown that 5 percent of Americans--12.5 million people--have been infected with HBV. In addition, these studies have shown that about 300,000 people have been infected with HBV each year for the two decades prior to 1990, and that the risk of infection is much higher among African-Americans than whites. These studies have shown that at least 25,000 children have been infected with HBV each year. These children acquire their infections in their households, as well as in the community. The virus is present in saliva and blood and is spread when these fluids come in contact with breaks in the skin or other body surfaces. Hepatitis B is approximately 100 times more contagious than HIV.

The importance of these childhood infections is illustrated in figure 1. Because infected children are at greatest risk of chronic infection, they contribute disproportionately to the number of persons with chronic HBV infection. Said another way, a large proportion of adults with chronic HBV infection got their infection as infants or children. If we do not prevent these childhood infections, especially the early childhood infections, we cannot effectively control hepatitis B liver disease in the United States.

It has been said that hepatitis B only affects certain groups of Americans, many of whom engage in activities that place them at risk. While there are high risk groups, many of the cases do not fit into these groups. Between 15 and 30 percent of cases in recent years, or about 45,000 to 90,000 newly infected persons annually, have no identified risk factors, and thus would not be preventable by programs targeted only to high risk groups.

Hepatitis B Vaccine

The hepatitis B virus was discovered in 1965, and by 1970 diagnostic tests were available for routine screening of blood donors to prevent this type of transfusion-transmitted hepatitis. The first vaccines to prevent hepatitis B were developed in the mid-1970's; clinical trials were conducted in the late 1970's that showed greater than 90 percent efficacy in preventing chronic infection; and hepatitis B vaccine was first licensed in the United States in late 1981.

Hepatitis B vaccine provides protection against infection with HBV by producing immunity or antibodies to the surface protein or outer coat of the virus. This outer coat is called hepatitis B surface antigen or HBsAg. The first vaccine was produced by purifying this surface protein from the plasma of chronically infected persons. Subsequently, this surface protein was produced in yeast by recombinant DNA technology. The vaccines used in the United States since about 1989 have only been produced by recombinant DNA technology. However, plasma-derived vaccines continue to be used widely throughout the world.

Hepatitis B vaccine provides greater than 90 percent protection to infants, children, and adults immunized before being exposed to the virus. The efficacy of plasma-derived and recombinant hepatitis B vaccine in preventing acute and chronic infection has been demonstrated in controlled clinical trials conducted with adults, children, and infants. In addition, a number of studies have examined various vaccination schedules and dosages and all have documented short-term vaccine safety.

Hepatitis B immunization has been ongoing in a number of childhood and adult populations in the United States and other countries since the vaccine was first licensed in 1981. CDC and others have conducted studies to evaluate both the effectiveness of hepatitis B immunization and the long-term protection provided by the initial 3-dose vaccine series. Infant immunization has been ongoing for 14 years among Alaska Natives, who have higher rates of HBV infection than found in much of the United States. Previous studies have shown that 8 percent to 13 percent of Alaska Native children were chronically infected with HBV, and Alaska Natives have had the highest rate of liver cancer in the United States. Since 1983, all Alaska Native infants have been routinely vaccinated with the available licensed hepatitis B vaccines, beginning at birth. In a study conducted in 1993, it was shown that among the children less than 11 years of age -- that is, children routinely vaccinated since 1983 -- none had chronic HBV infection.

Other studies conducted among American Samoan children, children in the Gambia and children in China have shown that routine hepatitis B immunization lowers the HBV infection rates by more than 90 percent. In addition, studies in Taiwan have shown that there has been a significant reduction in cases of liver cancer among children since the introduction of routine hepatitis B immunization over 10 years previously. These studies provide evidence that hepatitis B immunization will prevent liver cancer and chronic liver disease.

Concerns have been raised about how long protection will last. In other words, will vaccinated infants be protected when they are adolescents and adults? A number of follow-up studies have also shown that the initial 3-dose immunization series provides protection from HBV infection

for years. These studies have followed more than 2,000 persons vaccinated either as infants, children, or adults, and the periods of follow-up have ranged from 5 to 15 years. All studies indicate that immunity is long-term and may be lifelong. While immunized people may lose antibody circulating in their blood, they still retain protection from chronic HBV infection because their immune cells remember that they were vaccinated — we call this "immune memory." The immune cells of a person immunized with hepatitis B vaccine and who has lost antibodies in their blood will remember that they were immunized and rapidly make antibodies when they are exposed to HBV. In the case of hepatitis B, the long incubation period for HBV infection allows enough time for the immune system to mount a protective response.

Vaccine Recommendations

CDC vaccine recommendations are made through a careful, deliberative process involving advice and guidance from the Advisory Committee on Immunization Practices (ACIP). The ACIP is a Federally chartered advisory committee with the goals of providing to the Director, CDC, and the Secretary, Department of Health and Human Services (HHS), advice on decreasing disease through the use of vaccines and other biological products, and on improving the safety of their use.

The ACIP currently includes 12 voting members selected based on their infectious disease expertise, experience in the evaluation of vaccine performance and safety, and knowledge about the implementation of immunization programs. Members of ACIP come from academia, clinical practice and State and local health departments. In addition, ACIP meetings are attended by *ex officio* members who represent Federal agencies, liaison members who represent professional societies and groups implementing vaccination programs, and the general public. A list of the organizations that are liaison members of the ACIP is attached in Appendix 1. All ACIP meetings are open to the public. Agendas are published before each meeting in the Federal Register and time for public comment is included at each meeting. Vaccine manufacturers are represented at ACIP meetings by the liaison representative from the Pharmaceutical Research and Manufacturers of America. Manufacturer representatives may be invited to present data that

are not yet published, for example, from recent clinical trials, and also can make statements during the public comment period.

Vaccine recommendations initially are drafted by a working group that includes ACIP members and *ex officio* and liaison representatives, assisted by CDC experts. Vaccine manufacturers may participate in this process because not yet published and proprietary data often are useful in developing appropriate recommendations. Draft recommendations are sent to all ACIP members for comment, discussed during multiple public meetings, finalized, and adopted by vote of ACIP members.

Federal advisory committee members are subject to Federal conflict of interest laws, which are modified to take into account the nature of their service. Since vaccine research is largely funded by vaccine manufacturers, some advisory committees inherently have members who may have potential financial conflicts of interest because members are chosen for service based on their expertise in the areas in which advice is sought by the government. Congress has recognized the need for service by these experts on Federal advisory committees, despite the potential for conflicts of interest, by providing under 18 U.S.C. 208(b)(3) for waivers of the conflict of interest prohibitions when "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved." CDC is sensitive to concerns about potential conflicts of interest. Therefore, rather than issuing blanket waivers to members of the ACIP, CDC has chosen to grant only limited waivers as follows: an ACIP member with a conflict of interest is granted a waiver to participate in all committee discussions, but only if the member (1) publicly discloses all relevant interests at the beginning of each ACIP meeting and (2) abstains on votes pertaining to entities with which the member has a financial interest. In this manner, the agency can fully utilize the expertise of the committee member, with the assurance that CDC, fellow committee members and the public are aware of each individual member's related financial interests and ultimately the formal recommendation of the committee is only made by members without any kind of financial conflict.

Upon being finalized by the ACIP, a vaccination recommendation is submitted to CDC for consideration. If the agency accepts the recommendations, the document is edited and published in the Morbidity and Mortality Weekly Report (MMWR) as an ACIP recommendation. As new data become available on the effectiveness of disease prevention or on adverse events, these also may be discussed and may lead to published updates or revisions of previous recommendations.

Hepatitis B Recommendation

Recognizing the severity of hepatitis B infection and the availability of a safe and effective vaccine, the first recommendations on hepatitis B vaccine by the US Public Health Service's Advisory Committee on Immunization Practices (ACIP) were published in June 1982. The available epidemiologic data at the time indicated that infections among adults contributed almost all of the disease burden in the United States. Groups for whom vaccination was recommended included health care workers and hospital staff, clients and staff of institutions for the developmentally disabled, hemodialysis patients, hemophiliacs, men who have sex with men, household and sex contacts of HBV carriers, injection drug users, and inmates of long-term correctional facilities. In addition, vaccination of Alaskan Eskimos was recommended along with postexposure immunization of infants born to women with chronic HBV infection.

Since 1982 a large amount of new information has become available on the epidemiology of HBV infection; HBV disease burden; hepatitis B vaccines; vaccine immunogenicity, schedules, doses and safety; long-term efficacy of immunization and hepatitis B immunization practices and strategies. As information has become available, presentations were made to the ACIP by staff from CDC, FDA, and other government agencies, non-government investigators, and vaccine manufacturers. Hepatitis B immunization issues were on the ACIP agenda on 20 occasions during the 40 meetings that were held from 1986 to 1999. As sufficient new information became available, hepatitis immunization recommendations were updated and revised.

Beginning in 1990 presentations were made to the ACIP describing the increase in incidence of hepatitis B that occurred during the early 1980's despite the availability of hepatitis B vaccine.

Other data presented demonstrated that few adults at risk of infection were being vaccinated and that perinatal and early childhood infections contributed to a substantial proportion of the chronic hepatitis B disease burden in the United States. As part of the June 1990 recommendations, *Protection Against Viral Hepatitis,* the ACIP stated that "For vaccine to have an impact on the incidence of hepatitis B, a comprehensive strategy must be developed that will provide hepatitis B vaccine to persons before they engage in behaviors or occupations that place them at risk of infection." In addition, the ACIP stated that "As an alternative to high-risk group vaccination, universal vaccination of infants and adolescents needs to be examined as a possible strategy to control transmission of disease."

Such a comprehensive strategy was developed by the ACIP over the next year and published in November 1991, and subsequently was endorsed by the American Medical Association and the American College of Obstetricians and Gynecologists. At about the same time, the American Academy of Pediatrics, and the American Academy of Family Physicians developed and endorsed the same comprehensive hepatitis B immunization strategy. The objective of the strategy is to eliminate transmission of HBV infection. The components required to achieve this objective are (1) prevention of perinatal HBV infection by screening all pregnant women and providing postexposure immunization to at-risk infants of chronically infected mothers; (2) routine hepatitis B vaccination of infants as part of the childhood immunization schedule; (3) routine vaccination of adolescents; and (4) vaccination of adolescents and adults in groups at increased risk of infection.

Routine maternal screening to prevent perinatal HBV infection has been successfully implemented with greater than 85 percent of pregnant women being screened. Similarly, 84 percent of children born in 1996 have been fully vaccinated against hepatitis B, which is particularly important since young children are most at risk from chronic infections, complications, and death if exposed to the hepatitis B virus. Routine vaccination of adolescents has been widely accepted; however, we do not know what percent of teenagers have been immunized. High-risk adult immunization has only been effective among persons at

occupational risk of HBV infection. It is estimated that over 70 percent of health care workers have been vaccinated, and almost all new health care workers are being immunized. In the mid-1980's it was estimated that 18,000 health care workers were infected each year with HBV. This has dropped to fewer than 1,000 today. Only limited success has been achieved in the immunization of high risk adolescents and adults in settings including public health clinics, correctional facilities, drug treatment centers, and physicians' offices.

The goal in the hepatitis B prevention program is to achieve high levels of immunization coverage to stop transmission within the United States. This will protect not only the children who are vaccinated, but children who cannot be protected by vaccination, such as children with leukemia who cannot mount adequate immune responses to the vaccine. A decision to vaccinate a child protects that child and the community. A decision not to vaccinate a child not only puts that child at risk for hepatitis B, but others in the community as well.

Information for Parents

In addition to any disclosure that may be required by State medical consent laws, all health care providers, both public and private, are required to provide parents/patients with vaccine information materials before administering particular vaccines. As required by the National Childhood Vaccine Injury Act of 1986, the Secretary, HHS must develop vaccine information materials for all vaccines covered by the National Vaccine Injury Compensation Program. This authority has been redelegated to the CDC. Vaccine Information Statements (VIS) are developed after notice to the public and a 60 day comment period, and in consultation with the HHS Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and health care provider and parents' groups. VIS must include a concise description of the benefits and risks associated with a vaccine. Information is included on risks that have been scientifically established as published in the ACIP statement, the Institute of Medicine report on vaccine adverse events, and expert evaluation of the peer-reviewed medical literature. Alleged adverse events that have not been scientifically associated with a vaccine, as reviewed by the ACIP, are not included in the VIS.

Safety of hepatitis B vaccine

CDC is strongly committed to assuring the safety of the vaccination program. This is especially important because many vaccines are administered widely to children and are mandated by States for children entering school. Reflecting this commitment to safety, recent changes in the vaccination program to decrease the occurrence of adverse events have been made, such as recommendation of acellular pertussis vaccines to replace more reactive whole cell vaccines and use of inactivated polio vaccine to diminish use of oral polio vaccine which very rarely causes polio itself. Carefully considered recommendations by the ACIP, information on vaccine benefits and risks based on Vaccine Information Statements, and compensation for those injured by vaccines under the National Vaccine Injury Compensation Program are important components of a system where optimal disease prevention is achieved when vaccination rates in a community are high and where risks to the individual are minimized and, injuries, should they occur, are compensated.

Before licensure, vaccines are rigorously evaluated for possible adverse events. Because severe adverse events may occur rarely and the population included in pre-licensure studies is relatively limited, post-licensure safety evaluation of widely administered vaccines is important. Hepatitis B vaccines are among the safest vaccines we have. In pre-licensure studies, severe adverse events were not detected and local reactions were no greater in persons receiving hepatitis B vaccine than persons who received a placebo or another vaccine.

Since licensure, the safety of the vaccine has continued to be monitored. Several reviews have occurred and have not shown a scientific association between hepatitis B vaccination and severe neurological adverse events such as optic neuritis and Guillain-Barré syndrome. In addition, preliminary data from French and British studies have shown no significant association between hepatitis B vaccination and multiple sclerosis. On August 21, 1998, the National Multiple Sclerosis Society reported, "In the view of the medical advisory board of the National Multiple Sclerosis Society, there is no current evidence of a link between hepatitis B vaccination and MS."

Similar conclusions were reached by the European Viral Hepatitis Prevention Board and the World Health Organization.

Allegations have been made that hepatitis B vaccination of infants causes Sudden Infant Death Syndrome (SIDS). Because almost 10 million doses of hepatitis B vaccine are administered to infants each year, some infants will die shortly after vaccination by coincidence alone. Available scientific data do not support any causal role of vaccination in the deaths. In fact, in 1992, the first full year after the hepatitis B vaccine was first recommended universally for infants, there were 4,800 SIDS deaths, and hepatitis B vaccination coverage was 8 percent. In contrast, as shown in figure 2, by 1996 when coverage had risen to 82 percent, the number of SIDS deaths had actually decreased to 3,000 deaths. These data are reassuring because if Hep B vaccine were a major cause of SIDS, we would have expected an increase in SIDS, not a decrease. SIDS deaths have continued to decrease as a result of the effort to change infant sleep position despite a marked increase in hepatitis B vaccination coverage.

Nevertheless, the CDC is committed to continuing the evaluation of the safety of hepatitis B vaccine in a careful, scientific fashion. Ongoing studies are investigating whether other alleged adverse events are associated with vaccination, including multiple sclerosis and other demyelinating diseases, diabetes mellitus, rheumatoid arthritis and other autoimmune disorders.

Case reports of adverse events following vaccination rarely provide a convincing link between the event and vaccination. While reports to the Vaccine Adverse Event Reporting System (VAERS), jointly managed by FDA and CDC, can provide valuable information regarding serious adverse events that **may** be associated with a vaccine and are useful for generating hypotheses, they only rarely can be used to determine whether a vaccine actually caused the adverse event. Moreover, case reports of serious adverse events obtained through VAERS often do not represent true consequences of vaccination -- they may be temporally linked but causally unrelated -- they may not represent the correct diagnosis and they may be duplicate reports. By chance alone, some patients who develop symptoms of illness, will do so within several days of

receiving a vaccine. Or in some cases, a vaccine may lead to the earlier recognition of an illness without increasing the overall risk of that illness occurring. Because of the limitations of VAERS, other systems have been developed to evaluate whether vaccines are scientifically associated with an adverse event.

To determine the association between vaccination and a potential adverse event requires documenting that the event is more likely in someone who recently has received vaccine than in someone who has not. Because serious potential adverse events are uncommon, documenting a statistical association of an adverse event with vaccination requires a large population of vaccinated and unvaccinated persons. In 1990, CDC established the Vaccine Safety Datalink (VSD) which links computerized vaccination, hospitalization, and outpatient medical records for members of four large managed care organizations serving about 2 percent of the U.S. population. VSD evaluations include identifying the health outcome of interest (i.e., the potential adverse event), linking these data with vaccination records, and comparing the frequency of the health event in persons who recently were vaccinated with those who are unvaccinated or had been vaccinated at a different time. All analyses must carefully be controlled for other factors that may be associated with disease occurrence or with the likelihood of being vaccinated. Several ongoing studies using the VSD are investigating whether a link exists between potential adverse events and hepatitis B vaccination.

Conclusion

In summary, as my testimony has noted, hepatitis B causes approximately 4,000 to 5,000 deaths per year in the United States. If exposed to the virus, infants and young children are most at risk from chronic infections, complications, and death. Further, in most children, the virus is a silent killer. It destroys the liver or induces liver cancer often over 20 to 40 years or more. Fortunately, we have a safe and highly effective tool to prevent the transmission of this destructive and often deadly virus. We have a vaccine that provides long-term protection and prevents liver cancer. Both pre- and post-licensure reviews have shown that hepatitis B vaccines are among the safest vaccines we have.

Immunization of infants and children is supported by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, the American Medical Association, the Infectious Diseases Society of America, the Hepatitis Foundation, the American Liver Foundation, and virtually all other medical authorities and their professional organizations.

Routine infant immunization is a proven strategy to prevent the transmission of serious infection and chronic liver disease. Only by achieving high vaccination rates, can we optimally protect all children and all communities. We would be remiss in our responsibilities as public health professionals, policy makers, and parents if we did not take all the steps necessary to control, eliminate, and hopefully, one day eradicate this virus.

APPENDIX I

Advisory Committee on Immunization Practices
Liaison Representatives

American Academy of Family Physicians

American Academy of Pediatrics

American Association of Health Plans

American College of Obstetricians and Gynecologists

American College of Physicians

American Hospital Association

American Medical Association

Association of Teachers of Preventive Medicine

Canadian National Advisory Committee on Immunization

Hospital Infection Control Practices Advisory Committee

Infectious Diseases Society of America

Mexico's Health Secretariat

National Medial Association

Pharmaceutical Research and Manufacturers of America

Age at Infection of Persons with Chronic HBV Infection, United States

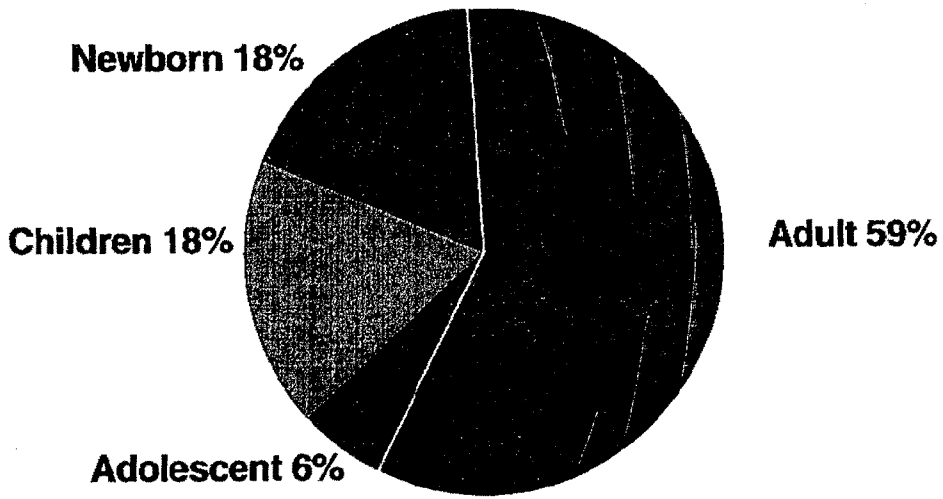
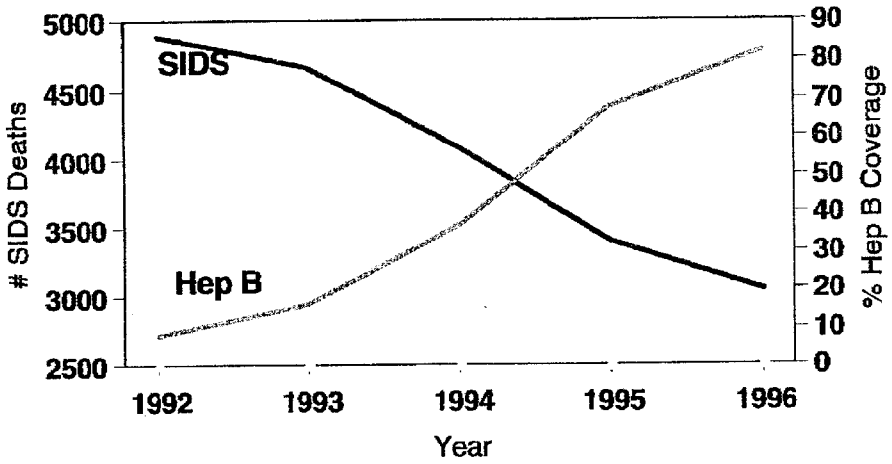


Figure 1

Sources: NHANES III; N Engl J Med 1989;321:1301-5
Pediatrics 1992;89:269-73; Pediatrics 1995;96:1113-6

CDC

SIDS Deaths* and Hepatitis B Vaccine Coverage in 19-35 Month Old Children 1992-1996



*U.S. residents, NCHS annual mortality files

Figure 2

CDC

Mr. MICA. Thank you both for your testimony. I have several questions.

First of all, Dr. Margolis, you mentioned in your presentation that studies have shown that at least 25,000 children are infected with the hepatitis B virus each year. Is this an estimate or are these reported cases?

Dr. MARGOLIS. As I pointed out, infection in young children is rarely symptomatic. We have looked, using blood tests, at a very large sample of the United States, and this is an estimate from that large study called the National Health and Nutrition Examination Survey, and those estimates come from those surveys done actually on two occasions 10 years apart.

Mr. MICA. So this is an estimate. If it is an estimate, what age group are you talking about in children?

Dr. MARGOLIS. The data comes from looking at children down to 5 years of age. The study didn't go below that, at least for hepatitis B, but repeated on two occasions, has again shown consistency of that estimate in terms of those numbers.

Mr. MICA. Did it go below 5 years of age, 5 to what, teenage or 18?

Dr. MARGOLIS. It actually went through adults. The first study was done through 2 to 70-year-olds. The second study 10 years later——

Mr. MICA. So the figure is sort of an estimate and it doesn't deal with those under 5 and it includes adults, so it does not really deal with children?

Dr. MARGOLIS. No, it is a statistical sample of the United States. So it represents the U.S. population of children under 5 years of age. That was done in 1970—1979; and then in 1990 it also included children 6 years of age and over. So it is our best estimate with a valid scientific sample.

Mr. MICA. So these are estimates.

Can you tell me the number of reported cases of hepatitis B in children under the age of 1, for example, for say the last year?

Dr. MARGOLIS. Well, I can tell you reported cases. Now, one of the things, I have to go back 1 minute, from the estimate we then matched that with our reported cases, and we can put what we call a correction factor in there that takes into account that very high rate of asymptomatic infection.

Mr. MICA. Reported cases under 1 in a timeframe like the last year?

Dr. MARGOLIS. Yes. In 1997 there were 95 reported cases of children under 2 years of age.

Mr. MICA. Across the entire United States?

Dr. MARGOLIS. Yes. That has been since immunization began in 1991. So 1997, if we go back to 1990 before immunization began, there were 266 reported cases of children under 2 years of age.

Mr. MICA. That is under 2?

Dr. MARGOLIS. That is the way that we have the data put together.

Mr. MICA. And there were 87——

Dr. MARGOLIS. Ninety-five in 1997.

Mr. MICA. In 1997, there were 95 children reported?

Dr. MARGOLIS. Under 2 years of age.

Mr. MICA. Under 2 years of age, and you are comparing apples and apples then?

Dr. MARGOLIS. In 1990, which was before immunization of children began, there were 266.

Mr. MICA. I mentioned, I think, in my opening statement a study in New Hampshire. For example, there were 48 adverse reactions to the vaccine in children aged 1 to 10 in recent years. There were 16 times greater the number of cases of the disease—16 times more, I guess, adverse reaction than cases of the disease. There were three reported cases of the disease in children?

Dr. MARGOLIS. Correct. That is what you said in your opening statement.

Mr. MICA. Well, is it possible that the preventive measure is riskier than the disease itself, given these statistics?

Dr. MARGOLIS. The first thing I would like to go back and readdress is, since an infant or a young child who becomes infected is very unlikely to be a case, to have symptoms and thus be reported, as we heard, this is a silent infection. As we heard today, many people did not know they were infected. That is the problem with early childhood infections. You can only discover the magnitude by doing these surveys with the blood test. So what I would say is, those three cases represent many infections and, in fact, the multiplier may be as high as 100.

In other words, for a symptomatic case, you may see—90 percent are going to be asymptomatic and not reported.

Mr. MICA. There were 3 cases of the disease and there were four times as many child deaths, 11 reported; is that correct? Are you aware of this New Hampshire study?

Dr. MARGOLIS. I am not aware of the New Hampshire data.

Mr. MICA. If there were 11 reported deaths—and this brings me to the reporting system—what kind of statistics do you have in children 1 and under, or 2 if we can use 2 as a comparison—I don't know if you would have the same timeframe—but how many died from adverse reactions?

Dr. ELLENBERG. Well, we cannot tell you from these data how many died from adverse reactions. What we can tell you is how many deaths occurring shortly after a vaccination were reported to our system.

Mr. MICA. Can you give me that figure?

Dr. ELLENBERG. Yes.

Mr. MICA. We have 95 reportable cases in children under 2 in 1997, is that correct, across the country?

Dr. MARGOLIS. Correct.

Dr. ELLENBERG. If you will give me just a minute—I have too many folders in here. Find the one with the deaths. We will give you the exact numbers in a minute, the number of deaths under a year of age, and you must remember that most of these——

Mr. MICA. We want to be fair. I think we are trying to compare 2 years. Dr. Margolis' statistics are 2 years.

Dr. ELLENBERG. The vast majority of the deaths in children are under age 1 because most of them are attributed to SIDS and that occurs only in infants, so there are very few deaths in children over the age of 1.

1997, is that the year?

Mr. MICA. I think that is your year. I am just trying to get some idea. If, in the case of the New Hampshire data, you have four times as many child deaths as we have cases of the disease——

Dr. ELLENBERG. Right. I can tell you the numbers, but the problems are all in the interpretation.

In 1997, VAERS reported 41 deaths in children under the age of 1; two deaths in children aged 2; and two additional deaths in other children.

Mr. MICA. So we are looking at about 43 deaths, and we had 95 reportable cases?

Dr. ELLENBERG. But it is important to recognize that these deaths have not been causally attributed to the hepatitis B vaccine. The bulk of these were reported after children received multiple immunizations with multiple vaccines. We have no way of knowing whether any of them had anything to do—this is simply an association in time that is reported.

The number of deaths has been going down as consistent with the data that Dr. Margolis showed. In 1994 we had 64; this is, in age, under 1, we had 64. Then 60 in 1995, 48 in 1996, and 41 in 1997.

The number of childhood deaths is going down, just as the increase in hepatitis B vaccine coverage in this age group is going up.

Mr. MICA. Well, again we had the number of deaths that we think were caused by adverse reactions.

Dr. ELLENBERG. No, I have to take exception to that. We have no idea whether these—there is nothing in the medical record to indicate or suggest that these deaths were caused by anything in the vaccine. As Dr. Margolis said, we have 4 million babies a year vaccinated.

Mr. MICA. So basically you are telling me we can't tell?

Dr. ELLENBERG. We can't, from what is in the medical record. The SIDS rate today is 1 in 2,000. Until the Back to Sleep campaign, the rate was about 1 in 1,000. You don't have to be a mathematician to see that with 4 million babies and the rate of 1 in 1,000 per year, you are going to have a certain number of deaths following vaccination.

Mr. MICA. Well, you said that you also did a study. Was it in—sometime in the 1990's, about problems with adverse reactions, possible signals of potential problems, I think you said, and there was no new consensus as a result of that study about problems. When was that conducted?

Dr. ELLENBERG. We did a thorough investigation. This was several years ago, actually prior to some of these concerns being raised. We did a thorough review of all of the adverse reactions.

Mr. MICA. What year was it?

Dr. ELLENBERG. 1996 it was published, so we were doing the study in 1995 or even earlier. And we have reviewed all of the data in VAERS from 1991 to 1994 in infants to see whether there were any patterns, any particular pattern of events that suggested that they might be associated with the vaccine—this is what we do with the VAERS data, we review them very carefully—and there was nothing. Most of the reports, as I indicated, were of transient, self-limited conditions, only about 50 percent.

Mr. MICA. Is that a published study?

Dr. ELLENBERG. Yes, it is a published report.

Mr. MICA. And peer-reviewed?

Dr. ELLENBERG. Yes, sir.

Mr. MICA. There are 42 States that mandate this hepatitis B vaccination. Can you tell me how many children are getting this vaccination, say, at birth or how many are getting the vaccination at a later date? Because if they are not getting the vaccination, you might have lower figures.

Dr. ELLENBERG. I think that would be something that Dr. Margolis might better answer.

Dr. MARGOLIS. We know that approximately 85 percent of children are fully vaccinated—that is, as of this last year—by the time they are 18 months of age. Thirty percent——

Mr. MICA. With the hepatitis B vaccine?

Dr. MARGOLIS. With the hepatitis B vaccine.

And 30 percent of children begin their immunization some time within the first month of life. So ''near birth'' or ''at birth,'' the way that the question is asked. The schedule allows much flexibility to give the vaccine over the first 18 months.

Mr. MICA. The vaccine hasn't been mandated by the Federal Government, but the States have instituted a requirement for entering public school or other public activities, I guess. We have 42 States, and I am trying to get a picture; was that instituted in 1991 or 1992, 1993, or has this been a transitional——

Dr. MARGOLIS. That is correct. It has been transitional and evolving, and many States actually—now their school entry requirement is only beginning to happen in 1999, in 2000. As you see from that coverage data, that yellow line has a higher proportion of children. Remember, you are vaccinating in the first 2 years of life, and then they come into school. So the majority of these States now, by the year 2000 or 2001, will require a child to be fully vaccinated.

Mr. MICA. The studies or reports indicated an increase in incidence of adverse reaction as we are having an increase in vaccination. Maybe you can answer that, Dr. Ellenberg?

Dr. ELLENBERG. No, I don't believe there has been any increase in the total number of adverse events. Well, I should back up because as a vaccine becomes—as the coverage increases, you will certainly have increases in the number of reports. Most of the reports in the system are actually of things that we can relate causally to vaccines, things like injectionsite reactions, running a fever, we know that vaccines can cause these problems.

While we had very few reports involving hepatitis B in children in 1991 when the recommendation for universal immunization was first made, the numbers shot up in successive years because millions of children were then receiving the vaccine. But over the last few years, there has been a tapering off and a decrease in the total numbers of reports.

Mr. MICA. So there was an increase in adverse reactions and reporting in the system, as there was an increase in the vaccination?

Dr. ELLENBERG. That is right. As one would expect.

Mr. MICA. And now you have seen that trailing off?

Dr. ELLENBERG. Yes.

Mr. MICA. One of complaints that we heard today is that individuals, parents or those who were inoculated as adults or later, did

not feel that they had adequate warning about the adverse reactions. Today we have developed an incredible warning system. Cigarettes have warning systems on them. Every time you turn on the television, half the ad is the warning about the potential of the drug that you may be taking.

From your experience and from seeing the statistics that we have seen here, it sounds like there are cases of adverse reaction. Does it not appear that there is inadequate warning either to the parents or those about to be vaccinated?

Dr. MARGOLIS. Well, I can speak both from the vaccine information statement that the CDC supplies—and again it is up to the individual to use that—where we say that a vaccine, like any medicine, is capable of causing serious problems such as severe allergic reactions. The risk of the hepatitis B vaccine causing serious harm or death is extremely small. As a clinician, when I talk to parents, I advise them of this potential.

Mr. MICA. Is the warning adequate, given the numbers of adverse reactions? If we just take the New Hampshire incidence, we have more deaths from the vaccine than we have deaths from the disease.

Dr. MARGOLIS. The CDC and the ACIP, whom we go to with these potential or alleged adverse events, review the data in terms of association, scientific association and potential causality, and at this time there are no data that would show that these deaths, including the SIDS deaths or the other serious neurologic adverse events that we have heard about, are associated with the hepatitis B vaccination; and that is why at this time they are not included in the information statement.

Mr. MICA. Dr. Ellenberg, did you want to respond about adequate warning?

Dr. ELLENBERG. Just to say that the adverse reactions that are known at the time that a vaccine is licensed are included in the label for the product. And as we learn new information about possible risks of the vaccine, those can be added to the label.

Mr. MICA. Do either of you recommend additional studies? Another complaint we heard today and something that should be a concern to us is that we don't have enough data, enough studies, to find out what is really going on here.

Dr. Margolis.

Dr. MARGOLIS. The CDC has seven studies ongoing at this time to look at the various types of adverse events which have been described, to see if there is——

Mr. MICA. What is the sequence of their being initiated? Is this recent or ongoing?

Dr. MARGOLIS. The first studies with the hepatitis B vaccine began in the mid eighties, and they were two reviews looking at neurologic events at that time; and then additional studies have begun, subsequent—there was an early study looking, soon after widespread use of the hepatitis B vaccine in infants in 1993–1994, and then these additional studies in the last several years for which data collection is still ongoing and final results are not in.

Mr. MICA. So you think that this does need more study? Is it getting more study? And you recommend additional study?

Dr. MARGOLIS. Yes. It is part of our keeping vaccines safe.

Mr. MICA. Dr. Ellenberg.

Dr. ELLENBERG. Vaccine safety is so important, I don't think that we can ever have enough studies. It is very difficult sometimes to uncover very, very rare risks because of all of the problems in interpreting data. So more studies, yes, would be very useful.

Mr. MICA. We heard from Mr. Belkin, and he brought a chart up here that showed the sequence of events as he saw them. And when it got down to the VAERS study or repository, his chart indicated that the information went nowhere. What is the case with the reporting system?

Dr. ELLENBERG. Well, we have a staff that review these reports very carefully. There is more detail——

Mr. MICA. But beyond reviewing them, what happens? Is there anything happening with that information?

Dr. ELLENBERG. Yes. When we review them, when we do a thorough review, we provide this information to the medical community in the way of presentations and publications.

If there is a need for making this information—putting this information on the label, we can work with the manufacturers to have that happen.

I am not quite sure—that is our job, to see what information is in there that people need to know in order to improve everybody's understanding about vaccine safety.

Mr. MICA. Dr. Margolis.

Dr. MARGOLIS. The other things that VAERS do, these case reports generate—these larger studies, one looks at vaccinated versus unvaccinated children to see if there is a true association. So it is fed back into a loop.

Mr. MICA. Do we have information on that as it relates to hepatitis B?

Dr. MARGOLIS. Those are part of the seven studies that I described, but we don't have the complete information at this time.

Mr. MICA. My last question deals with its efficacy, for how long the vaccines are effective. I have read 7 years in one report. The manufacturer says—indeterminable was something that was said, testified to. Someone else said 4 years in India. It doesn't sound like we know how long these vaccinations are effective for. Do we, Dr. Margolis?

Dr. MARGOLIS. Unfortunately, when we start out with any vaccine, we don't know how long it is going to be effective. Hepatitis B vaccine is one where we started following children and adults, and we are out now 15 years, to see how long the immunity will last.

Yes, there has been controversy, and our friends in Europe and India, some have said we should test everybody and revaccinate every 4 years. There has been a change as data has become available. There are studies out 15 years showing that a child vaccinated either as an infant or a young child is still protected, including as they have grown up, become sexually active, and are exposed in settings where there is a high rate of hepatitis B.

So we feel comfortable that we know about 15 years. We don't know about the future, but these studies are ongoing. They are part of CDC's program to follow this vaccine and determine if we need booster doses.

Mr. MICA. Did you want to respond, Dr. Ellenberg?

Dr. ELLENBERG. No, that is a very complete answer.

Mr. MICA. The hearing so far raises as many questions as I think we have had answers provided, but at this time I would like to yield to Mr. Tierney.

Mr. TIERNEY. In that vein, let me say that one of our colleagues, Rod Blagojevich, asked me to put a question to you on the record, Dr. Margolis. I think you have answered it, but in deference to him, I am going to ask it again.

What efforts have been made to compare the overall outcomes of children who are vaccinated against those who are not vaccinated?

Dr. MARGOLIS. Again, there have been several long-term studies in populations. One is among the Alaskan native children and has shown the ongoing effectiveness of immunization now for 10 to 15 years.

Mr. TIERNEY. The second part of his question, are there clinical trials, control groups or other ways of measuring the general health of the vaccinated versus the unvaccinated?

Dr. MARGOLIS. These again have been done in these large population-based studies, and especially where one is looking for a potential adverse outcome.

Mr. TIERNEY. I want to pose to you a question one of the skeptics of the vaccine has published before. The question that this doctor says is worth asking is, does a baby born of stable parents in a good environment have enough chance of getting hepatitis B to warrant subjecting it to what he perceives as an unknown danger?

Dr. MARGOLIS. When we look at the 20,000 to 25,000 infections that occur in children in the United States, and the majority don't have a risk factor, there is not someone in their household who is infected, and so those are a very important group because if we don't prevent those, they are going to grow up and have chronic liver disease.

Also, as people may have high-risk behaviors as adolescents or adults, we have found it very difficult to vaccinate before you get infected. There is that additional margin of protection that occurs.

Subjected to a rigorous and peer-reviewed analysis of this, both in terms of prevention—and we were quite conservative in our prevention; we only said 60 percent of children would be vaccinated, we have done better—it becomes both cost-effective and prevention-effective to do this.

Mr. TIERNEY. How many manufacturers produce the vaccine?

Dr. MARGOLIS. There are two that are licensed in the United States. There are many more worldwide.

Mr. TIERNEY. Dr. Ellenberg, we have—I think you talked about one study that seemed to document people who use vaccines, and then looked at the reactions that were claimed.

Do we actually ever do an analysis of VAERS, things that are claimed, to see if there are any common characteristics between the individuals who are making those reports?

Dr. ELLENBERG. You mean to see whether one could identify people who are particularly at risk for having reactions?

Mr. TIERNEY. Yes.

Dr. ELLENBERG. We have done that, but we need to do more of that. It is something that with regard to—for example, the gender

issue that was raised by a previous witness, this is something that we have studied.

Mr. TIERNEY. You have studied the gender difference?

Dr. ELLENBERG. To some degree; not as intently—we have not completed our investigation.

Mr. TIERNEY. Do you have any preliminary results on that?

Dr. ELLENBERG. With regard to the hepatitis B vaccine, I can say that there is a predominance of reports in females in the adult age group. That is because the largest group of people who get the hepatitis B vaccine as adults are healthcare workers, and this is a predominantly female occupation.

When we look at the adverse events in children, there was no difference, males versus females, in the adverse events reports. But this is an important issue not just for vaccines, but for other medical products, and it is something that we hope to pursue in more detail.

Mr. TIERNEY. What are we doing exactly to pursue it?

Dr. ELLENBERG. Trying to get additional resources.

Mr. TIERNEY. You have made an application to Congress for that?

Dr. ELLENBERG. Yes.

Mr. TIERNEY. Let me ask you, Doctor, are there any criteria for reporting to VAERS? Are there any conditions that have to be met before a report can be filed?

Dr. ELLENBERG. That is correct. Any time anybody feels that there might have been—a vaccination might have been implicated, they are encouraged, because we have found things that nobody would have thought were associated with the vaccine. And when we have a number of reports, we are able to see that maybe in some rare cases it is, and some of that example is in the written testimony.

Mr. TIERNEY. Can you tell us what your datalink project is designed to do?

Dr. ELLENBERG. The Vaccine Safety Datalink is actually a program of the CDC, so they may want to elaborate on this. But it is a collaboration of four health maintenance organizations where you can link the vaccination history of children with their medical outcomes. And so we don't have some of the problems that we have in VAERS in terms of knowing how many people were vaccinated and how many people had certain kinds of events.

One can construct rates in a way that you can't do with the VAERS system. When we identify a signal of a possible problem in VAERS, we can go to the Vaccine Safety Datalink, which met last week, and suggest that perhaps these things could be looked at in the Vaccine Safety Datalink, and that has happened on numerous occasions.

Mr. TIERNEY. Has there been a problem with the VAERS system for double counting?

Dr. ELLENBERG. Yes. We get duplicative reports. We have continued work to develop algorithms to sort these out. We don't want to discourage—we are more anxious to get the reports in the first place, but it is problematic. We have more duplicative reports of the serious events and fatalities; 10 to 15 percent of those are du-

plicates as compared to the less serious reports where there is not as much of a problem with duplicates.

Mr. TIERNEY. Is there anything that Congress can do with that particular issue? Is that something that you are working with within the administrative end of it?

Dr. ELLENBERG. The issue of trying to do quality control of the data base is difficult. Anything that Congress can do to provide us additional resources to analyze these data bases and to do followup studies would be most appreciated.

Mr. TIERNEY. Is it accurate to say that the majority of people that are contracting hepatitis are, in fact, infants or adolescents, or do you have it broken down?

Dr. ELLENBERG. That, I will have to defer to my CDC colleagues.

Dr. MARGOLIS. As that pie chart showed, still the majority who contract it are adolescents and adults.

Mr. TIERNEY. That is diagnosed or contracted?

Dr. MARGOLIS. Both. If you look at it both in terms of reported, or if one goes to the surveys and the estimates, you see it both—you see it as being similar.

Mr. TIERNEY. So there is no way to tell when someone contracted it once you have diagnosed it?

Mr. MARGOLIS. That is correct, but the two appear to mirror each other. You can use acute disease reporting to show you what happened in the past.

Mr. TIERNEY. I have no other questions. Thank you.

Mr. MICA. Thank you.

Let me go back if I can just a second. I discussed the number of cases of children under 2, and we got to 95 reported cases of hepatitis B nationwide. Was that right, Doctor?

Dr. MARGOLIS. Correct.

Mr. MICA. That was in 1997. Then I asked Dr. Ellenberg the number of deaths attributed to adverse reactions in the same period, and we got to about 45?

Dr. ELLENBERG. Well, those were deaths reported to VAERS, but one could not attribute them to the vaccination. They are associated in time, but there is no way to determine that the vaccine was responsible for those deaths.

Mr. MICA. They are attributable under some circumstance, in some way, or does the reporting make any sense if——

Dr. ELLENBERG. As I have said, there is no restriction on reporting. If someone's child——

Mr. MICA. You said there was also underreporting?

Dr. ELLENBERG. There is underreporting——

Mr. MICA. And we don't have that causal evidence on other cases, so we are guesstimating that these 45 would be adverse reaction deaths, right?

Dr. ELLENBERG. No, we cannot draw that conclusion.

Mr. MICA. Do you have any idea what is going on?

Dr. ELLENBERG. We have a nonrestrictive system so that anything that happens after a vaccine we can look at. We might be able to find some cluster of symptoms that does suggest that the vaccine was causal. But we don't have that.

Mr. MICA. So our guesstimate is 45 adverse——

Dr. ELLENBERG. That is not my estimate. I don't know how many of these deaths, if any, were related to the vaccine.

Mr. MICA. How many deaths did we have in infants or children under 2 from hepatitis B, as reported—deaths? Now, if they have hepatitis B, we can probably get that in a task, and that would be reportable as a death, OK.

Who can tell me?

Dr. MARGOLIS. Deaths from hepatitis B in children under age 2 or in children in general are very rare.

Mr. MICA. I am trying to get one——

Dr. MARGOLIS. There is——

Mr. MICA. We are looking at children under 2. Is there any evidence? I know that has to be reported somewhere, because we can definitely tell who has hepatitis B in children under 2.

Dr. MARGOLIS. I don't have that number. I can tell you——

Mr. MICA. Is it more than 45?

Dr. MARGOLIS. No, it is going to be less than that. That is again because as you have heard from me and other witnesses, that the deaths from hepatitis B occur many years later. They occur from the chronic liver disease. Death from acute hepatitis B, we estimate there are only 150 to 200 in all of the United States. That is from the new acute infection; fomenting hepatitis is rare.

Mr. MICA. That is from hepatitis nationwide in 1997?

Dr. MARGOLIS. Yes.

Mr. MICA. How many were there?

Dr. MARGOLIS. Around 100. That is acute. That is the new case. If one looks at chronic liver disease, that is the 4,000 to 5,000.

Mr. MICA. Attributable to hepatitis B?

Dr. MARGOLIS. Attributable to hepatitis B. You asked me about new acute cases. That is what is reported to us or acute cases. People who get ill with hepatitis acutely, the new infection.

Mr. MICA. Given some of what we have heard today and some of what you know, there are—currently 16 States have conscientious or philosophical exemptions available from the mandatory vaccination laws. Do you feel we should expand this? Sixteen States now have it—or redefine it?

Mr. LIVINGOOD. This is John Livingood from the National Immunization Program. The construction and implementation of State laws for mandatory immunization has been entirely a State function and not a Federal function.

We have been prepared to support States, however they chose to enact and implement their State law.

Mr. MICA. We also penalize them——

Mr. LIVINGOOD. We do not penalize them for the content of their State law. States receive incentive funding based upon the amount of four doses of diphtheria, tetanus, and pertussis vaccine.

Mr. MICA. So, in effect, they are not being financially rewarded?

Mr. LIVINGOOD. Hepatitis B does not play a role in incentive funding. It is not included in the formula for incentive funding. Incentive funding is based on DPT, MMR, and polio containing vaccines.

A State also measures immunization levels at the time of school entry, but we don't reward or allocate funds based on hepatitis B

as a component of the immunization program in a reward or incentive way.

Mr. MICA. So basically no one is going to commit to anything from this panel as far as any exemptions for conscientious or philosophical exemptions from the vaccine?

Mr. LIVINGOOD. If States implement such a law, we will support them; and we are in complete agreement with however the States choose to do their own——

Mr. MICA. There are 16 States that have this exemption. Have we done any study, if there are any higher or lower vaccination rates or incidents? Is that part of any ongoing study, Dr. Margolis?

Mr. LIVINGOOD. Not for hepatitis B, but there is an article that will be coming out in the next several months in the Journal of the American Medical Association. Not surprisingly, States that have persons who are allowed philosophic exemptions, those persons themselves are at increased risk of disease because they are not immunized compared to the other population.

There is also a small increased risk that appears for the general population of those States, but it is not a major impediment to immunization coverage levels per se, since most States have rather low levels of philosophic exemptions by the time of school entry. It is usually in the single digit percentages.

Mr. MICA. Well, I thank our witnesses. Did you have any additional questions, Mr. Tierney?

We have been joined by Mr. Towns, the gentleman from New York. Did you have any questions at this time?

Mr. TOWNS. I have a couple, Mr. Chairman.

Mr. MICA. Go right ahead. You are recognized.

Mr. TOWNS. Let me also thank you for holding this hearing.

Today it is fashionable, among teenagers in particular, to get tattoos and engage in body piercing, and also fraternities have fraternity brands. Knowing what you know about the transmission and effects of hepatitis B, what do you think about this trend from a health standpoint?

Dr. MARGOLIS. Well, anytime one puts a needle into their body, there is a potential for transporting blood-borne viruses. I had this discussion with this committee for hepatitis C and HIV.

However, if you look at persons with acute disease where we do the surveillance to find out risk factors, we do not see this as a substantial risk factor. The potential is there and so we feel that if people choose to do it, they should do it safely.

Mr. TOWNS. Don't you think we should be a little more aggressive about it in terms of getting information out, because nobody really talks about it? Colleges are doing it and they are doing it on university campuses. Don't you think some statement should be coming forth in terms of the possible risk here?

Dr. MARGOLIS. Actually, the CDC has made that statement as the possible risk. In information about hepatitis C, there have been a number of health education materials from non-CDC groups that point out that potential. And as information—and about all blood-borne infections, that that potential is there. We agree.

Mr. TOWNS. One other question. I am concerned about daycare workers. Are there any Federal guidelines which require daycare workers, who have close contact with children by changing diapers

and all of those other kinds of things, be tested for or immunized against hepatitis B?

Dr. MARGOLIS. In a number of studies——

Mr. TOWNS. By not doing this, are we jeopardizing our children?

Dr. MARGOLIS. For hepatitis B, many studies have shown there is not transmission either from the child to the daycare worker or from daycare workers to children. And at the time, the occupational safety and health regulation about blood-borne pathogens was developed and implemented in 1991, this actually had been looked at and so that is not considered an occupational risk and it is really not considered a risk from the daycare worker to the child. And there have been a number of studies that have looked at that.

And so again, while this is a blood-borne infection that is relatively easily transmitted, it has not been transmitted in the daycare setting.

Mr. TOWNS. Let me ask you this. Do you have any other feelings of explanation for that if that is actually true?

Dr. MARGOLIS. Well, we know actually in the hospital setting that a transmission, again more likely because of needle sticks and those kinds of sharp injuries, goes from the patient to the healthcare worker. Transmission from a possibly infected healthcare worker does not go to the patient. So again, those blood exposures are rarely there, and they are even more rare in the daycare setting.

Mr. TOWNS. I just think that for some reason we are not paying enough attention to prevention. I could be wrong. In fact, I hope that I am wrong, but I am willing to bet that I am not wrong.

Dr. MARGOLIS. I think now children—because of routine childhood immunization, most children in daycare are vaccinated. So the potential for transmission between children or from a child to a daycare worker would even be rarer than it already is.

Mr. TOWNS. My other question is, are we requiring this daycare worker to be immunized?

Dr. MARGOLIS. Not against hepatitis B.

Mr. TOWNS. OK, I have no further questions.

I just think, Mr. Chairman, that really once we—if we stressed it at the beginning, I think we might be able to solve some problems later on.

There is not enough information out. I think that is a big problem here. Once a person has hepatitis B or C, there is no treatment for it.

Dr. MARGOLIS. It is largely treatment through interferon treatments. With end-stage liver disease, a transplantation is required. So prevention is the thing.

Mr. TOWNS. Let me ask a question, what is the difference between B and C?

Dr. MARGOLIS. Two different viruses. Both live in the liver, but two different viruses in terms of their outcome.

Mr. TOWNS. Can I say that C is much more aggressive and much more devastating?

Dr. MARGOLIS. There are more people infected with C, but they are actually both equally aggressive.

Mr. MICA. Thank you, Mr. Towns.

We did hear today different instances about the effect on people's lives and some pretty dramatic testimony. You mentioned in your testimony about some studies that you are doing, and also I think you mentioned that the British and French have conducted studies.

I have got a headline from an Associated Press wire story from October 1998. It says "French Suspend Hepatitis B Inoculations," and it starts out, "Faced with a potential health disaster, France has suspended hepatitis B vaccine inoculations of school children 4 years after mass immunization program began."

I am just wondering if you would like to respond to what the French have done.

Dr. MARGOLIS. What I would like to do is clarify what happened in France, and several of us were involved with the World Health Organization and close to that issue.

The French did not suspend infant, adolescent, or adult high-risk hepatitis B vaccination. What they suspended was vaccination of teenagers in schools, and what they said was, you as a teenager should be vaccinated in your healthcare providers' office, not in the school. Often in the translation—that was not there in the early headlines, but that is in fact the policy in France.

Mr. MICA. I hate to say this, Dr. Margolis, that raises even more questions because now we have taken—well, we have questions already about the infant adverse reactions based on several studies, and we will hear some more about that; but this raises a whole new area of concern about teenage vaccination and why one country would suspend that. And it sounds like you——

Dr. MARGOLIS. They did not suspend teenage vaccination. They suspended it in the schools. So the recommendation is still there, as we have in the United States, for routine vaccination of adolescents.

What the French Minister of Health said is, go to your physician and have it done, do not come to the school and have it done. They did not do that because there were any data that showed that there was an association with adverse events.

Mr. MICA. Well, I guess this is a hearing to be continued. We have gone on with this panel for some time. I will have additional questions that I would like to submit to you and ask that they be made part of the record, without objection. And if we have any other questions, we will submit them. We will dismiss you and thank you for your participation and call our third panel of experts on the subject.

We have a series of doctors who will testify, including Dr. Samuel Katz, with the Infectious Disease Society of America; Dr. Bonnie Dunbar, a molecular biologist with Baylor College of Medicine. Dr. Burton Waisbren, Sr., F.A.C.P., and Dr. Barthelow Classen, president and CEO of Classen Immunotherapies.

With our witnesses in place, I would like to welcome all four of you as experts on the subject at hand. I would remind you that we try to limit your oral presentation before the subcommittee to 5 minutes, and if you have a lengthy statement, we will enter it as part of the record.

This is an investigation and oversight subcommittee of Congress and so if you don't mind, please stand and we will swear you in.

[Witnesses sworn.]

Mr. MICA. The witnesses have answered in the affirmative.

We are going to recognize Dr. Samuel Katz who is with the Infectious Disease Society of America. Dr. Katz, welcome. You are recognized.

STATEMENTS OF DR. SAMUEL KATZ, THE INFECTIOUS DISEASES SOCIETY OF AMERICA; DR. BONNIE DUNBAR, MOLECULAR BIOLOGIST, BAYLOR COLLEGE OF MEDICINE; DR. BURTON WAISBREN, SR., F.A.C.P.; AND DR. BARTHELOW CLASSEN, PRESIDENT AND CEO, CLASSEN IMMUNOTHERAPIES, INC.

Dr. KATZ. Thank you, Mr. Mica. It is a pleasure to appear before you and Mr. Towns and Mr. Tierney. I also have submitted a more lengthy statement.

Mr. MICA. Without objection, that will be made a part of the record. And if people in the audience have conversations, I would like them to take them outside so we can hear the witnesses.

You are recognized, Dr. Katz.

Dr. KATZ. I am Dr. Samuel Katz, a pediatrician who has spent the last 42 years of my life working to develop the best vaccines in the world to protect the health of infants, children, and adults. I was privileged to be one of the two scientists who developed the measles vaccine more than 35 years ago that has saved tens of millions of lives of children in this country and around the world.

Today, I was invited to speak on behalf of the American Academy of Pediatrics, as well as the Infectious Diseases Society of America and the Pediatric Infectious Diseases Society, groups whose membership represent more than 55,000 pediatricians and 6,000 infectious disease experts who take care of patients, do research and teach, and participate in public health in the United States.

Parenthetically, I would add in relation to an earlier discussion, that I am currently a member of the Advisory Commission on Childhood Vaccines, the one that you discussed that was established by the 1986 National Childhood Vaccine Injury Act, and the membership consists of parents, attorneys, and physicians.

Today, we are here to talk about hepatitis B, a particularly insidious disease, as you have heard, especially for children who acquire it within the first 5 years of life. Of those 25,000 hepatitis B-infected children, 30 to 90 percent are destined to acquire chronic hepatitis, which then leads to cirrhosis of the liver and liver cancer 30 to 40 years after they acquire the infection.

However, we can prevent this disease with a vaccine that has been in use for more than a decade. It is effective and it is safe. It has been given to more than 500 million people around the world with the most striking results imaginable. The benefits of this vaccine are so impressive that more than 100 countries around the world routinely administer it, and in those countries the incidence of cirrhosis and liver cancer due to hepatitis B has plummeted.

It is important, Mr. Chairman, to note that everyone is at risk for this disease. No matter their age, their race, their lifestyle or their socioeconomic status. As you have heard, at least 30 percent of people who have the hepatitis B virus have no idea how they acquired it. It is far more contagious than the virus that causes AIDS, and in this country it causes at least 5,000 deaths each year.

The vaccine, like all recommended vaccines, has gone through rigorous, exhaustive processes of testing for safety and effectiveness by multiple groups, both within and outside our government, as well as in countries abroad. The safety systems currently in place are highly effective, and we persist in assessment of the safety of the vaccine, continually seeking new ways to decrease any possible risks.

Parenthetically, Mr. Chairman, let me note that some of the statements you may hear in the media border on the irresponsible. The statements are not based on solid scientific facts, and they serve to shake the public's trust and threaten to reverse the incredible gains that this vaccine has provided.

When you heard from parents today whose children have acquired hepatitis B, you can be certain there is nothing they want more than to turn back the clock so they might have made this vaccine available to their children.

Parents can continue to have the utmost confidence in their pediatricians and other health professionals and rest assured that they are focused solely on providing the best health and happiness for these children in recommending the vaccine to prevent hepatitis B.

Let me add, in closing, that I am a grandfather whose eight grandchildren ages 2 months to 4 years have all received hepatitis B vaccines, as their parents and their pediatricians strive to assure them the best in healthy and happy lives.

Hopefully, all American children will continue to receive these same benefits. Hepatitis B is a serious, often life-threatening infection. The vaccine is both effective and safe. Pediatricians will continue to provide parents the most reliable information regarding all vaccines, including that to prevent hepatitis B.

Time does not permit my answering many questions you may pose, but I will be happy to respond to any in the discussion. Thank you.

[The prepared statement of Dr. Katz follows:]

Statement of

Samuel L. Katz, MD

Professor Emeritus

Department of Pediatrics

Duke University Medical Center

Representing:

The Infectious Diseases Society of America

The Pediatric Infectious Diseases Society

And the

American Academy of Pediatrics

Before the

Subcommittee on Criminal Justice, Drug Policy

and Human Resources

Committee on Government Reform

U.S. House of Representatives

May 18, 1999

Release Only Upon Delivery

Good morning.

My name is Dr. Samuel Katz. I've been asked to talk to you this morning to represent the perspective of the American Academy of Pediatrics, the Infectious Diseases Society of America, and the Pediatric Infectious Diseases Society. The American Academy of Pediatrics represents over 55,000 pediatricians in the United States and the Infectious Diseases Society and the Pediatric Infectious Diseases Societies are the professional societies of infectious diseases researchers, clinicians and public health professionals in the United States. These two societies have a combined membership of over 6,000 infectious disease specialists. I've also been asked to speak with you this morning since I was the Chair of the Advisory Committee on Immunization Practices (ACIP) for eight years. Indeed, I was the Chair in 1991 at the time that the Committee recommended to the Director of the CDC and the Assistant Secretary for Health that hepatitis B vaccine be added to the childhood immunization schedule to reduce the morbidity and mortality of hepatitis B infection, a serious infection that could be safely and effectively prevented with this vaccine. In addition, I was asked to speak with you this morning because I have been personally involved as a practicing pediatrician and in immunization research, development and policy for over 40 years. I am also a father and a grandfather whose eight grandchildren (ages 2 months to 4 years) have all received the hepatitis B vaccine. I fully recognize, as does this Committee, that the deliberations and recommendations that come from Committees like this, as well as those on which I have served, are not merely interesting discussions but will eventually

affect every child in the United States -- including my own. We all keep pictures of these youngsters in our mind's eye every day as we make our decisions and recommendations, and as we monitor the impact that these decisions have.

During this time, I have had the honor and good fortune to serve this country, in regard to immunization issues, in a number of ways. I have served on a number of committees that study, review, and formulate vaccine research and immunization recommendations. These committees have been convened by the Institute of Medicine (IOM), the National Academy of Sciences (NAS), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the World Health Organization (WHO). In addition, I am currently a member of the Advisory Committee on Childhood Vaccines. This committee brings together people with a wide range of backgrounds, from parents to immunization scientists, to assure that the vaccines we provide for our children continue to be as safe and effective as possible. In the rare instances where children are injured by vaccines, this Committee assures that they and their families are appropriately compensated.

I am also the co-chair, along with Dr. Louis Sullivan, of a special project of the Infectious Diseases Society of America and the Pediatric Infectious Diseases Society. Dr. Sullivan, as you may know, is the president of Morehouse School of Medicine and a former Secretary of the Department of Health and Human Services. This project—the Vaccine Initiative—was undertaken to help effectively address the types of questions that your committee is asking today. Those of us

working to protect our children's health recognize the need to ensure that parents and health care providers are able to make fully-informed decisions regarding vaccines. We want parents and providers to have the best information that modern science has to offer. If emotion plays a disproportionate role in making decisions about the use of a vaccine, those decisions are less than fully informed. Yes, vaccines and "shots" can cause minor reactions—and in extremely rare cases, serious reactions. However, it is important to remember, that in the vast, vast majority of cases, vaccines bring considerable health benefits.

As a parent, grandparent, and physician, I feel great sympathy for the people who testified on the first panel. I wish we could find the true causes for serious, complicated, and often vexing medical conditions such as multiple sclerosis and autism. But the fact is, there are no scientifically sound studies that demonstrate current immunization recommendations are a cause of autism, diabetes, asthma, inflammatory bowel diseases, SIDS, multiple sclerosis, or any number of acute or chronic illnesses. If a vaccine were shown to be a cause of such medical conditions, you can rest assured that we, as the physicians who care for the nation's infants and children, would be the first to raise the questions. Rather, as a pediatrician who has been seeing patients since 1955, I can tell you that vaccines are among our most effective medical tools. Were it not for the widespread use of vaccines in this country, we would have a far greater number of infant and childhood deaths. We would also have many, many children suffering from the painful, chronic, and often crippling effects of infections

caused by meningitis, polio, diphtheria, measles, pertussis, and congenital rubella.

In speaking on behalf of the pediatricians of this country, they asked that I remind you that their principal and guiding interest is to guarantee the health and well-being of the children for whom they have the privilege of caring. It is our mission to ensure that scientifically accurate, unbiased information goes into important decisions that protect the health of our children and our communities. With that, I would also like to mention that I have included a letter to the Committee from Dr. Joel Alpert, President of the American Academy of Pediatrics, as part of my written testimony.

Hepatitis B infection is often a silent infection that emerges years later in the form of chronic liver disease, cirrhosis and cancer. As the World Health Organization has noted in a letter to the Committee, the hepatitis B vaccine, given to hundreds of millions of people in 100 countries around the world, has been more than 90% effective in preventing acute and chronic disease. In a study published in the *New England Journal of Medicine* in 1997, the use of this vaccine in Taiwan was shown to be responsible for a remarkable downward trend in liver cancer. Hepatitis B vaccine is truly our first anti-cancer vaccine. It is also important that you are aware of another study in the *New England Journal of Medicine* that was published in March of this year. This study documented an increase in liver cancer in the United States, especially in communities of color, largely attributed to hepatitis B and hepatitis C virus infections. This highlights the importance of

using hepatitis B vaccine to protect the next generation. Finally, it is critical to recognize that hepatitis B infection is not simply a "lifestyle" infection. In fact, in at least one-third of people infected with this virus, the source of infection is completely unknown! As you have heard this morning there are many people with hepatitis B, including parents of children with hepatitis B, who would give anything to wind the clock back so they could have taken advantage of the protection this vaccine offers.

Making recommendations: ACIP, AAP, AAFP, and others

The Advisory Committee on Immunization Practices (ACIP) is an Advisory Committee assembled to provide expert advice. Its voting members, appointed by the Secretary of the Department of Health and Human Services, are physicians, researchers and other experts in immunization selected for their expertise in a wide array of fields relevant to the evaluation of immunologic, clinical, and epidemiologic data, including vaccine clinical trials. For the most part, these experts come from academia and from State and local health departments. Their advice and recommendations are considered by the Director of the CDC who has final discretion to accept or reject recommendations.

Further, the ACIP is not the sole group of experts that reviews immunization data and formulates immunization recommendations. Depending on the vaccine in question and the population for which it is intended, other groups including the American Academy of Pediatrics, the American Academy of Family Physicians,

and the American College of Physicians, have a similar, yet independent process. Each organization selects expert panels to review and make independent recommendations. In addition to the AAP, many of those groups are represented here today. Even though there wasn't time for you to hear from them during today's hearings, I urge you to talk with them after the hearing.

In addition, when relevant, as with the case of hepatitis B vaccine, many other groups, such as the National Multiple Sclerosis Society and the International Federation of Multiple Sclerosis Societies undertake an independent review of the data to provide their constituents with the best information that will affect their health. I can think of no group who would like to find a cause for multiple sclerosis more than the National MS Society. It is therefore noteworthy that their Scientific Advisory Board has reviewed the hypothesis of a causal association between hepatitis B vaccine and multiple sclerosis and has rejected it. The cause of multiple sclerosis remains unknown.

The ACIP process

The ACIP does not make hasty decisions. The Committee's review of information about hepatitis B vaccine demonstrates this quite clearly. Since the early 1980s, the ACIP has been considering and routinely evaluating appropriate recommendations for the use of hepatitis B vaccine. The Committee asked the CDC's Hepatitis Branch to prepare a draft update statement on hepatitis B

vaccine. This statement addressed the issues of: 1) the overall trends of use of hepatitis B vaccine to date; 2) the evidence of safety and effectiveness of the recombinant DNA vaccine; 3) the need for booster doses; 4) indications for testing for antibody status after vaccination; 5) safety of new and old vaccines; and, 6) a strategy for perinatal testing. Over the next several meetings, each of these issues was discussed in order to advise the Director of CDC on these issues. Beginning in October of 1990 the Committee began to discuss strategies toward improved hepatitis B virus control. The early discussion focused around the prevention of perinatal transmission and universal immunization for infants in high risk populations (e.g., Alaska, Native American communities). In February 1991, the Committee voted 8-0 in favor of including hepatitis B vaccine as part of the current immunization program. Following the review of the draft ACIP statement in June 1991 the committee voted, again unanimously, for universal infant immunization and the immunization of adolescents "until the impact of universal immunization is felt."

It is worth highlighting that all recommendations resulted from an exhaustive and comprehensive expert review of the available information. There are no voting members of the Committee from any Government agency and no voting members from any vaccine manufacturer. Committee members with any perceived conflict of interest (e.g., the principal investigator or participant in a vaccine trial supported by a vaccine manufacturer) are prohibited from casting a vote on any question involving a vaccine manufactured by a company with which they have such a relationship.

Informed decision-making, parental choice, individual health and community health.

While the ACIP provides recommendations to the CDC Director, decisions about the health of the citizens of the United States are made at the State level and not enacted "nationally." Each state's legislature and governor, along with its respective public health advisory groups must reach its own conclusions about whether to adopt and how to implement each recommendation. It is quite appropriate that these decisions are made in each state by those best situated to judge what is best for their community.

As I mentioned before, the Infectious Diseases Society of America and the Pediatric Infectious Diseases Society have embarked on a special project that is designed to address concerns that patients are discussing with their doctors about immunizations. As a necessary first step, we have gone out to listen to what parents think about when it comes to their children's immunizations. We currently have a national survey in the field of parents of young children. With results expected shortly, I would like to share with you this morning what we have learned from focus groups of parents that we have conducted across the country over the past three months on this issue. Not surprisingly, the vast majority of parents agreed that they should be allowed to make choices about the decision to immunize their children. However, when asked if they would want to send their children to schools where all parents had that same choice,

their near-universal response was one of concern about the health and safety of that school. Some parents worried that in such settings diseases might circulate that could possibly overwhelm the protection provided by immunization. In fact, several parents recognized that immunization is just one of many things that we do as a society to assure the health and safety of our children, our neighbors and our communities. How would we feel about the safety of our roads if stopping at a stop sign were optional?

We all recognize the role and value that the introduction of informed consent has had on medical research and on medical practice. In every field of medicine this has been a central point of discussion with patients and parents about benefits and risks of medical interventions and procedures. However, the concept of informed consent has limitations when it comes to preventing epidemics in our communities. In the late 1960s and early 1970s, despite the availability of a safe and effective measles vaccine, we continued to experience regular epidemics of measles. These outbreaks led to school closings and other disruptions in the normal functioning of communities. One of the reasons that these outbreaks occurred was individual discretion in the use of the vaccine. Left to individual choice we were only able to achieve utilization rates of 60-70% in most communities. For measles, a 60-70% coverage rate will not provide sufficient "community immunity" to dampen an outbreak.

Fortunately, an effective public health tool exists for increasing the coverage rate to a level that virtually eliminates epidemics. That tool is universal vaccine use

among infants and children to ensure that they are protected. I can assure you, based on experience in communities in the United States as well as the experiences reported from other countries, that unless we continue to achieve high levels of immunization coverage, terrible diseases will return – some in epidemic form and some, like hepatitis B, that won't fully emerge until after infection, in the form of chronic liver disease, cirrhosis and liver cancer. If that occurs I can also assure you that many people will suffer unnecessarily and die prematurely from these diseases. This has been seen in other countries when immunization programs were halted. Frankly, we would all like to avoid being invited to a future Congressional subcommittee hearing to explain why we failed to rely on the best that science had to offer and act appropriately.

Conclusion

Let me offer a few concluding remarks to help you put all that you hear today into proper perspective. As noted in some of the fliers about this hearing and the events surrounding it, some are calling for a "full investigation." If, as an outcome of these hearings, this is what you decide, let me suggest what you are likely to find.

First, vaccine safety is not a "new issue." Even before this hearing was called, the federal government, state governments, academic institutions, and vaccine manufacturers had been and continue to be involved in a wide range of

programs and activities designed specifically to ensure that the vaccines that we provide to children, adolescents and adults are held to the highest standards of safety and efficacy. You will find that there exists a robust system of checks and balances that monitors the safety and efficacy of our vaccines. These efforts are designed to assure that our recommendations about immunization practices and procedures reflect the best available science.

Second, you will find that the immunization community - the public and private sector and academia -- has been alert and responsive to vaccine safety needs. For example, when we recognized the need to improve the safety of the whole cell pertussis vaccine, we focused our collective efforts to thoroughly investigate, and then license, an acellular pertussis vaccine. The new vaccine, which has largely replaced the earlier generation whole cell pertussis vaccine, has resulted in a significant decrease in actual, as well as reported, adverse events. A similar result has happened with polio vaccine with the adoption of new recommendations that move away from the live virus oral polio vaccine in an effort to further reduce the occurrence of vaccine-associated paralytic poliomyelitis. These two examples illustrate the responsiveness of the entire immunization community when it comes to vaccine safety.

You will find that the Department of Health and Human Services recently published the report of the Congressionally-mandated Task Force on Safer Childhood Vaccines. This report, presented to a number of advisory committees and available on the Web, describes the vast network of current vaccine safety

activities. These activities ranging from basic science, through clinical trials, to licensure and use, result in the superb quality of the U.S. immunization program. The report also made recommendations to further strengthen this program.

You will find that the National Vaccine Advisory Committee and the ACCV, committees with broad representation -- including the voices and views of consumers - has had a long-standing subcommittee on Vaccine Safety. Your investigation will also find that these and many other questions have been brought before independent committees of the Institute of Medicine for their review. There have been many IOM vaccine safety studies, meetings, and workshops. Two important reports from the IOM have reviewed the existing safety data on childhood vaccines. While each report has pointed to the need for ongoing research, they both have concluded, from all types of evidence, that serious adverse events are extremely rare. As I have already mentioned, there were no substantive data to support the linkage of vaccines to a variety of chronic medical or autoimmune conditions.

Third, there is absolutely no need to set aside special funds for independent vaccine safety research. There is already a structure in place for the scientific investigation of vaccine safety research questions. As you must know the National Institutes of Health, the premier biomedical research organization in the world, is already charged with that mission. Congress relies on NIH to set the standards necessary to assure that tax-payer dollars go to those scientists and organizations who know how to pose research questions and have the ability to

address them. If your Committee concludes that our existing well-established and highly-regarded processes and structures of scientific peer-review are not the most effective for addressing vaccine safety science, you will be embarking on a slippery slope. I see at least three serious problems with such a consideration.

First, you will need to create a new system and infrastructure to allocate these special funds. How will you assure taxpayers that your new system is an effective and cost-efficient use of tax dollars? Who will establish the scientific criteria and guidelines for evaluating proposals? You should realize that those who seek these special funds are likely to be those whose research proposals were unsuccessful in meeting the criteria of current NIH study sections.

Second, any researchers who receive these special funds will, by virtue of accepting the funding, become government-sponsored researchers, therefore raising the question of what is an "independent researcher?"

Third, you will ultimately end up with more government, not less.

In closing, I welcome the opportunity to speak with you today and am glad to see that you too are concerned about the safety of our vaccines. As a result of these discussions, I hope that you will become convinced, as I have over my many years in this field, that the vaccines that we give to our children and grandchildren are carefully scrutinized at every step in the process -- from

development to production to use in the population. This system, the best in the world, assures that our vaccines are held to the highest safety standards, and are effectively preventing serious, often life-threatening infections.

Attachments

(for the official hearing record)

1) Letter from Joel J. Alpert, M.D., FAAP
President, American Academy of Pediatrics

2) Letter from Louis W. Sullivan, M.D. and Samuel L. Katz, M.D.
Co-Chairs, Vaccine Initiative Steering Committee

American Academy of Pediatrics

Reply To:
Department of Federal Affairs
American Academy of Pediatrics
The Homer Building
601 Thirteenth Street, NW
Suite 400 North
Washington, DC 20005
202/347-8600
800/336-5475
Fax: 202/393-6137
e-mail: kids1st@aap.org
http://www.aap.org

May 14, 1999

The Honorable John D. Mica
Chairman, Subcommittee on Criminal Justice
Drug Policy and Human Resources
House of Representatives, Committee on Government Reform
B-273 Rayburn House Office Building
Washington, DC 20515-6143

RE: Hepatitis B vaccine

Dear Congressman Mica:

Pursuant to your subcommittee hearing on hepatitis B, the American Academy of Pediatrics (AAP), which represents 55,000 pediatricians, wishes to go on record as recommending hepatitis B virus vaccine for all children as part of their routine immunization schedule to protect them against this disease. **Hepatitis B virus** is a preventable cause of liver failure and liver cancer, a public health problem that is underestimated by many individuals. Before the vaccines were widely used, over 300,000 infections occurred each year and about 5,000 people died from hepatitis B complications.

Academy Recommendations

Academy recommendations on the use of vaccines are formulated by the Committee on Infectious Diseases and reviewed by several other groups within the Academy before receiving Board of Directors approval as official policy. In an effort to minimize confusion among health care providers and the public, the Academy invites representatives from the Centers for Disease Control and Prevention (CDC) to participate as liaison members in meetings of the Committee on Infectious Diseases and two members of this committee serve as liaison members to the Advisory Committee on Immunization Practices (ACIP). The AAP, CDC, and also the American Academy of Family Physicians (AAFP) all recommend the use of hepatitis B virus vaccine as part of the routine infant immunization schedule.

Vaccines are Very Effective

All parents, physicians, public health officials and legislators want children to grow up in the safest environment possible. Immunization against infectious diseases has produced enormous health benefits in recent years by preventing infections caused by measles, mumps, rubella, polio, diphtheria, tetanus, whooping cough, *Haemophilus influenzae*, chickenpox, and hepatitis B.

AAP Promotes Safety

The Academy is committed to improving the health of children using the safest possible interventions. The Academy has a longstanding policy of supporting the safest possible products for children including promoting the use of the safest possible vaccines for children as evidenced by support for development and use of safer acellular pertussis vaccines in recent years and the ongoing transition from live to inactivated poliovirus vaccines.

SIDS Decreasing after Routine Hepatitis B Vaccination

The Academy has monitored concerns about hepatitis B virus vaccine including some reports that a variety of illnesses have been caused by hepatitis B virus vaccine. The scientific evidence does not support hypotheses that hepatitis B virus vaccines may have caused Sudden Infant Death Syndrome (SIDS), multiple sclerosis or other demyelinating disorders. In 1992, the Academy became aware of scientific data indicating that the risk of SIDS was reduced for infants who were put to sleep on their backs rather than on their stomachs. This led to the Academy's Back to Sleep program that has been associated with a dramatic decline in the incidence of SIDS in recent years. This progressive decline in the incidence of SIDS occurred during the introduction of routine hepatitis B virus vaccination for infants. Thus, there is no reason to hypothesize that this vaccine increases the risk of SIDS. Additional studies in individual states including Alaska and Hawaii where universal hepatitis B virus vaccination was first introduced in the mid 1980's indicated no increased risk of any other serious medical conditions in infants who have received hepatitis B vaccination at birth.

Coincidental Associations

Thus, the available scientific evidence indicates that the relationship between these unfortunate events and the hepatitis B virus vaccination are coincidental and not due to cause and effect. It is easy to understand how a family can believe that a vaccine might have caused the sudden unexpected death of their infant.

We all want explanations for events that come unexpectedly and have no specific identifiable cause. Intense research has been conducted for many years into the cause of SIDS and we are making further advances in our understanding. While we sympathize with the parents of children who have died from SIDS, we should not assume that events, which occur in the hours, days or weeks following vaccination, are necessarily caused by the vaccine.

False Belief of Other Vaccines and SIDS

Whenever vaccines are administered, there is always the risk that coincidental illnesses, especially those of unknown etiology will occur and may be falsely attributed to the vaccine. During the late 1970's and early 1980's there was great concern about the possibility of SIDS being caused by pertussis containing vaccines. It took several years and multiple carefully conducted studies to disprove this hypothesis. Although there are some cases of SIDS that occur within two days after DTP, the risk in vaccinated children is lower than the risk for children who have not received the vaccine. Thus, the scientific evidence convincingly demonstrates that DTP

does not cause SIDS.

Multiple Sclerosis

With regard to multiple sclerosis and other demyelinating diseases, the Academy is aware of data from preliminary studies conducted in France and the United Kingdom that do not demonstrate an increased risk of multiple sclerosis or other demyelinating diseases in persons who received hepatitis B vaccines. We know that additional studies are in progress in France, Italy and the United States. The Academy will monitor additional scientific data as the studies are completed and reviewed by expert groups.

Need for Good Science, not Opinion

We must demand good science from our public health decision-makers, Congress, the Food and Drug Administration (FDA), National Institutes of Health (NIH) and CDC. Similarly, we should demand that decisions made in response to allegations about safety should also be based upon good science, not hypotheses. We encourage your subcommittee to demand scientific evidence from those alleging these concerns.

Children Should Receive Hepatitis B Vaccine

Children will be best served by continuing the current policy of universal hepatitis B immunization. The benefits from this vaccine are well documented. Any withdrawal of support for universal immunization would have a harmful effect on efforts to prevent the serious complications or death from the liver failure, which can be prevented by hepatitis B immunization. We would appreciate having the position of the American Academy of Pediatrics on this issue placed in the public record.

Sincerely,

S/

Joel J. Alpert, MD, FAAP
President, American Academy of Pediatrics

JA:hh

IDSA
INFECTIOUS DISEASES SOCIETY OF AMERICA

May 14, 1999

John L. Mica, Chairman
Subcommittee on Criminal Justice, Drug Policy and Human Resources
B-373 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Mica :

Thank you for your interest in the safety of the hepatitis B vaccine. As co-chairs of the Vaccine Initiative, a joint project of the Infectious Diseases Society of America and the Pediatric Infectious Diseases Society, we are particularly concerned about protecting the health of children and families.

The Vaccine Initiative was created to provide the public, health care providers, policy makers, and the media with up-to-date, scientifically valid information for the purpose of enabling their accurate understanding of the issues and facilitating informed decision-making.

Hepatitis B is a serious threat to the health of children in this country and other countries around the world. However, the evidence about the vaccine is clear – it is extremely effective and safe for use with children of all ages and adults.

Over 500 million doses of the vaccine have been administered worldwide, and numerous studies have been conducted to assess the long-term consequences of receiving the vaccine. The American Academy of Pediatrics, the World Health Organization, and several other expert panels have reviewed those studies and reached the same conclusions:

- The hepatitis B vaccine is highly effective in preventing the disease in children and adults.
- Preventing disease among children is particularly important, because when the disease is contracted in childhood, it is far more likely to lead to liver cancer and death by the age of 40.
- All of the properly done studies have shown that the vaccine does not have serious side effects or lead to the development of chronic diseases later in life.

Based on the evidence, we strongly support use of the hepatitis B vaccine. It is a safe and effective way to prevent tens of thousands of new cases of hepatitis B and thousands of deaths from the disease in the U.S. each year.

Thank you again for your careful consideration of this important public health issue.

Sincerely,

Louis W. Sullivan, M.D.
Co-Chair, Vaccine Initiative
Steering Committee

Samuel L. Katz, M.D.
Co-Chair, Vaccine Initiative
Steering Committee

Vaccine Initiative
c/o Department of Preventive Medicine
A-1124 Medical Center North (MCN)
Vanderbilt University Medical College
Nashville, TN 37232-2637
tel: 615/343-6306
fax: 615/343-8722
e-mail:
bruce.gellin@mcmail.vanderbilt.edu

IDSA Headquarters
99 Canal Center Plaza
Suite 210
Alexandria, VA 22314
tel: 703/299-0200
fax: 703/299-0204
Internet Address:
info@idsociety.org
Home Page:
http://www.idsociety.org

May 14, 1999

John L. Mica, Chairman
Subcommittee on Criminal Justice, Drug Policy and Human Resources
B-373 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Mica :

Thank you for your interest in the safety of the hepatitis B vaccine. As co-chairs of the Vaccine Initiative, a joint project of the Infectious Diseases Society of America and the Pediatric Infectious Diseases Society, we are particularly concerned about protecting the health of children and families.

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Mr. MICA. Thank you. I recognize now Dr. Waisbren. Is that Waisbren?

Dr. WAISBREN. Waisbren.

Mr. MICA. Senior, FACP. Thank you.

Dr. WAISBREN. I would like to thank this committee for the opportunity to share with them my concerns regarding the vaccination policies of the Centers for Disease Control and Prevention and the Food and Drug Administration.

I am a physician and clinical investigator who has practiced internal medicine, infectious diseases, and immunology in Milwaukee, WI, for 48 years. I am a member of the Infectious Disease Society of America, and I will point out that nobody asked me, as a member, my opinion about this subject. No ulterior motives or special interests are responsible for my being here.

I am here because I feel an injustice has been done to the children of the United States. Included among these children are my 16 grandchildren. I want to make it clear from the onset that I fully support hepatitis B vaccination for individuals who have known risk factors for hepatitis B infection.

My involvement in the field of vaccine toxicity began in 1979 when I discovered that central nervous system demyelination as evidenced by multiple sclerosis had been cause in some individuals by the swine flu vaccine. My involvement was heightened when I found the same thing occurred after hepatitis B vaccination. Incidentally, everything I am saying is documented in this material that I'm going to submit.

These findings have been confirmed by many others and have been extended to include other untoward reactions to the hepatitis B vaccine. Reactions include other autoimmune diseases such as rheumatoid arthritis, optic neuritis, postvaccinal encephalomyelitis, which one of the persons who talked to you has, and possibly juvenile diabetes which you will hear more about.

An autoimmune disease is defined by the fact that it is caused by the body's immune system turning against its own tissue, be it the nervous system, the heart, or the cartilage. Since the discovery of the autoimmune aspects of vaccine complications and confirmation by numerous investigators, I have been searching the medical literature and studying a good number of patients to try to figure out the mechanism or mechanisms by which these autoimmune complications occur.

While many explanations have been suggested, the exact mechanism is still unknown. However, this study of the medical literature of the patients and a great number of the reports sent to the Vaccine Adverse Event Reporting System [VAERS], has convinced me that a serious, probably unique, problem with that exists in regard to the hepatitis B vaccine.

There are at least 16 articles in the peer-reviewed medical literature about the occurrence of diseases of autoimmunity, such as multiple sclerosis, after hepatitis B vaccination. The editors of these renowned medical journals in which these articles appear felt that these cases should be brought to the attention of the medical professions.

There are thousands, yes thousands, of reports by health professionals to the VAERS that adverse events have occurred after hep-

atitis B vaccination. I am aware of dozens of cases brought against pharmaceutical companies because of damage due to the hepatitis B vaccination. Many of these cases have been settled out of court with the proviso that the settlements remain a secret.

The fact that these well-established adverse reactions to the hepatitis B vaccine have not been acknowledged or are being denied by both the CDC and the FDA is the root cause of the concerns that I am to share with you now. The first concern is that caused by the experiment, not the strategy, sponsored by the CDC, which is designed to determine if vaccination at birth of all babies in the United States will eventually decrease the frequency of cancer of the liver caused by hepatitis B infection.

To arrive at the end point of this experiment will take many years. This experiment is based on the following assumptions. One, the vaccine is safe and effective. While the vaccine is effective, we all know that no vaccine is entirely safe as evidenced by the above mentioned information.

The second assumption: I have read that they say that 5 to 20 percent of the people in the United States will eventually contract the hepatitis B infection. I doubt these statistics as I doubt many of the other statistics that have been presented. They mentioned up to 25 or 30 percent of patients with hepatitis B infection cannot remember where they got the disease.

Isn't it understandable that people with risk factors such as multiple sex partners and injected drug use will not be able to pinpoint where and when they were exposed to the disease?

The fourth assumption, and they repeatedly say this: There is no other way to control hepatitis B infection in the United States. Does anyone in this room agree that there is ever only one way to accomplish a purpose?

I hope this committee will ask for an independent analysis of the rationales for the universal hepatitis B vaccination. In looking at the data, they should remember that the reports by the CDC are not peer reviewed and are reports, and that much of the data that is cited were given at symposiums sponsored by medical journals by invited speakers. Therefore they were not peer reviewed.

This brings up my second concern, that is, how can an experiment such as universal hepatitis B vaccinations be adopted nationwide without congressional involvement or approval?

Apparently this was accomplished by the joint efforts of an official of an agency that stood to gain much influence and power by the program and by an executive of a drug company which stood to make billions of dollars by the project. The references in that regard are available to you. What techniques were used and were conflicts of interest involved? Were the rights of parents and children infringed upon?

My third concern lies in the fact that the FDA has apparently not been reacting to the many theories in the medical literature regarding the causes of neurologic complications of vaccination. The FDA does not ask if proposed vaccines exhibit molecular mimicry with human tissue, a possible cause of the difficulty.

They do not ask if a vaccine exhibits complimentarity with common viruses that may be in the patients. Again, a possible explanation. They have not demanded that HLA patterns of patients

who have untoward results be determined. This would react to the question brought up here today of who would get reactions.

They have not encouraged the development of synthetic vaccines that contain only immunogenic antigens and nothing else. I am very concerned that we may see the same or similar adverse reactions to new vaccines.

The new Lyme vaccine is a case in point since that vaccine has more theoretic dangers than does the hepatitis B vaccine because of the autoimmune nature of the disease itself. When the material I have presented here is considered en toto, I believe that it indicates that the present universal hepatitis B vaccination experiment being conducted in the United States should be abruptly halted for the following reasons.

It appears likely that serious untoward events, particularly of the nervous system, involve the vaccine. In view of this, is it reasonable to suppose that some babies who have little or no chance of getting hepatitis B will suffer unnecessary damage to their nervous system?

Three, information regarding the risk-benefit ratio of this vaccine is not known and therefore cannot be given to parents in an informed consent.

Four, there is some doubt as to whether the rights of babies are being violated when they are subjected to an experiment even with their parents' consent.

France has already at least mediated their program of hepatitis B vaccine because of reports about multiple sclerosis following the vaccination. I hope this country will follow their lead. If not, I'm afraid that public confidence in our vaccination programs will decrease, and they are excellent as described by Dr. Katz.

This would be detrimental to the excellent vaccination programs already in place in the United States. I would like to thank the committee again for allowing me to share my concerns with them. Documentation of all that I have said here is available in the supplemental material that I have given this committee. Thank you.

Mr. MICA. Thank you for your testimony and that supplementary material will be made part of the record. Thank you. We will withhold questions until we have heard from everyone.

[NOTE.—Additional information provided by Dr. Waisbren may be found in subcommittee files.]

[The prepared statement of Dr. Waisbren, Sr. follows:]

Testimony before the U.S. House of Representatives Subcommittee on Criminal Justice, Drug Policy and Human Resources

By

Burton A. Waisbren, Sr., M.D.,
F.A.C.P., F.I.D.S.A.

May 18, 1999

I would like to thank this committee for the opportunity to share with them my concerns regarding the vaccination policies of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

I am a physician and clinical investigator who has practiced internal medicine, infectious disease and immunology in Milwaukee, Wisconsin for 48 years. No ulterior motives or special interests are responsible for my being here. I am here because I feel an injustice is being done to the children of this country. Included among these children are my sixteen grandchildren.

I want to make it clear from the onset that I fully support hepatitis B vaccination for individuals who have known risk factors for hepatitis B infection. The risk factors include: sexually active heterosexual adults with more than one sex partner in the prior six months or a history of sexually transmitted disease; homosexual and bisexual men; illicit injection drug users; persons at occupational risk of infection; hemodialysis patients; household and sex contacts of persons with chronic hepatitis B infection; and infants born to hepatitis B infected women.

My involvement in the field of vaccine toxicity began in 1979 when I discovered that central nervous system demyelination (Multiple Sclerosis) had been caused, in some individuals, by the swine flu vaccine. My involvement was heightened when I found the same thing occurred after hepatitis B vaccination. These findings have been confirmed by many others and have been extended to include other untoward reaction to hepatitis B vaccine. Reactions include other autoimmune diseases such as rheumatoid arthritis, optic neuritis, postvaccinal encephalomyelitis and possibly juvenile diabetes.

An autoimmune disease is defined by the fact that it is caused by the body's immune system turning against it own tissue, be it the central nervous system, the heart, or cartilage. Since the discovery of the autoimmune aspects of the vaccine complications and confirmation of this by numerous investigators, I have been searching the medical literature and studying a number of patients to try to figure out the mechanism or mechanisms by which these autoimmune complications occur. While many explanations have been suggested, the exact mechanism is still unknown. However, this study of the medical literature, of the patients, and of a great number of the reports sent to the *Vaccine Adverse Event Reporting System (VAERS)* has convinced me that a serious, perhaps unique problem, exists in regard to the toxicity of the hepatitis B vaccine. There are at least sixteen articles in the peer reviewed medical literature about the occurrence of diseases of autoimmunity such as multiple sclerosis after hepatitis B vaccination. The editors of the renowned medical journals, in which these articles appear, felt these cases should be brought to the attention of the medical profession. There are thousands, yes thousands, of reports by health professionals to the *VAERS* that adverse events have occurred after hepatitis B vaccination. I am aware of dozens of cases brought against pharmaceutical companies because of damage due to the hepatitis B vaccine. Many of these cases have been settled with the proviso that the settlements remain a secret.

The fact that these well-established adverse reactions to hepatitis B vaccine have not been acknowledged or are being denied by both the CDC and the FDA, is the root cause of the concerns I am about to share with you now.

The first concern is that caused by the experiment sponsored by the CDC which is designed to determine if vaccination at birth of all babies in the U.S. will eventually decrease the frequency of cancer of the liver caused by hepatitis B infection. To arrive at the end point of this experiment will take many years.

This experiment is based on the following assumptions:

1. **The vaccine is safe and effective.** While the vaccine is effective we all know that no vaccine is entirely safe as evidenced by the above-mentioned information.

2. **Five to twenty percent of the people in the U.S. will eventually contract hepatitis B infection.** I doubt these statistics.

3. **Up to 25 percent of patients with hepatitis B infection cannot remember where they got the disease.** Isn't it understandable that the people with the risk factors such as multiple sex partners and injected drug use will not be able to pin point where and when they were exposed to the disease.

4. **There is no other way to control hepatitis B infection in the U.S.** Does anyone in this room agree that there is ever only one way to accomplish a purpose?

I hope that this committee will ask for an independent analysis of these rationales.

This brings up my second concern. That is: how can an experiment such as universal hepatitis B vaccination be adopted nationwide without congressional involvement or

approval. Apparently this was accomplished by the joint efforts of an official of an agency that stood to gain much influence and power by the program and by an executive of a drug company which stood to make billions of dollars by the project. What techniques were used and were conflicts of interest involved? Were the rights of parents and children infringed upon?

My third concern lies in the fact that the FDA has apparently not been reacting to the many theories in the medical literature regarding the causes of neurologic complications of vaccination. The FDA does not ask if proposed vaccines exhibit molecular mimicry with human tissue. They do not ask if a vaccine exhibits complimentarity with common viruses that may be in the patients. They have not demanded that the HLA patterns of patients who have untoward results be determined. They have not encouraged the development of synthetic vaccines that contain only immunogenic antigens and nothing else. I am concerned that we may see the same or similar adverse reactions to new vaccines. The new Lyme vaccine is a case in point since that vaccine has more theoretic dangers then does the hepatitis B vaccine because of the autoimmune nature of the disease itself.

When the material I have presented here is considered en toto, I believe it indicates that the present universal hepatitis B vaccination experiment being conducted in the U.S. should be abruptly halted for the following reasons:

1. It appears likely that serious untoward events particularly of the nervous system have followed the vaccination.

2. In view of this, it is reasonable to suppose that some babies who have little or no chance of getting hepatitis B will suffer unnecessary damage to their nervous system.

3. Information regarding the risk/benefit ratio of this vaccine is not known and therefore cannot be given to parents in an informed consent.

4. There is some doubt as to whether the rights of babies are being violated when they are subjected to an experiment even with their parent's consent.

France has already stopped their program of universal hepatitis B vaccination of babies because of reports that surfaced about multiple sclerosis following the vaccination. I hope our country will follow their lead. If we do not, I am afraid public confidence in our vaccination programs will decrease. This would be detrimental to the excellent vaccination programs already in place in the U.S.

I would like to thank the committee again for allowing me to share my concerns with them.

Documentation of all that I have said here is available in the supplemental material I have given this committee.

BURTON A. WAISBREN, Sr. M.D.
F.A.C.P., F.I.D.S.A.*

WAISBREN CLINIC
INNOVATIO SERVATIO SCHOLARIS
EST. 1951

INTERNAL MEDICINE
INFECTIOUS DISEASES
IMMUNOLOGY
IMMUNOMODULATION THERAPY

2315 NORTH LAKE DRIVE, SETON TOWER, SUITE 815, MILWAUKEE, WISCONSIN 53211
TELEPHONE (414) 272-1929

September 2, 1999

Congress of the United States
Representative John Mica
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Representative Mica:

I wish to congratulate you on the hearing. Its balance lent to its credibility. I sent the corrections you requested to Lisa Wandler.

Enclosed with this note is a paper I have recently written and should be published shortly. If you don't mind, I will keep you informed regarding ideas that may help solve the problem of indiscriminate vaccination which will have the net result of damaging the fine vaccination practices in the U.S.

Sincerely,

BAWaisbren

Burton A. Waisbren, Sr., M.D.

*Fellow American College of Physicians • Fellow Infectious Disease Society of America

In Press

UNIVERSAL HEPATITIS B VACCINATION: A MORATORIUM SHOULD BE PLACED ON THIS EXPERIMENT.

By

Burton A. Waisbren, Sr., M.D., F.A.C.P., F.I.D.S.A.

My position is that the program of universal hepatitis B vaccination in the United States (U.S.) is an experiment being performed on our babies. A moratorium should be placed on this experiment until risk/benefit ratios are clearly defined.

First, I will explain why and how this experiment was implemented. I will then analyze the rationales used to sell the program to the public health establishment, state legislatures, and then the pediatricians. I will discuss the methods used to implement the experiment. Finally, I will offer opinions as to why a moratorium on universal hepatitis B vaccination would be beneficial to all concerned.

The concept of universal hepatitis B vaccination in the U.S. was conceived by Dr. Harold Margolis, the head of the hepatitis branch of the CDC and his staff. The concept was based on the following assumptions: Hepatitis B vaccine is safe; the attempt to vaccinate high risk individuals in the U.S. is failing to stem the spread of the disease; five percent or more of the individuals in the U.S. can be expected to get this disease; hepatitis B

infection is spread by those without known risk factors; the "only way" to solve the problem of hepatitis B infection in the U.S. is by universal vaccination of babies.

Let us first examine these rationales.

1. **Hepatitis B vaccination is safe.**

   Safety is not even mentioned in the initial presentations regarding universal hepatitis B vaccination. In later discussions flat assertions are made that the vaccine is safe.

   We all know that no vaccine, medication, or procedure is completely safe. The question always is, how safe? One wonders how the CDC continues to claim safety for this vaccine when they must be aware of thousands, yes thousands, of reports to the Vaccine Adverse Event Reporting System (VAERS) of adverse events that followed hepatitis B vaccination. Included among these are numerous autoimmune diseases such as multiple sclerosis (M.S.), Guillain Barre' Syndrome, and autoimmune arthritis. One wonders how the CDC and FDA continue to reassure the public about the safety of the vaccine when the government program to pay individuals who have had adverse reactions to vaccine has paid out millions of dollars. One wonders how these agencies can continue their claims of safety when they must be aware that pharmaceutical companies have settled millions of dollars worth of claims for "failure to warn" vaccine sufferers about adverse reactions. They did this rather than letting the cases go to trial. Secrecy was always the caveat of these settlements. One wonders how these agencies and pharmaceutical companies continue to make flat statements regarding safety when there are at least twenty

articles in the peer reviewed medical literature about diseases such as M.S. and optic neuritis that occurred after hepatitis B vaccination.

2. **The attempt to vaccinate high risk individuals in the U.S. is failing to stem the spread of the disease.**

   This may well be true but data presented about this is not entirely convincing.

3. **The incidence of hepatitis B infection is such that 5% of the population can be expected to get the disease in their lifetime.**

   The basis for this assertion was a study done by the National Center for Health Statistics entitled the National Health and Nutrition Examination Survey (NHANES II). The values in the NHANES reports were estimates extrapolated from data obtained from 14,488 persons who were chosen as representative of the U.S. population. One wonders about the accuracy of values based on such a relatively miniscule sample (.000054 percent of the population). This concern has recently been voiced in an editorial in the January issue of the *American Journal of Public Health,* which was written by physicians from the CDC. They said: "While these conclusions may be valid, they fail to provide a context that takes into account the sample size limitations of NHANES..."

4. **Thirty percent of cases of hepatitis B occurred in individuals with no known contact to risk factors.**

Evidence used to support this assertion was based on questionnaires sent to sufferers of the disease. Does anyone truly believe that individuals who got the disease from promiscuous sexual activity or drug use would "finger" their contacts on a questionnaire? I could find no other proof of significant lateral transmission in the literature.

5. **Universal hepatitis B vaccination is the "only way" to stem this infection in the U.S.**

Who among us will agree that in science there is only "one way" to accomplish a goal? One wonders why the CDC has not used its energy and influence to see to it that every woman in the U.S. who delivers a baby in a hospital is mandated to have a blood test for hepatitis B (and for that matter AIDS). We hear the argument that this might violate the woman's civil rights. One might wonder about the civil rights of the babies being experimentally vaccinated. Certainly, universal blood testing of pregnant woman would be a way to stem the problem. Wider use of chemotherapy, which even at this early stage, is said to cure a significant number of people with chronic hepatitis B, would be another way to approach the problem.

Parenthetically, the fact that there are multiple ways in which the spread of hepatitis might be blunted makes the endpoint selected to see if universal hepatitis B vaccination is of value illogical. It is stated that we will see if universal hepatitis B vaccination is of value, if twenty-five years from now the incidence of cancer of the liver in the U.S. decreases. Do the proponents of this experiment think that universal

hepatitis B vaccination will be the only factor influencing cancer of the liver in the next twenty-five years?

In view of the questions raised above, one asks: How did the proponents of universal hepatitis B vaccination get their experiment implemented? It seems that one method used was their participation in seminars sponsored by drug companies and published in journals as supplements. This avoided vigorous peer review of the original articles because the presentations were invited. Another method was to get acceptance of the program by national pediatric organizations that apparently accepted the rationales on face value. A third method was the personal visits by CDC members to State Boards of Health. Whatever the methods used, a question can be raised as to how an experiment proposed by an agency of the federal government and supported and published about in pediatric journals by an executive of a pharmaceutical company could have been accepted and implemented by the entire public health establishment and many state legislatures. This acceptance occurred in spite of the fact that the babies vaccinated could not be assured of the time-honored criteria for vaccination, a proven positive risk/benefit ratio.

I submit that the information discussed to this point makes it reasonable to declare a moratorium of the experiment of universal hepatitis B vaccination in the U.S.

This moratorium should be called for jointly by the CDC, FDA, the congressional oversight committees of the CDC and the FDA, and the state and local health

departments. While the moratorium is in place, federal injunction relief should be obtained in regard to the laws forcing babies or children at no risk for hepatitis B to get vaccinated. This would be on the basis of their civil rights being violated.

This moratorium would be good for all concerned.

Babies-This moratorium would protect babies with no risk factors from a potentially dangerous vaccine that has no benefit.

CDC-This moratorium would help the public regain confidence in the CDC. It would give the CDC a chance to rethink their vaccination strategies on the basis of risk/benefit ratios rather than on other theoretical grounds. They would then be able to present to their congressional oversight committees for approval, programs for vaccination initiatives that meet all ethical standards.

FDA-This moratorium should act as a wake up call for this agency to strengthen its VAERS program so that it will be more sensitive to reports of adverse reports received from clinicians. During the moratorium, the FDA also might demand that pharmaceutical companies face up to the theoretical causes of vaccine toxicity. These would include studies for molecular mimicry, studies for complimentarity between viral antigens, and attempts to make synthetic vaccines that only have immunogenic polypeptides.

Pharmaceutical Companies-This moratorium would increase public confidence in their companies. It would also give them time to boost up their reactions to VAERS reports. At present, they seem to shift this responsibility to the FDA. "A firestorm" of lawsuits is developing against these companies for "failure to warn" about complications. Rather than stonewalling these suits or settling them in secrecy, pharmaceutical companies might be better served by accepting responsibility when it is theirs. If they are reticent to do this they might talk it over with their counterparts at Dow Chemical and the tobacco companies. At the end of the moratorium, detailed package inserts should be ready that clearly delineate that the vaccine is to be used only for patients with bona fide risk factors.

State and local health departments-This moratoruim would allow them to reassess their relationship with the CDC to see whether they have been too compliant in following suggestions that may not be applicable to their locale. They might consider whether programs of the federal government that pay them for each child they vaccinate might be clouding their judgement.

Primary physicians-This moratorium will help physicians realize that they might need more information about the risk/benefit ratio before they advise that babies be vaccinated with hepatitis B vaccine. The practitioner who reads this should ask: How many children with hepatitis B have I seen in the past 5 years?

Dr. Margolis has stated that his universal hepatitis B vaccination strategy is to act as the forerunner of future vaccination programs. Already there is a campaign in place for mandatory chicken pox and rotovirus vaccination. Both of these diseases have very effective treatments so there can be serious doubts as to whether a universal vaccination program is indicated.

There will be those who think that bringing reservations such as I have voiced out into the open will be detrimental to the excellent vaccination programs that have been in place in the U.S. for many years. To the contrary, truth never has hurt any program and facing it should only be advantageous to any worthwhile public health effort.

Finally, it should be pointed out that my remarks here only pertain to universal hepatitis B vaccination in the U.S. The World Health Organization has instituted this concept in many parts of the world where the disease is rampant. I have no argument with this program.

A more detailed and documented discussion of this topic is available on my website (http://www.waisbrenclinic.com).

Mr. MICA. Next we will hear from Dr. Bonnie Dunbar, molecular biologist with Baylor College of Medicine. You are recognized.

Dr. DUNBAR. Thank you, Congressman Mica, for your invitation to speak to this committee. I also have a full report and some documentation that I would like to submit.

Mr. MICA. That will be made part of the record without objection.

Dr. DUNBAR. Thank you. I have been a professor at Baylor College of Medicine for approximately the last 15 years, but I have been working in vaccine development for 26 years.

I will get to why I am going to be speaking here, but inasmuch as this is my first time addressing Congress and my time is limited, I have taken the advice of my lawyer, Mike Butler, who is a former chairman of the Federal Energy Regulatory Commission and who has testified on numerous occasions. He suggested I summarize the detailed report that I sent you and follow up with some questions.

Mr. Butler and his wife are here at the hearing today, not as my legal counsel but as concerned grandparents whose grandchild was vaccinated with the hepatitis B vaccine against his mother's specific wishes and became subsequently vision impaired.

With respect to your first question, on the FDA VAERS reporting system and how it works, I have a few comments. I got involved in this issue about 5 years ago when I reported serious and permanent adverse reactions to the hepatitis B vaccine by two individuals working in my laboratory.

One of those is my brother, Dr. Bohn Dunbar, who is currently disabled and has been acknowledged by over 12 physicians to have permanent disabilities due to this vaccine. He could not be here today because of his serious reaction to one of his treatments.

Despite the seriousness of these reactions, there has been no followup to my reports to the FDA adverse reporting system. I have also found that there is no scientific or official mechanism for research scientists studying these reactions to communicate with the FDA or to get adequate information.

I did find out, however, that the thousands of reactions reported to the FDA show the overwhelming correlation with the reactions that I reported to the FDA. I have received hundreds of calls from patients and doctors now about their patients having similar reactions.

What is interesting is that these reactions are also identical to the over 100 published reports of adverse reactions that are currently in the literature. Many of these are in excellent peer review articles, and I have submitted this for the committee's review.

Finally, and I think a big concern, has come from communication with my former medical students. I have been teaching medical students basic sciences for over 15 years. A student told me in tears, on one occasion, that the supervisory physicians in the hospitals have told them not to report vaccine adverse reactions or to get involved.

In one situation, two babies were dying and they were specifically told not to report it. I feel strongly that this reporting system needs to be improved so that we can have a greater impact on vaccine safety.

With respect to the risk benefit issues of infants, you have heard much about this today and I won't reiterate. But from a scientific viewpoint, I challenge any of my colleagues, scientifically or medically, to claim that we understand the newborn immune system.

Without detailed scientific studies to demonstrate vaccine safety, efficacy, and duration of protection for an adult behavior-associated disease, I find it hard to justify wide-scale immunization. In fact, in our animal models, we can easily perturb the immune system of the newborn to cause adverse immune reactions.

With respect to the CDC and pharmaceutical company interactions in conflict, I as well as other people here have overwhelming documentation on organizations receiving funds from drug companies, doctors carrying out clinical trials while being paid handsomely as expert witnesses and consultants for promoting the vaccine, doctors who have switched from being expert witnesses for the plaintiffs that were injured by the vaccines when they got paid more money to become an expert for the drug companies.

Lobbyists have been paid simultaneously by healthcare organizations and drug companies. I recommend strongly that your distinguished committee investigate and evaluate these conflicts of interest, and I have documentation on that that I will be glad to provide you.

Finally, with respect to the informed consent issue, many of our current and former medical school curricula do not emphasize details of immunology, a scientific field which has expanded tremendously within the past two decades. This expansion includes many of the scientific hypotheses which Dr. Waisbren just discussed. These could easily explain the autoimmune problems that are associated with genetic groups of populations in particular.

They can also explain what has not been brought up today by any of the speakers, which I find surprising: the fact that many individuals—depending on the publication as many as 10 percent, and in some reports 30 percent of people—don't even respond and make antibodies to this vaccine.

Therefore, it may be that if we are not following up who is a nonresponder, we may not be affecting the incidence of the disease itself in some genetic populations.

So in summary, no one, especially myself, would ever assert that the hepatitis B virus is not causing serious health problems in the world. However, if this or any other vaccine by nature of the proteins or the parts of that protein, native or produced from a recombinant cDNA protein, has the ability to adversely affect the immune system of large numbers of individuals resulting in severe adverse reactions, even if restricted to some genetic populations, then all of the public reaction to all vaccines including those that we don't have related adverse reactions will be doomed in the public's eye. This includes the development of vaccines to evolving airborne viruses that might become a serious threat to the world population.

Thanks to the success of the Government-funded Human Genome Project and advances in our computer programs, it may soon be possible to evaluate potential molecular structures to predict these problems with the vaccines in advance or in early vaccine development.

In addition to your investigation with adverse reactions to this vaccine, I would urge you to help provide research funds, which are certainly not available now, to study these serious and what appear to be very common adverse reactions to this vaccine as well as other vaccines. I thank you for your attention.

[The prepared statement of Dr. Dunbar follows:]

Dr. Bonnie S. Dunbar
2001 Holcombe, #2401
Houston, Texas 77030

May 12, 1999

Congressman John L. Mica
Chairman,
Subcommittee on Criminal Justice, Drug Policy and Human Resources
United States House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515-6143

Good morning and thank you for this opportunity to discuss these critical health care issues. My name is Bonnie Dunbar, and I am a research scientist and medical and graduate student professor who has worked in the areas of autoimmunity and vaccine development for over twenty five years (the past 17 years at Baylor College of Medicine in Houston).

I have been honored by the National Institutes of Health as the first Margaret Pittman lecturer for my pioneering work in vaccine development. This honor was special for me because Dr. Pittman's contributions were instrumental in early aspects of vaccine development and because I understand the impact that some vaccines have had, and will continue to have, on our society. My ongoing research in the area of vaccine development continues to be a major commitment. I have worked extensively with the US Agency for International Development and the World Health Organization programs and have a life long commitment to carrying out research to understand, and hopefully, to help solving problems associated with world population as well as disease problems.

As I have been invited to speak to this distinguished subcommittee, it is important to discuss my experience with the clearly apparent severe adverse effects of the Hepatitis B vaccine. About five years ago, I had two individuals working in my laboratory who were required to take the Hepatitis B vaccine. Both of those individuals developed severe and apparently permanent adverse reactions as a result of the vaccine. Both of them were completely healthy and very athletic before this vaccine and have now suffered severe, debilitating autoimmune side effects from the vaccine. I have studied the complete medical history of my brother, Dr. Bohn Dunbar, who developed seriously chronic joint and muscle pain, fatigue, and multiple sclerosis-like symptoms. And now he has further been diagnosed with POTS (an autoimmune, cardiovascular, and neurological problem) and subsequently with chronic inflammatory, demyelinating polyneuropathy. His problems have been attributed to the Hepatitis B vaccine by over a dozen different specialists around the United States of unquestionable medical expertise. He has now been rated permanently and totally impaired at greater than 90%. His health care has already cost the state of Texas about a half million dollars in the Texas Worker's Compensation Program to date, and that figure will continue to rise given the severity of his health condition.

My other student went partially blind following her first booster injection, a medical condition that was markedly exacerbated by her second booster that resulted in hospitalization. Personal communications are that her eyesight is continuing to deteriorate. Because she is in

medical school she has been, understandably in my opinion, afraid to pursue investigation into her medical problems because of her concern that they might affect her medical career.

I am extremely sensitive to the need to evaluate the risk vs. benefits of any vaccine. Because of my experience in this area, it became intuitively clear to me that these two active, healthy individuals working in my laboratory developed autoimmune syndromes within a predictable immunological time frame following their booster injections of the Hepatitis B vaccine. After carrying out extensive literature research on the nature of this virus and this vaccine, it became intuitively obvious to me that there is a significant scientific probability that the vaccine is the cause of those adverse reactions. Both the published studies of reactions to viral infection and the temporal relationship of vaccine administration to adverse events suggest strongly that these adverse reactions are related to the nature of the viral protein, the recombinant surface antigen of which is the principal component of the vaccine.

I have been in contact with numerous physicians and research scientists from several countries who have independently described identical severe reactions to the vaccine in thousands of Caucasians. Their observations have been, for the most part, denied or ignored by the public health systems, as is evidenced by the serious charges against healthcare officials and pharmaceutical companies brought recently in France. The reversal of the vaccine mandate for children in France was not based on lack of documentation. I have now been contacted personally by hundreds or more individuals (including parents of infants and children) who have reported deaths, severe health problems and life long disabilities, resulting in major medical costs following the administration of this vaccine. It appears that the adverse events related to this vaccine are within a gene pool that is capable of genetic definition. I respectfully submit that rigorous scientific studies into the possibility that the vaccine can cause severe autoimmune disorders is necessary.

The following points specifically address the issues listed in my invitation to speak to this committee.

1. The Food & Drug Administration has set up a system for reporting adverse reactions to the vaccine. How does this system work? What is being done to study these adverse reactions.

My first experience with this reporting system followed my observation of the two individuals in my laboratory who developed serious medical problems within a time frame predictable for immunological reactions. After seeing that these reactions were listed in the Physician's Desk Reference text as reported reactions to this vaccine, I learned about the VAER's reporting system. When I first called the FDA about this, I was told by an individual that "this vaccine is a problem and it is a big one." I was initially sent some information on reports of reactions that were similar, if not identical, to those of these two individuals. I attempted to initiate a dialogue with individuals at the FDA but was simply told that I could obtain the information under the Freedom of Information Act. I subsequently paid to obtain copies of these documents; and I was overwhelmed by the thousand of pages of documents I received listing thousands of reports, hundreds of which were identical to the reports I had filed for the two individuals working in my laboratory. Unfortunately, the details on these lists were insufficient for studies to critically evaluate the mechanisms by which these reactions occur.

There was no response to my subsequent correspondence with members of this branch of the FDA. (I am aware that the cutbacks in FDA funding may have played a role in this issue.) It became

apparent that the essential medical details (e.g. patient identity, genetic background, family history of autoimmune diseases, etc.) are not provided by this reporting system and that there is no way to contact physicians reporting these reactions. *This information is, therefore, inadequate and not accessible to those of us who are studying the serious adverse reaction events apparently related to this vaccine. It was also apparent that there is no follow-up on these reactions since the two patients I reported were never contacted to evaluate their deteriorating health conditions.*

What was obvious from the information I obtained from the VAERS reports were that there are thousands of reports listing such conditions as neurological damage, arthritis symptoms, and other serious immunological disorders. These are the same types of medical conditions that, in my extensively detailed investigation of the literature, have been published in dozens of medical journals that cite the correlation of this vaccine and severe immunological reactions. (Table of references to be provided at time of hearing). The fact that this reporting system is "passive", i.e. not mandatory, also suggests that only some fraction of adverse events (estimated by FDA officials as 1-10%). In summary it is my opinion that the VAERS system, as currently structured, is highly inadequate to collect scientifically useful information.

I have now been in direct contact with hundreds of severely ill patients (as well as with physicians who have hundreds more patients) having developed adverse reactions to this Hepatitis B vaccine. I feel that it is critical to investigate the early onset effects as well as subsequent development of autoimmune adverse reactions in the hope that we might find more directed treatments to avert the long term effects in those already afflicted with these problems. I believe this is possible in view of new technologies for treatment of autoimmune diseases that are targeted to the identification of specific autoantibodies to defined epitopes.

2. Do the benefits of administering the vaccine to infants outweigh the risks?

To date my studies have concentrated on the adult population. Sadly, even less is known about immunological reactions in infants. especially since they cannot communicate, as can older children or adults, their severe pain, fatigue, or other neurological or physical disturbances. In the event of deaths following vaccination, there is generally inadequate information collected by pathologists to adequately evaluate these reactions.

I would challenge any colleague, clinician or research scientist to claim that we have a basic understanding of the human newborn immune system. It is well established in studies in animal models that the newborn immune system is very distinct from the adolescent or adult. In fact, the immune system of newborns in animal models can easily be perturbed to ensure that it cannot respond properly later in life.

In contrast, it is highly improbable in the US that a newborn has any significant risk of contracting Hepatitis B as a child because the disease is caused by a blood-borne virus. Newborns are not likely to engage in intravenous drug use or promiscuous sex. Nor are they likely to suffer an accidental needle stick, as might a medical worker. About the only way they are likely to be exposed to the disease is by being born to an already infected mother.

In view of this lack of scientific and medical information of neonatal immunology, it is remarkable to me that newborn infants, especially those not at risk for the Hepatitis B disease itself are being administrated multiple injections of this vaccine and that there have been few, if any,

clinical trials to adequately evaluate the potential long term effects of neonatal immunization especially as it relates to genetic diversity.

3. What process does the CDC employ to make a recommendation for a vaccine: What role do pharmaceutical companies play in that process? Do conflicts of interest exist?

As I am not an expert on public health policy, I am not familiar with all of the nuances of policies for recommending vaccine mandates. It is well documented, however, that committee members advising the CDC and members of organizations (such as the American Academy of Pediatrics, and the World Health Organization) obtain substantial funding from pharmaceutical companies. Furthermore, it is well documented that investigators who have carried out clinical trials on this vaccine also benefit personally and obtain laboratory funding as consultants promoting the vaccine and as expert witness in legal conflicts. It is also documented that lobbyists who consult for pharmaceutical companies are the same lobbyists for medical health care providers. I leave it up to this distinguished committee to investigate and evaluate the seriousness of these apparent conflicts of interest.

However, it is also apparent to me that the lack of government funding specified for independent scientists to evaluate adverse vaccine reactions is a major reason for scientists to seek funding for experiments dictated by pharmaceutical companies.

4. What disclosure is required before the vaccine is given? Is it adequate?

It is apparent to me, as it is to many others who have been investigating this issue, that adequate long-term follow-up information was not collected in clinical trials for this vaccine. This is particularly true with respect to the Caucasian population. One might therefore ask: "Is there is sufficient information concerning risks of this vaccine to be disclosed"? The ominous lists of potential reactions listed in the vaccine inserts appear not to be given to patients by their physicians. The physician-patient relationship is fiduciary. That is why the lawyer representing my brother, who had an adverse reaction to this vaccine, made a claim of fraud, a claim which this lawyer says has a strong basis in the Restatement of Torts.

Many physicians and medical students have told me that, if this vaccine is recommended and mandated by government officials, "why should they look at it or discuss it with their patients?" Others have said that their colleagues do not report these incidences because they "don't want to get involved." They further tell me that they have been informed that this vaccine is the safest ever developed because it is a recombinant DNA vaccine and "therefore you can't get the disease". Unfortunately, they have clearly missed a major point of basic immunology. Any peptide (a limited sequence of amino acids of a protein) or a full length or truncated protein (produced by purification from a biological source or using recombinant cDNA technology) when introduced into the body will be "processed by the immune system" and, depending on the nature of that protein, could result in long term autoimmune reactions.

Sadly, in basic science courses in medical schools, many of these details of immunology (a medical research field that has exploded over the last decade) are not taught. I have taught in the basic science curriculum for over 15 years so I am well aware of this limitation. In fact, I recently was invited to speak at the Institute of Medicine at the National Academy of Sciences on this subject. I was quite shocked when a senior member of a national health committee (involved in

recommending mandates for childhood vaccines) came up to me and said: "Very interesting talk. I know you teach beginning medical students. Could you recommend me a basic immunology textbook? I think I need to catch up on some of this immunology stuff."

In summary, it is essential in my opinion that physicians be better educated on the potential risks of this vaccine, as well as the interactions with other vaccines and the increased risks of vaccinations of sick children. It is also critically important to conduct the research necessary so that they will have better information to identify people at risk for adverse reaction. In any event early diagnoses of these reactions will result in more effective therapies.

My colleagues and I have submitted proposals to investigate the scientific bases for these vaccine adverse reactions. Many of these reactions are similar to those reactions from individuals having the virus itself. It is also apparent that there are major histocompatability, genetic linkages among patients who are having the severe reactions. It has already been shown that as many as 10 to 30% have been reported as not developing antibodies when they are vaccinated and, therefore, they may not to be protected from the disease. This non-responsiveness may be attributed to the individual histocompatability genes.

We have proposed to carry out research to determine the long-term prognosis for patients having such adverse reactions for two purposes: (1) Developing a prophylactic strategy of identifying those likely to react adversely so they can avoid the vaccine if at risk; and (2) developing a therapeutic strategy by early and more effective identification of those who have had adverse reactions with the hope of developing more specific therapies. I and my collaborators have well equipped laboratories for state of the art immunological and biochemical analyses and we have already collected blood samples throughout the period of these adverse reactions. We therefore, have unique samples to begin to scientifically pinpoint the reasons for the adverse reactions. We have significant preliminary evidence that may explain these responses and we will continue to seek funding to continue these studies. We have obtained some limited funding from private sources but as yet there are no government funds allocated for studying adverse reactions to this vaccine, so the progress of these studies is slow.

It is apparent that the Hepatitis B virus (and vaccine developed from the Hepatitis B surface antigen) is very unique from many other viruses and vaccines. New theories and experiments (i.e. molecular mimicry and anti-idiotypic antibodies) have been developed which could explain reasons for autoimmune reactions caused by this virus or the viral protein used in the vaccine. (The December 26, 1996, New York Time's article which summarizes studies on "molecular mimicry" theories for viruses causing autoimmune diseases may be right on point.) The fact that there are dozens of publications on the correlation of this virus as well as the vaccine with autoimmune and other connective tissue disorders provides strong evidence for the correlation of this viral antigen causing autoimmune diseases.

In summary, no one, especially myself, would ever assert that the Hepatitis B virus is not causing serious health problems in the world. However, if this, or any other vaccine, by nature of the protein or parts of the protein (native or produced from a cDNA as a recombinant protein), has the ability to adversely effect the immune system of large numbers of individuals resulting in severe adverse reactions (even if restricted to some genetic populations), then the public reaction to ALL vaccines, including those that clearly DON'T have related adverse reactions will be doomed in the public's eye. That includes the development of vaccines to evolving airborne viruses that might

become a serious threat to the world population. Thanks to the success of the Government funded Human Genome Project and advances in computer programs, it may soon be possible to evaluate potential molecular structure to predict these problems with vaccine in advance or early in vaccine development.

I will conclude by relating an observation. In my research on vaccines that have been used for the humane control of animal populations, I have had the opportunity to observe first hand African elephant family behavior. Whenever a baby cries, the entire herd of up to a hundred will immediately trumpet, and charge with great flurry to surround the infant elephant. When it is apparent that there is no danger, they will one by one touch trunks with that infant, ensuring that he is okay before going about their business. They would certainly never allow a single baby or family member to be exposed to unknown danger.

I ask you in your task of investigating our public health system that as do our friends the elephants, listen to the cries of babies (and family members) that might have been adversely affected by this vaccine or who may be at risk. Please demand adequate scientific documentation and medical information to make responsible decisions concerning mandating vaccines for children. In addition to your investigation on the adverse reactions of this vaccine I would urge you to help to provide research funds which are currently not available to study the serious adverse reactions of this vaccine as well as other vaccines.

Thank you for the opportunity to appear before this distinguished subcommittee. I will be glad to answer any of your questions or provide you with additional information you may request.

Sincerely,

Bonnie S. Dunbar, PhD, Professor
Department of Cell Biology
Baylor College of Medicine, One Baylor Plaza
Houston, Texas 77030

Mr. MICA. Thank you for your testimony, and I now would like to recognize Dr. Barthelow Classen, president and CEO of Classen Immunotherapies, Inc.

Dr. CLASSEN. Thank you. I am going to talk about the link between the hepatitis B vaccine and the increased risk of insulin-dependent diabetes. Vaccine policy in the United States is based on safety followup of about 30 days or less, that is, the child is immunized and they are followed for about 30 days for the development of adverse reactions.

We have been studying the long-term effects of vaccines, looking at the development of autoimmune diseases. In particular, our model is insulin-dependent diabetes, a model for other autoimmune diseases.

This is some of our published peer review data. Shown here is a 60 percent rise in the incidence of diabetes in New Zealand following a massive hepatitis B immunization program. You would expect to see a large or significant rise in autoimmunity following an immunization program because vaccines are immune stimulants. They stimulate the immune system. And then when we expect it to cause a rise in autoimmunity, we see this as shown here.

The CDC did some studies to verify our findings which are published. They found, in fact, in their small preliminary study, that hepatitis B immunization, when given after 2 months of life, was associated with almost a 90 percent increase in the incidence of diabetes, very similar to what we found in New Zealand, so confirming our studies.

They also did some work to confirm another one of our studies showing that immunization starting early in life was associated with the decreased risk of diabetes, compared with getting it later in life. And in their study, they showed that the immunization before 21 days was associated with a decreased risk, compared to immunizations starting after 8 weeks of life.

We are doing more studies on the hepatitis B vaccine, but we now have confirming data from other vaccines including the hemophilus influenza B vaccine, another relatively new vaccine. Shown here is one of our studies where we show the incidence of diabetes more than doubled in the United States following the introduction of the hemophilus influenza B vaccine in the Pittsburgh area.

The FDA relies on the VAERS system as well as the Large Link Data base system to look for adverse reactions. Our studies, however, showed that vaccine induced diabetes may not occur until years following immunization as shown here from some data from Finland. The vaccine was given in the first year of life, but the extra cases of diabetes occurred many years later. As shown here, the red curve is higher than the yellow curve as extra cases of diabetes occurred later in life.

Regarding risk benefits, we characterize this quite for hemophilus influenza B vaccine in Finland. We show that there are about three cases of diabetes for every child that would expect to benefit from the vaccine.

The data is not as clear for the hepatitis B vaccine. We don't have as much data. It appears that there may be one case of death from diabetes for every life we save in the hepatitis B vaccine, from

preventing hepatitis B with the vaccine. However, you have to remember the cases of hepatitis B are skewed into certain high-risk groups. So, in low-risk groups, the risk of diabetes, just one autoimmune disease, seem to exceed the benefit of the vaccine.

Cost effectiveness studies do not involve vaccine-induced diabetes. We estimate that there may be 10,000 cases of vaccine-induced diabetes in this country every year costing over $10 billion a year, with cumulative liabilities reaching maybe $250 billion.

Now, the U.S. law requires vaccine manufacturers to demonstrate safety prior to the vaccine being placed on the market. However, we have proven that safety has never been demonstrated for this vaccine, yet many kids are being forced to be immunized. We attribute this to conflicts in interest.

Our proposal is that first of all, there needs to be equal access to the Large Link Data base. Scientists representing the parents as well as the established medical community need to have access to that Large Link Data base. There needs to be more testing on the effect of vaccines on diabetes and autoimmunity.

Parents need to be aware of toxicity studies in animals and in humans linking vaccines to diabetes. Parents also need to be aware that funds are not available to cover many adverse reactions and the development of safer immunization technology that needs to be made a priority above developing new vaccines.

Mr. MICA. Does that conclude your testimony?

Dr. CLASSEN. Yes.

Mr. MICA. Thank you.

[The prepared statement of Dr. Classen follows:]

J. Barthelow Classen, M.D., M.B.A.
President and Chief Executive Officer
Classen Immunotherapies, Inc.
6517 Montrose Avenue
Baltimore, MD 21212 U.S.A.
Tel: (410) 377-4549 Fax: (410) 377-8526
E-mail: Classen@vaccines.net

May 17, 1999

The Honorable John L. Mica, Chairman
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy, & Human Resources
Washington, DC 20515

Dear Congressman Mica,

Thank you for the opportunity to discuss my findings on the association between hepatitis B vaccine and insulin dependent diabetes. I want to state that as a physician I have received the hepatitis B vaccine and believe it is a potentially useful tool for reducing the risk of hepatitis in certain high risks groups such as health care workers exposed to blood products. I am however opposed to universal hepatitis B immunization of the general public because the risks are greater than the benefit when the vaccine is given starting after 8 weeks of life.

The US government approves vaccines for marketing and makes universal immunization recommendations based on safety studies which typically follow patients for 30 days or less post immunization. Our research involves studying the risk of autoimmune induced diabetes in people immunized with certain vaccines and in control populations which do not receive the vaccines. Our results show that the risk of immunization with several recommended vaccines including the hepatitis B vaccine are likely to exceed the benefits of immunization in low risk groups and the adverse events may cost US citizens over $10 billion a year as I will discuss later.

Our research has focused on the effect of vaccines on insulin dependent diabetes (diabetes), an autoimmune disease. An autoimmune disease is a condition where a person's immune system destroys their own tissue. The effect of vaccines on the development of diabetes are expected to reflect the effect of vaccines on other autoimmune diseases. Vaccines are immune stimulants and would thus be expected to increase the risk of autoimmune disease. We found that the incidence of diabetes rose 60% in New Zealand following a massive hepatitis B immunization program (1). The CDC initiated a study to verify our findings. Their preliminary data has been published and shows hepatitis B immunization when given starting after 8 weeks of age is associated with a 90% increase in the risk of diabetes (2), supporting our findings. The study also indicated immunization starting within 21 days of life was associated with a decreased risk

of diabetes compared to immunization starting after 8 weeks of life, which also supports our findings (3).

Currently we are attempting to collect additional data on the hepatitis B vaccine as well as data on other vaccines. Our data shows the hemophilus vaccine is likely to cause diabetes (4) and we have confirmed a rise in diabetes in the US (5) and UK (6) following the introduction of the hemophilus vaccine.

The FDA can tract vaccine adverse events through both the VAERS system and the Large Link Database. The VAERS system relies on voluntary reporting of adverse events shortly after immunization. Our data on diabetes shows that vaccine induced diabetes may not occur for 3 or more years following immunization. The Large Link Database is thus an essential tool for monitoring adverse events.

Our data shows the risks of several vaccines are likely to exceed the benefits in low risk groups and cost US citizens over $10 billion a year. Our recently published data (4) shows that for every child that may have a prolonged benefit from the hemophilus vaccine, 2 to 3 children may develop vaccine induced diabetes. There is less accurate data to compare the risks and benefits of the hepatitis B vaccine. However, there are reportedly about 4,000 to 5,00 deaths each year attributed to hepatitis B. If we immunized every child after 8 weeks of life with the hepatitis B vaccine there may be an extra 4,000-5,000 cases of diabetes per year. All told we estimate that there are over 10,000 cases of vaccine induced diabetes in the US each year. On average each case may cost $1 million in lost productivity and medical expenses. The estimated liability cost of the vaccine induced diabetes is over $10 billion per year. The current cumulative liabilities to the US government and to manufacturers could exceed $250 billion.

US law prohibits the marketing of vaccines until they have demonstrated safety. We have proven the hepatitis B and other vaccines do not meet this standard yet they are on the market and children are being forced to receive them. I attribute this to the numerous conflicts of interests in those who are regulating vaccines and setting policy. Let me give you just one example.

I attended a meeting where a senior vaccine executive, and former federal employee, was repeatedly stating to the audience that his company's vaccine was proven to be safe. I discussed with a senior FDA employee who attended the meeting that I was disturbed by how the vaccine executive over stated the safety of his product and how I believed that US law prohibited manufacturers from making false claims about their products. The FDA employee agreed but stated it was so hard to enforce the laws. Later this former FDA employee began working for an vaccine manufacturer. Both his employer and the vaccine executive's employer have a financial interest in the hepatitis B vaccine.

Several changes need to be made to the current policy. Independent researchers representing parents need to have equal access to the large link database as those representing the interests of the established medical community. Manufacturers need to perform long term testing of their vaccines on the development of diabetes and other autoimmune diseases. Parents need to be informed of animal toxicity data (7) and epidemiology data linking vaccines to diabetes and

that the age when the first dose is given may affect the risk of diabetes. In addition parents need to be informed that there are insufficient funds to cover expenses of many vaccine adverse events. Development of safer immunization technology should be given priority over the development of new vaccines.

Thank you for the opportunity to present our views and data on this important issue.

Sincerely,

John Barthelow Classen MD

J. Barthelow Classen, M.D., M.B.A.
President and Chief Executive Officer

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Mr. MICA. Dr. Katz, you said that you felt there were some irresponsible statements being made, either in testimony or with this hearing. You have just heard several witnesses here testifying. Would you like to comment on anything they have said?

Dr. KATZ. I hate to be put in a position of being a critic, but let me give you one example.

Mr. MICA. Go right ahead. That's why we have you here.

Dr. KATZ. Thank you. Dr. Classen quoted all of these data, for example, from Finland. A meeting was held sponsored by the National Institutes of Health, including the physicians and the epidemiologists from Finland who had accumulated those data, including experts on diabetes, experts on vaccines, experts on immunology, experts on genetics.

There was unanimous agreement that there was no indication whatsoever that there was any relationship of immunization to the onset of insulin-dependent diabetes mellitus. Dr. Classen was a participant in that meeting. If there was a vote, it was 128 to 1, and he was the one.

I am not one who is here to analyze Dr. Classen's presentation, but only to tell you that the government in the form of the NIH, and the CDC, the Vaccine Safety Institute of Johns Hopkins, the Infectious Disease Society's Vaccine Initiative, all put up the funds to sponsor that meeting.

Everyone was given a chance to present, including Dr. Classen, and there was absolutely no support for his theory, his hypothesis. Hypotheses are fine, but you have to accumulate the scientific data to substantiate your hypothesis. At least with the diabetes data, Dr. Classen has failed to do that in the opinion of worldwide experts.

Mr. MICA. I don't want to get into a debate, but I did want to hear your response on that. One of the things that you just mentioned is that we rely on data and the need to study and we had the CDC, Dr. Margolis, we had the FDA representative here.

They said that they felt this whole matter about efficacy, about adverse effects and others, needs additional study. They said that there are some number of them going on, have been going on. I think they said seven, and additional. Do you support that continued review?

Dr. KATZ. Absolutely. I would be the last to say that there isn't information which we don't yet have regarding vaccines, regarding the etiology of autoimmune diseases, similarly to the multiple sclerosis question.

The World Health Organization held meetings to discuss this very issue. They were attended by immunologists, neurologists, experts on multiple sclerosis, epidemiologists, vaccineologists. And they concurred that there was no evidence that multiple sclerosis was in any way related to the receipt of hepatitis B vaccine.

Now, I would be very quick to say that if Dr. Dunbar or others have theories that they can put to scientific test, we should be supporting that type of experimentation. We don't ever have the ability to prove the null hypothesis.

What we don't know today we may know tomorrow. I don't mean that we should be complacent, but until we have some scientific,

concrete evidence to support these hypotheses, I don't believe that we should be taking actions based on these.

Mr. MICA. In your written testimony, you said there is absolutely no need to set aside special funds for independent vaccine safety research, and you felt that there was also inadequate——

Dr. KATZ. I think that you are taking that out of context, Mr. Mica. What I was saying was that money that is set aside for safety research should be set aside through the peer review process; that if the NIH or others have grants submitted to them to make these investigations that——

Mr. MICA. You felt that that was adequate——

Dr. KATZ. That they provide the peer review.

Mr. MICA. Again, I don't want to take anything out of context, but do you feel there is adequate funding, adequate opportunity for research for this area? Or is this something that Congress is neglectful of and that warrants additional attention?

The reason for this hearing isn't to scare anyone about vaccines. The reason is to find out if we are doing what we need to do. I have been in Congress since 1993. I have never had so many requests to be heard on an issue since I came to Congress. We merely try to respond and try to do it in a balanced fashion and then see if we are doing our job.

So my question is, are there adequate funds? Are there adequate resources? Funds, believe it or not—the NIH is in our oversight responsibility and legislative responsibility. What do you think?

Dr. KATZ. It's always easy to sit outside of Congress and tell you how to spend your money. Let me say this: as a member of the Advisory Commission on Childhood Vaccines—that is the committee that is the oversight committee for the program, the National Vaccine Injury Compensation Act—we report directly to Secretary Shalala.

There is an excise tax that that act put forth which is levied on every vaccine that is produced and distributed. That excise tax is used to accumulate the funds to reimburse families and children who feel that they have, under the judgment of independent medical review, that these are legitimate adverse events that have happened due to vaccines.

Those funds are managed very wisely and very judiciously to the extent that there has now accumulated over $1 billion in a trust fund which is apparently inviolate unless you do something in Congress to make that available. Those billion dollars could very well be used to fund a number of studies such as those you are hearing requested today.

Mr. MICA. That's your suggestion. Now, Dr. Dunbar, you were very specific in your testimony when you advocated additional studies and research and funding.

Dr. DUNBAR. Well, first of all, I would like to make two comments about the studies that we have heard about all day including those I think a lot of scientists are calling, the "phantom WHO meeting" studies.

For 5 years I have been asking questions of people and I have been quoting these studies. None of us scientists could get that data. If this committee could get that data for us, many of us would appreciate that. The other thing is that, in many of those studies,

it has become a semantics game. For example, where everyone is saying that this is not multiple sclerosis. Most of these cases, thousands of cases, we are looking into are not MS.

We have to look at the broad range of autoimmune diseases. Most importantly, from the grant funding point of view. I myself have been a standing member of NIH subcommittees and I am well aware of the politics right down the road here. When you send in a grant on this topic, it goes to one of the vaccine committees where everybody on the committee develops vaccines.

Most of those people are working with the pharmaceutical companies. There is a great prejudice by many scientists on those committees against anyone saying anything negative about a vaccine. I believe strongly and so do my other colleagues, such as Ron Kennedy in Oklahoma and Willy Hildebrand, who is head of the National Bone Marrow Association Program, who are helping us, that funding is needed.

Now, fortunately we have private funding for this. But I find it sad that we have to get private funding, and that government funding is not supporting this, particularly when there are so many vaccine mandates out there.

Dr. WAISBREN. May I just make a comment?

Mr. MICA. Dr. Waisbren.

Dr. WAISBREN. I think we all agree there have to be more studies. But I think we have to admit that people like the vaccine advisory groups, the CDC, and the FDA have a conflict of interest. They have been pounding the drum for universal vaccination for 10 years, and they have made every attempt to denigrate results to the otherwise.

They have used institutions, such as the Institute of Medicine, as their evidence that nothing has happened. I think that the hope would be that a committee such as yours would be able to have an independent investigation of the statistics upon which the universal hepatitis B vaccination experiment is based to see if you can believe that they are adequate by a statistical group that has no conflict of interest.

Mr. MICA. Dr. Katz, we heard from some folks before in a panel, one lady in particular, who I think medically has been able to verify that through the vaccination she has suffered adverse reaction and it has caused some problems.

Dr. KATZ. Are you talking of Ms. Fluck?

Mr. MICA. Yes. She has not applied to the fund account that was set up.

Dr. KATZ. I asked her husband why she hadn't.

Mr. MICA. One of my concerns—and again I hope that we are not acting irresponsibly, but it's 13 years since we passed the legislation that provided compensation for those that are adversely affected. We have $1 billion in the funds, and we are getting complaints that people aren't getting compensated or feel that they have access to be compensated. That's one problem.

The other problem is that they are saying they are having difficulty in determining the causal relationship and verifying that it is a result of the immunization.

Maybe you could comment on this. Is the fund operating properly? And then the problem of getting access to the fund and verifying cases.

Dr. KATZ. I think it would be very helpful to you if you talked to the people who run the fund. The committee of which I spoke is actually called a commission, not a committee, and is chaired by a gentleman whose child was the victim of an adverse event. The parents who sit on that committee are all of that ilk. The attorneys who sit on that committee are the attorneys who pursue these cases on behalf of plaintiffs who feel that they have been injured.

So, if it is a biased committee, it's biased in favor of those who feel that they have been adversely affected. There are only 3 of us out of 10 on the committee, actually 2 out of 10, who are physicians. So it's not a physician-dominated committee. There is only one from the pharmaceutical industry on the committee, one representative. So the majority are the very people from whom you heard today.

I would urge you to talk to Dr. Geoffrey Evans and Mr. Tom Balbier who are the two people who run that program. They issue a regular report every 3 months documenting the number of cases heard, the adjudications, and the awards made. I think that the program is working very well.

There is one problem, and that is, sometimes people aren't aware of it. Every effort is being made to promulgate the information so that families who feel that they have had an adverse event will know how to file before this committee. They have cutoff the grandfather clause. It used to be that you had to report within X number of years. They have extended that to longer and longer durations so that families that hear about it late are not cutoff because it's too late. I don't want to bore you with all of this.

Mr. MICA. No, that's exactly what we wanted to hear. We set up the fund and want to know if it was working.

Dr. KATZ. I think it is working wonderfully well.

Mr. MICA. And you have made some changes that you described at length in the eligibility. You also cited through your testimony that the fund has accumulated more funds than anticipated, and one of your recommendations—and I don't want to take words out of your mouth—is possibly some of these funds could be used for research. Is that correct?

Dr. KATZ. That's exactly what I hoped to say, yes. I think that the issues relating to the whole area are reviewed regularly. Dr. Waisbren mentioned the Institute of Medicine. The Institute of Medicine isn't funded by the pharmaceutical industry or by any other conflict. It is part of the National Academy of Sciences, which you and Congress set up under Abraham Lincoln, a Republican President, to provide advice to the government about unbiased scientific issues.

Mr. TIERNEY. I just thought that he and Abe were working in tandem at the same time.

Mr. MICA. I know him well.

Dr. KATZ. That group is one that reviews regularly the issue of vaccine-associated adverse events. It's so strict in its membership that any of us, if you will, us in an editorial fashion, who work with

vaccines can't be members of that committee because they don't want to have the bias that Dr. Waisbren feels is exerted.

There are immunologists, there are epidemiologists, there are people who are knowledgeable about science but who aren't biased by being proponents of vaccines.

Mr. MICA. I want to give the others an opportunity to respond. Dr. Dunbar.

Dr. DUNBAR. Well, obviously, I am not a lawyer and neither is my colleague, Dr. Katz, but there are clearly some issues on the Vaccine Compensation Act, and there are some lawyers in the room who I know can deal with that issue. One point is, I believe, there is some problem with the fact that after this summer, people who had the hepatitis B vaccine are going to be restricted from even filing. So, there clearly are some problems. I am not familiar with that, and I think that might be a good subject for a whole other hearing.

Mr. MICA. Dr. Waisbren, did you want to comment?

Dr. WAISBREN. I just wanted to make one comment about the Institute of Medicine. I have gone over their material carefully. They have said often, we cannot prove that the vaccine causes any difficulty. They also mention that they can't prove that it doesn't. So the question is open.

But time and time again, I hear people saying the Institute of Medicine says that the vaccine doesn't cause any trouble. So they cover themselves with the fact that they haven't proved that it does occur. All their study is, if you read in their books, is they have not proven that it doesn't hurt anybody.

In view of that, I think that the jury is out. As far as the members of that committee, I beg to differ. I corresponded with them, and there are vaccine proponents in Seattle and other places in the country.

Mr. MICA. Dr. Katz, I see you nodding.

Dr. KATZ. I keep prolonging this. The Institute of Medicine task force categorizes vaccine-associated injuries in several ways. One is what Dr. Waisbren has said, that is, that we can't prove that this is associated or not. Those are obviously the ones where a red flag goes up and where further investigation is needed.

There are others where they say, yes, definitely. This association is correct. Thrombocytopenia after measles and rubella vaccine is an example. There are others where they say, we can state definitively there is no association. So, they don't just categorize things one way or the other. They have a gradation.

Mr. MICA. Thank you. I'm going to yield now to Mr. Tierney, the gentleman from Massachusetts, for questions.

Mr. TIERNEY. Thank you, Mr. Chairman. Thank you to the members of this panel for their testimony. Let me ask generally just to get a feel for your opinions on this. Assuming there were studies or studying whether or not the hepatitis B vaccine might cause other types of issues or problems, are you all of a mind that we should stop giving this vaccine in the interim period while waiting for the results of these studies?

Dr. CLASSEN. I believe very strongly. I am a physician. I have been immunized with the hepatitis B vaccine, and in certain high-

risk categories I agree with Dr. Waisbren that, in fact, it may have some utility.

However, I think the forced immunization of children which is going on when, in fact, the risk may exceed the benefit as some of the data suggest, that again, I think there is a real problem there with forcing people to be immunized.

Mr. TIERNEY. Thank you. Dr. Dunbar.

Dr. DUNBAR. I concur. I think there are some high-risk groups, particularly as we are looking into the genetic populations where in some particular parts of the world genetically, some people are more likely to have a reaction to the vaccine and others in other countries or parts aren't.

But certainly for high-risk categories I see no problem. But we need to have more studies to find out who is going to be in the high-risk categories.

Mr. TIERNEY. Thank you.

Dr. WAISBREN. I believe very strongly that my grandchildren, who aren't as yet sexually active or alcoholics or any of those categories, do not have a significant chance of getting hepatitis B. And I think that the data that suggest that they are, when you examine it, is not there.

If, at the age of 12, they are wild, I would have no objection to them getting it. But to assume that they are going to have trouble these first few years of life I think is fallacious.

Mr. TIERNEY. Just before I left Dr. Katz, are you saying, Dr. Waisbren, that those are the only people that can contract hepatitis B?

Dr. WAISBREN. I say that the figure of this 30 percent is a red flag that cannot be established. I think it is done by a questionnaire of people who are blood donors. I suggest that a statistician go over the paper in which the CDC claimed that in 30 percent of hepatitis B cases, there is no evidence that risk factors are involved. The data in this regard appears to come from a questionnaire sent to hepatitis B patients in only four counties in the country. In my opinion, there is no credible evidence that what we call lateral spread of this disease occurs in any but extremely rare instances.

Mr. TIERNEY. Thank you. Dr. Katz, could you respond to both of those questions?

Dr. KATZ. Obviously, I disagree with my three colleagues. Let me see if I can remember the questions. First of all, regarding the use of the vaccine in very young children: I think I find Dr. Classen inconsistent. On the one hand, he is saying we should give the vaccine before 21 days of age. We give it to newborns. That's well before 21 days of age! I don't know how that adds up. That's apples and oranges.

Second, I think the issue of the 30 percent is a very real one. You heard one parent today. But that's only one parent. There have been very good studies to which Dr. Margolis alluded. In Alaska, children under the age of 10 have a very high rate of carrying the hepatitis B virus before they were sexually active. They had no injectable drugs. There were no apparent causes other than close living quarters where there were a lot of people who were chronic carriers.

Since the institution of the hepatitis B vaccine program in Alaska, which is 1 of our 50 States, there has been no child under the age of 10 in the 10 years since that program has been in place in the seven villages that they monitored, who has acquired hepatitis B carrier state.

I think that the vaccine as it is currently available and utilized is appropriate. I do not say that we shouldn't continue to study, but I think to halt the program at this point, which is eminently successful, would be a serious mistake.

Mr. TIERNEY. You mentioned, Dr. Katz, that the system to assure the vaccines are safe and effective is always improving. I think you said that during your testimony. What recommendations do you have to make to us about improving the system further?

Dr. KATZ. I think there is a vaccine branch of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health. I think they have a vaccine study section to which Bonnie alluded. I think that an infusion of funds that were deliberately aimed and targeted—I know that you don't like to target funds at NIH—but if you spoke to Dr. Varmus and to Dr. Fauci and explained to them what you saw as to the severity of this problem, never mind its magnitude but just the severity of concern on the part of the people that we have heard today, that there has to be an acceleration of research aimed to investigate these hypotheses. Individuals who are proven investigators can conduct peer-reviewed research. Then you would get some further action much more rapidly.

Mr. TIERNEY. Thank you. Dr. Dunbar, am I correct in understanding that you believe, or have a belief, that Caucasians may be susceptible to the side effects of the hepatitis B vaccine?

Dr. DUNBAR. We are actually doing some genetic studies to try to nail this on the head, as it were. But of the literally hundreds and thousands of people who have contacted me or doctors, so far they are all Caucasians.

I feel that if this is just vaccine hysteria, we wouldn't be seeing this kind of relationship. And they are all of the same types of people that I am studying. In particular, of the hundreds we have, they were perfectly healthy and they took the vaccine and now they are debilitated for life.

The other concern is not just the people that are having the adverse reactions. Dr. Katz has alluded to the group in Alaska where there is a high group of chronic carriers. We also know in Asia, where a lot of the clinical trials were done, you don't see adverse reactions. But this is a different population that we know "genetically" responds differently to the virus itself.

In fact, another point that was not brought out today is that 95 percent of the people that get the virus don't even have the flu or don't even know they are sick. So a lot of people respond normally without having any long-term side effects.

What we don't know about the whole vaccine itself, which Mr. Mica referred to this morning. We don't know a lot about why the different genetic populations respond differently with respect to the disease itself, let alone why the people with adverse reactions that we are seeing are responding with respect to the genetics. It was curious to me at the Institute of Medicine meeting at which I was

invited to speak that, when we asked about all of these new studies that are being done, I said ''great,'' we have the genetic data so we can break this out. They said, oh, no, we can't ask those questions.

So even though these studies are ongoing, we are not going to get the data we need. We need to have those studies where we can take into account the genetic populations in what we are seeing. So from what I could see of what they outlined at the Institute of Medicine, the studies that are in the works or are being planned are not going to be sufficient to evaluate these serious adverse reactions.

Mr. TIERNEY. Thank you. In the testimony there was reference to a molecular mimicry hypothesis. Could somebody there explain to me the relevance that that hypothesis has to the hepatitis B vaccine safety?

Dr. WAISBREN. When you look back as we developed—and I will try to make this brief—is that all living things have certain proteins that are of advantage to them whether they be viruses, bacteria, or humans.

So we have to assume that certain proteins are held in common by humans and bacteria and viruses. If those proteins are similar enough, when you inject a virus into a person the body will mistake that protein for itself and make antibodies or T-cells against the body itself, rather than the proteins in the virus.

It has been shown that in the hepatitis B virus, for instance, there is molecular mimicry between myelin, which is involved in multiple sclerosis, and the hepatitis B vaccine.

There are studies that should be done and have been done by the people of Harvard in which if you give a vaccine, you can find out whether or not antimyelin T-cells are circulating. This would be one easy way of studying vaccine toxicity. I recommended that to the Institute of Medicine 3 years ago at one of their meetings, and it just fell on deaf ears. So those sorts of things should be done.

Mr. TIERNEY. Thank you.

Dr. CLASSEN. Can I add one point, though? Molecular mimicry is only one hypothesis. In fact, there are probably several mechanisms of reactions. We are seeing increases in diabetes with many different vaccines which suggest that, in fact, there are other mechanisms as well.

Just giving Interferon, plain Interferon, to patients who are diseased increases the risk for autoimmunity including diabetes. Vaccines are known releasers of Interferon. So just by generally stimulating the immune system you would expect to see a wide range of autoimmune diseases following immunization.

Mr. TIERNEY. Thank you. Dr. Katz, would you like to say something?

Dr. KATZ. I was only going to say that there is no doubt, as Dr. Dunbar has pointed out, that there has been enormous advance in the field of immunology. There are now very large grants from the National Institutes of Health to diabetes centers around the country to look at the question of autoimmunity and what are the inductive factors.

In other words, diabetes, childhood juvenile diabetes, insulin-dependent diabetes may be an autoimmune disease. What is not un-

derstood is what is the trigger that sets off that autoimmune disease.

We are being besieged day and night by things that you inhale, by things you ingest. It isn't just what you inject with a vaccine. There are all sorts of proteins and carbohydrates, all sorts of antigens to which you and I are subject day and night.

To single out vaccines as the only target is being somewhat parochial. I assure you that these study programs that the NIH is now funding on diabetes will be looking at vaccines, at acquired infections and many other possible stimuli. To date there is no evidence that vaccines are the culprits.

Mr. TIERNEY. Thank you.

Dr. WAISBREN. There have been official pronouncements by the National Diabetes Association and by the Multiple Sclerosis Society that juvenile diabetes and multiple sclerosis do not occur after the hepatitis B vaccination. You wonder what influences these national organizations to make these statements in view of information discussed here and in the world literature.

Dr. DUNBAR. Just one quick comment, if I may. My medical student who has just taken her exam and is graduating today said that they had to learn an answer for the exam this year. The question in the study guide was, "what is the safest vaccine ever made?" and the answer was the hepatitis B vaccine.

So it's already infiltrated. Even without saying we haven't done these studies, the medical students are already being told in their minds that this is the safest vaccine ever made, yet we don't have any long-term followup clinical trials.

Dr. CLASSEN. I would like to make one point. I submitted additional testimony, written testimony, which I hope you will accept, and also I hope that you will look into the conflict-of-interest issues, as well, as described in my testimony.

[The prepared statement of Dr. Classen follows:]

J. Barthelow Classen, M.D., M.B.A.
President and Chief Executive Officer
Classen Immunotherapies, Inc.
6517 Montrose Avenue
Baltimore, MD 21212 U.S.A.
Tel: (410) 377-4549 Fax: (410) 377-8526
E-mail: Classen@vaccines.net

June 10, 1999

The Honorable John L. Mica, Chairman
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy, & Human Resources
Washington, DC 20515

Dear Congressman Mica,

Thank you for the opportunity to present my views and data on this important issue. I have enclosed copies of slides I presented at the meeting.

I have reviewed a transcript of the meeting and wanted to make several additional points to my written testimony which was already submitted.

1. Dr. Samuel Katz

Dr. Katz made statements pertaining to my research that were inaccurate and misleading which I want to address. According to my memory and a transcript of the meeting Fr. Dr. Katz said the following:

" Dr. Classen quoted all these data, for example, from Finland. A meeting was held, sponsored by the National Institutes of Health, including the physicians and the epidemiologists from Finland who had accumulated that data, including the experts on diabetes, experts on vaccines, experts on immunology, experts on genetics. And there was unanimous agreement that there was no indication whatsoever that there was any relationship of immunization to the onset of insulin-dependent diabetes mellifluous. Dr. Classen was a participant in that meeting. If there was a vote, it was 128 to one. And he was the one. Now I am not one who is here to analyze Dr. Classen's presentation, but only to tell you that the government, in the form of the NIH, the CDC, the National -- the Vaccine Safety Institute of Johns Hopkins, the Infectious Disease Society's Vaccine Initiative all put up the funds to sponsor that meeting. Everyone was given a chance to present, including Dr. Classen. And there was absolutely no support for his theory, his hypothesis.

Hypotheses are fine. But you have to accumulate the scientific data to substantiate your hypothesis. And at least with the diabetes data, Dr. Classen has failed to do that, in the opinion of worldwide experts."

Dr. Katz' s testimony grossly misrepresents what transpired at the meeting held May 14-15,1998. There was debate however there was no unanimous agreement. The fact is there was no vote, contrary to what Dr. Katz stated, and without a vote it is grossly misleading to state or imply a unanimous agreement. Furthermore Dr. Katz makes misleading statements about the acceptance of my findings. My research has been published in many different journals. Scientific and medical experts have reviewed my data and found it suitable for publishing. Several researchers at the May 14-15 meeting presented data supporting my data. A meeting was held on March 20,1998 by the Johns Hopkins, Institute for Vaccine Safety, which was funded by pharmaceutical companies hostile to my findings. Scientific experts attended the meeting and were asked to sign a consensus statement condemning my findings. The experts refused. No consensus was reached. Many of these same scientific experts were at the meeting mentioned by Dr. Katz which was held several months later. If a vote was taken these experts would have likely drawn the same conclusion and not reached a consensus.

2. Dr. Harold Margolis

In his written testimony Dr. Margolis seems to contradict himself.

He states "Fortunately, we have a **safe** and highly effective tool to prevent the transmission of this destructive and often deadly virus. We have a vaccine that provides long-term protection and prevents liver cancer. Both pre- and post-licensure reviews have shown that hepatitis B vaccines are among the safest vaccines we have."

However he admits that proper safety studies have not been performed, only short term safety studies have been performed.

"In addition, a number of studies have examined various vaccination schedules and dosages and all have documented **short-term vaccine safety**."

"Nevertheless, the CDC is committed to continuing the evaluation of the safety of hepatitis B vaccine in a careful, scientific fashion. Ongoing studies are investigating whether other alleged adverse events are associated with vaccination, including multiple sclerosis and other demyelinating diseases, diabetes mellitus, rheumatoid arthritis and other autoimmune disorders."

How can a product be safe if proper safety studies have not been performed? It is clearly premature to say a product is safe if safety has never been adequately tested. Safe is defined as free from injury, danger or risk. Clearly this is criteria is not met so the hepatitis B vaccines are unsafe by definition.

Dr. Margolis furthermore fails to mention two US government studies which link immunization with the hepatitis B vaccine to autoimmune disease. In one government study the

results showed a clear association between hepatitis B immunization and the development of autoimmune hair loss called allopecia (1). In a second government study the results support my finding of a large rise in diabetes mellitus linked to the hepatitis B vaccine (2). Again it is clear the vaccine has not been shown to be safe and is thus inherently unsafe.

Dr. Margolis also commented on the Hepatitis B vaccine policy in France. His testimony was misleading and failed to acknowledge the magnitude of the safety concerns in France which lead to the discontinuation of the hepatitis B school immunization program. The program was discontinued because of concerns that the vaccine causes autoimmune diseases in particular neurologic diseases. The CDC's own website contains links to the World Health Organization's (WHO) press releases on the subject. The WHO acknowledges that the motivation for discontinuation of the school Hepatitis B immunization program in France was concern regarding autoimmune neurologic diseases **(exhibits 1, 2).**

References:

(1.) Wise RP, Kiminyo KP, Salive ME. Hair loss after routine immunization. JAMA 1997;278:1176-8.

(2.) DeStefano F, Okoro C, Graffander P, Chen RT. The timing of hepatitis B immunization and risk of insulin dependent diabetes mellitus. Pharmacoepidemiology and Drug Safety 1997;6 S2:S60.

3. Dr. Susan Ellenberg

In her written testimony Dr. Ellenberg states: "Nevertheless, like all other medical products, vaccines are not entirely risk-free. While serious complications are **extremely rare**, they can occur. Since there is virtually universal exposure of our population to vaccines, it is important to identify even these **very rare** adverse reactions."

According to a transcript of the meeting she stated "There're (vaccines) extremely safe."

Dr. Ellenberg is aware of my data that large rises in diabetes have occurred following immunization. She is aware that the studies performed by vaccine manufacturers and public health organizations are insufficient to detect adverse events like diabetes which may occur years after immunization. She has admitted publicly that vaccine safety studies need to be larger in order to detect adverse events. How can vaccines be declared safe without performing proper long term safety studies? I thus find her testimony inconsistent with her previous statements and inconsistent with her knowledge of vaccine adverse events.

Thank you again for the oppurtunity to speak on this important issue.

Sincerely,

J. Barthelow Classen, M.D., M.B.A.
President and Chief Executive Officer

Exhibit 1

Press Release March 15 1999

from the French Minister of Labour and Solidarity/ Secretary of State of Health and Social Action

A risk/benefit analysis dealing with vaccination against hepatitis B has just been published in its entirety by the National Network of Public Health. The results of the study had been made public at a press conference on 1 October 1998 along with an assessment of the current related scientific knowledge. Taking into account the individual risk for hepatitis B as well as the potential risk of the vaccine and the need for a medical consultation including the personal and family history, it was decided that a vaccination campaign in schools would be discontinued. This decision was reached after consultation with numerous experts, as well as taking into account the results of the epidemiological study conducted on 800,000 persons and of an assessment of drug monitoring (pharmaco-vigilance).

Follow-up of drug monitoring was pursued in association with the R.E.V.A.H.B. As indicated on 1 October 1998, a study is in progress on the long-term potential association between vaccination and the occurrence of auto-immune diseases. An updated study of pharmaco-vigilence will be carried out by the "Agence Française de Sécurite Sanitaire des Produits de Santé" over the next few weeks. As for previous studies, all the results will be made public as soon as they become available.

At this time it is not planned to reinstate the vaccination campaign in schools. Regular information for physicians and the public, particularly regarding the need to immunize infants and individuals at high risk, will be continued so that the recommended immunization strategy will be well implemented. An assessment will be made before the end of the year.

(*Translated from the original French version*)

Version original en français

Communiqué de Presse de M. Bernard Kouchner, Secrétaire d'Etat à la santé et à l'action sociale, en date du 15 mars 1999.

L'étude "bénéfices/risques" portant sur la vaccination contre l'hépatite B vient d'être publiée dans sa totalité par le Réseau de Santé Publique. Les résultats de cette étude avaient été rendus publics, lors de la conférence de presse du 1er octobre 1998 avec le bilan des connaissances scientifiques à cette date. Prenant en compte l'appréciation du risque individuel à l'égard de l'hépatite B comme de l'éventuel risque vaccinal et la nécessité d'un entretien médical portant sur les antécédents personnels et familiaux, il avait été décidé de ne pas reprendre de campagne de vaccination en milieu scolaire.Cette décision avait été prise après consultation de nombreux experts ainsi qu'au vu des résultats des études épidémiologiques conduites sur 800 000 personnes et du bilan de la pharmacovigilence..

Le suivi de la pharmacovigilance se poursuit en liaison avec l'association R.E.V.A.H.B. Comme cela avait été indiqué le 1er octobre 1998, une étude portant sur les liens éventuels entre la vaccination et la survenue de maladies auto-immunes est en cours. Un bilan de pharmacovigilance actualisé sera effectué par l'Agence Française de Sécurité Sanitaire des Produits de Santé, dans les prochaines semaines. L'ensemble de ces données sera, comme les études précédentes, rendu public lorsqu'elles seront disponibles.

Il n'est actuellement pas prévu de relancer la vaccination en milieu scolaire. L'information régulière des médecins et du public, notamment sur la nécessité de la vaccination des nourrissons et des personnes à risques qui a été constamment réaffirmée, sera poursuivie, afin que la stratégie vaccinale définie soit bien appliquée. Un bilan sera fait avant la fin de l'année.

☐ **Click here if you are interested to read the Press Release** **WHO/67 2 October 1998**

Exhibit 2

Press Release WHO/67

2 October 1998

On 1 October 1998, the French Ministry of Health announced a decision to suspend routine HB immunization of adolescents in French schools, while continuing the immunization of infants and high risk adults. This decision followed concerns, despite lack of scientific evidence establishing a causal relationship, that Hepatitis B immunization might be linked to the development or flare-up of demyelinating diseases such as multiple sclerosis (MS), and comes in the wake of enormous pressure from anti-vaccine groups.

WHO, with the assistance of external experts in neurology, epidemiology, immunology and public health, has carefully reviewed the scientific evidence on whether Hepatitis B vaccine can cause demyelinating diseases such as MS. WHO believes that available scientific data does not demonstrate a causal association between HB immunization and central nervous system diseases, including MS.

Over 1 billion doses of Hepatitis B (HB) vaccine have been used since 1981 with an outstanding record of safety and efficacy, and the vaccine is 95% effective in preventing the development of the chronic carrier state of Hepatitis B. HB vaccine is the first vaccine against a major human cancer, as it is the chronic carriers of Hepatitis B who are at a high risk of death from cirrhosis of the liver and liver cancer.

Recognizing the enormous value of Hepatitis B vaccine, the World Health Assembly recommended in 1992 that all countries incorporate Hepatitis B vaccine into their routine immunization programmes. To date, 100 countries have added Hepatitis B vaccine into their national immunization programmes, and many industrial countries have begun programmes of immunizing adolescents as well.

Although France will continue infant and high risk adult immunization, WHO is concerned that the decision taken yesterday may lead to loss of public confidence in this vaccine, and decisions by other countries to suspend or delay introduction of HB vaccine. There are over 350 million chronic carriers of Hepatitis B at high risk from cirrhosis of the liver and liver cancer. Stopping immunization could see these numbers increase.

There have been previous experiences with other vaccines, such as Diphtheria, Tetanus, Pertussis (DTP) vaccine, where unsubstantiated hypotheses and anti-vaccine information lead to loss of public confidence and reduced coverage. Millions of cases of pertussis and hundreds of deaths followed reduced use of DTP in several countries.

WHO strongly recommends that all countries already using Hepatitis B vaccine as a routine vaccine in their national immunization programmes continue to do so, and that countries not yet using the vaccine begin as soon as possible.

Hepatitis B Vaccine and Insulin Dependent Diabetes

John Barthelow Classen, M.D.
David Carey Classen, M.D.

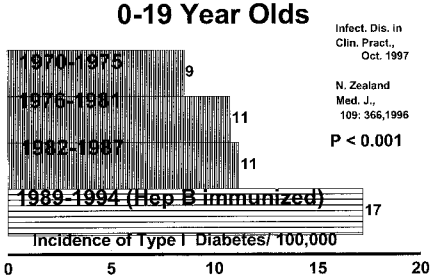
Insulin Dependent Diabetes

- Autoimmune disease
- Model for other autoimmune diseases

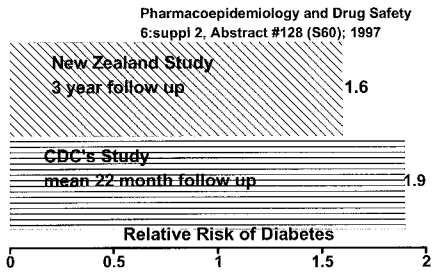
Policy and Vaccine Safety

- 30 days or less safety follow up

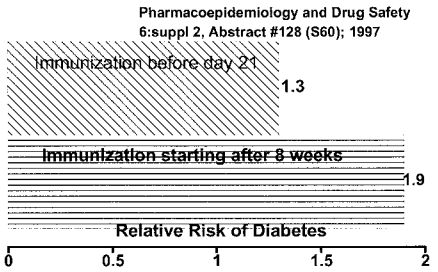
New Zealand: Hepatitis B Vaccine 0-19 Year Olds



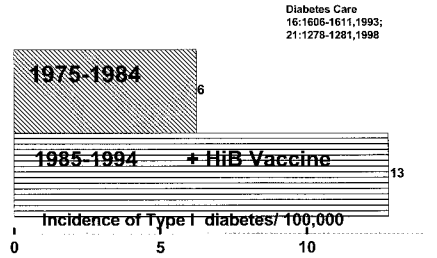
Hepatitis B Vaccine and Diabetes Risk



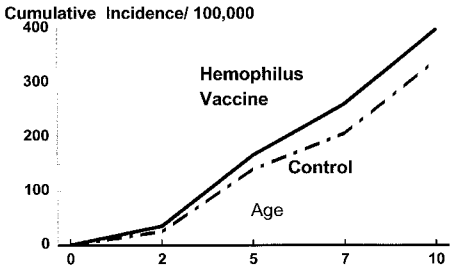
Age of First Dose Affects Diabetes Risk



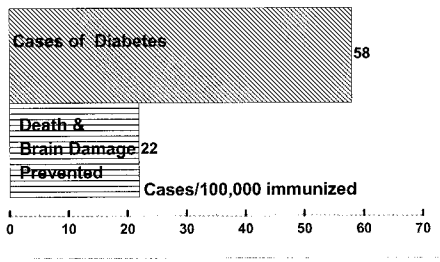
Pittsburgh: Diabetes 0-4 Year Olds



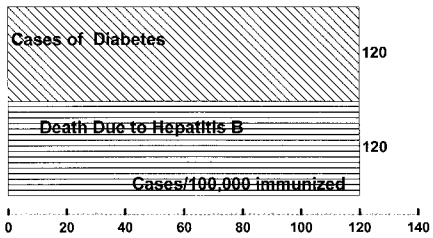
Finland: Diabetes 0-10 Year Olds



Hemophilus Vaccine



Hepatitis B Vaccine given starting after 8 weeks



Cost Effectiveness? Vaccines Induced Diabetes, USA

- >10,000 cases per year
- Cost >$10 billion year
- Cumulative Liability > $250 Billion

Requirements for FDA Approval

Vaccines: Demonstrate safety (21 CFR 601.2)

Devices: Reasonable assurance of safety (21 CFR 360.j)

Proposal

- Equal access to Large Link Data Base
- Testing & Disclosure
  - Diabetes prone animal toxicity data
  - Human data on diabetes
- Funds are not available to cover many adverse events
- Development of safer immunization technology

Mr. TIERNEY. Thank you. Thank all of you.

Mr. MICA. Thank you. Dr. Katz, I have a question. In your testimony you said that hepatitis B—and I think I wrote this down—is far more contagious than AIDS?

Dr. KATZ. HIV, the virus that causes AIDS, absolutely.

Mr. MICA. I am not a scientist. I am just a Member of Congress and it is pretty scary, isn't it? I just wonder. We had Ms. Hahn here. She has hepatitis B. She lives with her husband and four children and yet none of them tested positive.

I'm not sure if that same thing would happen with AIDS. Maybe it would. I don't know.

Dr. KATZ. I think that it's inappropriate to compare HIV and hepatitis B. I was only using that as an example of the contagiosity of hepatitis B. HIV is much more constrained in the way that it is passed by blood, by semen, by sexual encounter, by injectable drugs.

Hepatitis B, I was trying to point out, doesn't need any of them. I think it was Ms. Hahn who pointed out how long the virus survives if you spill it on a table top. HIV is very fragile. In a very short period of time if you were to have an accident, it is no longer infectious. That was the gist of what I was trying to express.

Mr. MICA. I'm not trying to put you on the spot, just a layman's question.

Ms. HAHN. I will answer that. I praise the Lord.

Mr. MICA. Maybe that has something to do with it, too. The other thing is based on the information that you all have. Do you think that we should provide additional warnings of adverse potential reactions based on your knowledge, Dr. Katz?

Dr. KATZ. I was a little bit chagrined and disappointed in listening to some of these presentations. Not in the presentations, but in what was said about physicians who had administered vaccines. We are required to provide the so-called vaccine information statements to parents and guardians or individuals who are old enough to read them for themselves.

If physicians are failing to do that, then we have failed in getting the message across to them that this is important. Those statements are clear. They do outline both the benefits and the risks of the vaccine, and they should be given to parents before they even bring their child in so they have time to digest this at home and not in the rush of 5 minutes in the waiting room of the office.

Dr. DUNBAR. But these vaccines are being mandated. They are even being given by schools and school nurses. Once it's mandated by the States, you take away that liability.

Dr. KATZ. They cannot give them in school without the parents' permission.

Mr. MICA. Again, is there adequate notice regarding the possible adverse effects, Dr. Waisbren?

Dr. WAISBREN. I would say that the fact is that the vast majority of babies are immunized in the hospital without the parents being consulted. This is based on my personal experience with my patients, my grandchildren, and so on.

I think that one of the solutions to advising parents is to make their physician become responsible for any adverse reactions that

happen even in the hospitals. They say, well—the American Association of Pediatricians or someone said that it's OK, so it's OK.

But I think if doctors have to take the responsibility for adverse results that perhaps they will look into the possibility and warn their patients more adequately.

Mr. MICA. Dr. Classen, I didn't give you an opportunity to respond.

Dr. CLASSEN. Yes. I think absolutely more warning needs to be made, both in animal toxicity studies. You have a lot of epidemiology data and people who are always going to say, well, maybe it's not the causality.

But animal toxicity data, I think, is crucial; and there is a lot of animal data, for example, with vaccines on different autoimmune diseases that they can exacerbate it. In that case it's clearly that the vaccines are causing and exacerbating autoimmunity in animals.

I think that the parents should be warned of that. I do believe that there is a real problem with physicians not notifying the patients. I had one classical example where I saw a patient with a vaccine adverse reaction. I didn't immunize the child. It was clear to me it was a vaccine adverse reaction. It was shingles following the chicken pox vaccine.

So I sent the patient back to the physician who had administered the vaccine for followup; and the physician who followed up, who administered the vaccine, denied that it was a vaccine adverse reaction. The parent had to go to a third physician to verify my diagnosis. And even when the result was overwhelming, the physicians want to avoid liability by never admitting they could have possibly harmed a child.

I think this is a big problem. This is probably why vaccine adverse reactions are not reported to VAERS, because the physician doesn't want to admit that they may have harmed one of their patients.

Dr. KATZ. But under the National Vaccine Injury Compensation Program the physician is not liable. That's the whole point of the program, to take it out of the adversarial position of having to sue in a tort system. If the case is presented, it is sent to the Vaccine Injury Compensation Program.

They have experts, whether they are neurologists or epidemiologists or pediatricians, depending on the particular type of case. They review it, and it is presented to a master. There is not the controversy. That was the whole point—not the whole point, but one of the points of the whole act, to take it out of the tort system and put it into something where parents and children would be treated fairly, whether they could afford a lawyer or not and whether they could get into the court system or not.

Dr. WAISBREN. This is the fatal error in your bill, if you will pardon me for telling you.

Mr. MICA. It wasn't my bill. Mr. Waxman.

Dr. WAISBREN. Your brother's bill. The point is, when you take the responsibility away from the doctor and the hospital, the doctor is not forced to really think the thing over and he says, "It's not going to hurt me."

I would suggest that the bill be kept in, but that it should be clearly stated that the person could go to court. And I think it is in the bill to get justice if he feels the system did not work correctly.

Mr. MICA. Dr. Katz is determined to get the last word in.

Dr. KATZ. Thank you, Mr. Mica. The physician is liable if what he commits is an act which is not within the recommendations of his State, his vaccine program. So that the physician can be sued if he has transgressed what is the recommended approach.

On the other hand, the idea that the system allows the physician to get off stark free is inappropriate. If the case is heard before the Vaccine Injury Compensation Board and rejected, the family still has recourse to the tort system. It is just that they have to go to the compensation program first.

Mr. MICA. I want to thank each of you for your testimony today. We have tried to conduct this in a responsible fashion. We have heard from representatives from the CDC, we have heard from representatives from the FDA. We have heard from Dr. Katz who is representing several very prestigious organizations. And we have heard from others.

However, I do want to announce that I will keep the record open for at least—I'm going to keep the record open for 30 days, which is unusually long, for additional information. I know there are some controversial matters in this, but we want to make certain that the record is complete and balanced, and that we hear from folks.

The reason for this hearing is not to excite anyone or as I said at the opening, to discourage anyone from vaccinating their children or anything of that sort. It's to, one, review the entire process. The law was passed in 1986. I wasn't here. I didn't pass the law. I didn't author the law.

Once every 13 years we may look at these things whether we need to or not and then responsibly see that we are doing our job. Is the proper research being done? Is proper notice being given? Is the system working?

And then also to hear from citizens. When a certain number of citizens want to be heard in a congressional process—and we do oversee the FDA and the CDC and MOPP—we have that responsibility.

Without objection, I will leave the record open for 30 days for additional testimony or for input for the record. I thank each of you for your testimony today and excuse you at this time. Thank you.

We have one final panel. That panel consists of Thelma Thiel, chairman and CEO of the Hepatitis Foundation International.

We also have Barbara Loe Fisher, president of the National Vaccine Information Center. This is our fourth and final panel today. I would like to welcome both of our witnesses.

As I mentioned to our previous panelists, this is an investigation and oversight subcommittee of Congress. We do swear in our witnesses which I will do shortly, both Ms. Thiel and Ms. Fisher. We also ask that if you have a lengthy statement or additional information that you would like made part of the record, we will do that upon request. I would also ask you to limit your oral testimony to approximately 5 minutes.

Again, I am pleased to welcome both of you, and if you could stand at this time and be sworn.

[Witnesses sworn.]

Mr. MICA. The witnesses answered in the affirmative and I am pleased to welcome to our subcommittee today our witnesses. First of all, we will hear from Thelma Thiel—I hope that I am pronouncing it right—chairman and CEO of the Hepatitis Foundation International. You are recognized.

STATEMENTS OF THELMA THIEL, CHAIRMAN AND CEO, HEPATITIS FOUNDATION INTERNATIONAL; AND BARBARA LOE FISHER, PRESIDENT, NATIONAL VACCINE INFORMATION CENTER

Ms. THIEL. Thank you, Mr. Mica, for giving me this opportunity to share our concerns with you. I am representing 50,000 victims of hepatitis in this organization, plus 300 support groups with thousands of people who are concerned about this disease.

I am also a registered nurse who lost a precious 4-year-old son 29 years ago to cirrhosis. I thought I would like to share with you some of the things that he endured with his cirrhosis.

Because his liver was so badly damaged, even a bloody nose was a hemorrhage. When he tripped over a toy, he broke his hip, not once but twice. His tummy was terribly distended because he had an enlarged liver and spleen and excess fluid.

His little arms and legs were scrawny because he couldn't metabolize proteins to build muscles. He was extremely jaundiced, almost to the point of looking green, but worst of all, he itched from head to toe, night and day.

Can you imagine being in a body cast with a fractured hip and itching constantly? He asked me one day if I could take his foot off because it itched inside.

Most people don't know that the liver is their internal chemical power plant, a very complex and noncomplaining organ that detoxifies everything that we eat, drink, breathe, and absorb through our skin. It helps us digest our food, stops cuts from bleeding and fights off infection. It makes hormones and muscles and maintains over 5,000 vital functions to keep us alive and alert.

When this hepatitis virus gets into the blood stream through an open cut, a scratch, or a puncture with a contaminated sharp needle or an instrument such as those used in body piercing or tattooing that was previously used by an infected person, even in an abrasion of the mucus membrane or a splash of blood in the eye that could happen in the dentist's office, this virus makes its way to the liver.

It quietly kills liver cells replacing them with scar tissue which is called cirrhosis. This virus can continue to assault the liver until there are so few good healthy liver cells remaining that the impact on body functions and healthy problems is devastated.

I had a woman who called me because she had two children. She needed to put them in a daycare center. One of them had hepatitis B. When she told the daycare center, they wouldn't allow her to enter the child in the school.

This mother had to go to work; and it was important that she get this child in daycare. She went to another daycare center, and didn't bother to tell them that the child was infected.

Now, every time that child gets a bloody nose or scratch, everyone in that daycare center will be exposed to this insidious disease.

I had a call the other day from a father who was very upset about his 13-year-old son, Rob. He had developed a severe case of diarrhea. There had been an E. coli outbreak, and he took him to a hospital. They did a thorough examination and found out that he had hepatitis B. He also had advanced cancer of the liver at the age of 13.

The father was terribly distressed, however, because he wanted to know whether his child who was on the wrestling team, might possibly have infected other children. Occasionally they get bloodied up during a wrestling match. We advised him to tell the school. We also found out that his mom had hepatitis B and was a carrier and did not know it.

Unfortunately, Rob had not been vaccinated at time of delivery. He had no signs or symptoms for 13 years with the potential to infect other children and now he was facing death.

Hepatitis B is an insidious disease often called a silent killer largely because the liver is a noncomplaining organ. Individuals can have serious liver damage without any signs at all. With the estimated one and a quarter million carriers of hepatitis B in this country, how many of them are sitting in the classroom with your child or your grandchildren?

Could a cut finger or a smear of blood on a page in a book shared with a classmate be a threat to your child? A little known fact is that the only treatment available for hepatitis B is chemotherapy. I can't imagine the guilt I would feel if my child became infected when he could have been vaccinated. If infected, he would have to go through chemotherapy given by injection for 6 months to a year, with only a 40 percent chance that he would have a positive response.

If the treatment fails, they can develop cirrhosis and cancer of the liver, going through many of the horrible things that my son went through. The other option, of course, is a liver transplant. However, organs are in very short supply, and we also know that the virus that remains in the body attacks the new liver with a vengeance.

Researchers are trying desperately to develop ways of controlling that virus, with limited success this process is very costly.

Losing a child to an incurable liver disease is a heart-wrenching tragedy, but I can't imagine the overwhelming guilt that I would feel if my child became infected and I had had an opportunity to protect him and didn't.

We who are well informed are aware of the risks that children can take. We don't always know when they are going to become sexually active. We have heard about children doing body piercing in the back room. We don't always know what risks they are taking. Many are not informed because there has been very little education to encourage our children to take responsibility for their own behaviors. Often their parents are uninformed.

We have a long way to go, and we are depending on you to make certain that you weigh the scientific facts and the lives that will be saved by this vaccination against the unsubstantiated reports that we have heard today. Thank you for giving me this opportunity.

Mr. MICA. Thank you for your testimony.

[The prepared statement of Ms. Thiel follows:]

HEPATITIS FOUNDATION
INTERNATIONAL

TESTIMONY

Presented by

Thelma King Thiel
Chairman and Chief Executive Officer
HEPATITIS FOUNDATION INTERNATIONAL

before the

House of Representatives Subcommittee
on

Criminal Justice, Drug Policy and Human Resources

30 Sunrise Terrace, Cedar Grove, NJ 07009-1423 973-239-1035 Fax 973-857-5044

HEPATITIS FOUNDATION
INTERNATIONAL

Good Morning Mr. Chairman and members of the Committee.

I am Thelma King Thiel, a volunteer who serves as the Chairman and CEO of the Hepatitis Foundation International. I am also a registered nurse who lost a precious four-year-old son, Dean, 29 years ago to a disease that caused cirrhosis of the liver. Diagnosed at two weeks of age, there was nothing doctors or I could do to save his life. Because his liver was so badly damaged even a bloody nose caused a major hemorrhage. When he tripped over a toy he broke his hip . . .not once but twice. His tummy was distended and his little legs and arms were scrawny because he couldn't metabolize proteins to build his muscles. He was extremely jaundiced to the point of looking green. And worst of all, he itched night and day from head to toe. He pleaded with me one day to take his foot off because it itched inside.

Most people don't know that their liver is their internal power plant . . . a complex organ that refines and detoxifies everything they eat, breathe and absorb through their skin. The liver provides us with energy, helps us digest our food, stops cuts from bleeding, makes immune factors, fights off infections, makes hormones and muscles, and over 5,000 vital functions that keep us alive and alert.

When hepatitis B virus (HBV) gets into the blood stream through an open cut, a scratch, a puncture from a sharp instrument or needle used by an infected person . . .or an abrasion of mucus membranes, or a splash of blood in one's eye, this virus makes its way to the liver. It quietly kills liver cells, replacing them with scar tissue, called cirrhosis. This virus makes non-functioning drones out of the employees in one's own personal power plant, the liver. Continued assault and destruction of liver cells by the virus leaves a diminishing number of healthy liver cells to do the job and the impact on many vital body functions can be devastating.

30 Sunrise Terrace, Cedar Grove, NJ 07009-1423 973-239-1035 Fax 973-857-5044

Babies born to infected mothers are at high risk because the mucous membranes in their eyes, nose, mouth and genitals are exposed to the mother's infected blood during the birthing process. These babies have an 85-90% chance of becoming chronically infected with their life expectancy severely compromised. The good news is that a combination of the hepatitis B vaccine and immune globulin given within 12 hours after birth can protect these babies from this insidious and life threatening disease.

Following one of my presentations, a young couple came up to me and told me their daughter had hepatitis B. They had taken the child to enroll her in a daycare center; however, when they told the administrators she had hepatitis B, they refused to allow her to attend. Desperately in need of someone to take care of their child . . .because both parents had to work . . .they took her to another daycare center and didn't bother to tell them that she was infected. Anytime that child has a nosebleed or cut, anyone coming into direct contact with that infected blood is at risk of contracting hepatitis B. Even if the blood is cleaned up with soap and water, this hardy virus can live for 7 – 10 days away from the body.

Recently, a very distraught father called to tell us that his 13 year old son, Ron had hepatitis B. He was concerned that Ron, a star on the wrestling team may have infected other students. Ron had not been sick a day in his life until a few days earlier when he had a bout of diarrhea. Laboratory tests showed that Ron had advanced cancer of the liver related to hepatitis B. His mother and dad were devastated. What they did not know, was that Ron's mother unknowingly was a carrier of hepatitis B and had infected Ron at time of delivery. Tragically, he had not been vaccinated at birth.

Hepatitis is an insidious disease that is often called a silent killer, largely because the liver is a non-complaining organ. Individuals can have serious liver damage without any outward signs. With an estimated 1.2 million carriers of hepatitis B in this country, how many of them are sitting in the classroom with your child or grandchild? Could a cut finger or a smear of blood on a page in a book or on a paper shared with a classmate be a threat to your child?

A little known fact that may convince you that we must protect our children by providing this highly effective vaccine, is the fact that, currently, the treatment for hepatitis B is chemotherapy given three or more times a week by injection over a period of six months to a year. It has many unpleasant side effects and is only effective in about 40% of those treated. Those who fail to respond will remain infected with the potential to develop cirrhosis and cancer of the liver. A few victims of HBV may be lucky enough to receive a liver transplant; however, the virus remains in the body and attacks the new liver with a vengeance. Extraordinary efforts are being made to control this attack with limited success at a cost of over $100,000 a year for the remainder of the patient's life.

Losing a child to an incurable liver disease is a heart-wrenching tragedy. But I can't imagine the overwhelming guilt I would feel if my child became infected with a devastating disease like hepatitis B, if I had made a decision not to protect him with this miraculous vaccine. Children do not have a voice in their own healthcare. We, who are well informed and aware of the risks they take by having tattoos, body piercing, and other activities that expose them to HBV, have a responsibility to protect all children . . .and especially those who are the most vulnerable . . . from being infected with hepatitis B.

Thank you for giving me this opportunity to share my concerns.

Mr. MICA. And we will now hear from Barbara Loe Fisher, who is president of the National Vaccine Information Center. You are recognized.

Ms. FISHER. Thank you, Mr. Chairman. My name is Barbara Loe Fisher, and I am president of the National Vaccine Information Center, formerly known as Dissatisfied Parents Together, which I cofounded in 1982 with parents whose children had been injured or died from the adverse effects of the DPT vaccine.

Our nonprofit organization represents tens of thousands of Americans, including families affected by vaccine reactions, healthcare professionals, and parents. We are working to prevent vaccine injuries and deaths through public education and to institute safety and informed consent protections in vaccination programs.

Some of us worked with Congress in the early 1980's in a bipartisan effort to help create and pass the historic National Childhood Vaccine Injury Act of 1986. One of our main goals was met in 1996 when a less reactive pertussis vaccine was licensed.

I want to thank you, Representative Mica, for having the courage and the vision to hold this hearing. As you have heard, vaccine safety is an issue charged with emotion because whether death or disability is caused by a disease or a vaccine, the pain is the same. And when children are suffering and their parents are grieving for them, there are no words to make the pain go away.

I think what is important at the end of the day is to acknowledge that we are all here because we love our children and we want to protect them from harm. We need to find ways to protect them from vaccine injury and death while we create public health policies designed to protect them from the ravages of disease.

There is no reason why we cannot accomplish both of these goals if we embrace the principle that every child's life is important and no child is expendable.

The National Vaccine Information Center has received hundreds of reports of injuries and deaths following hepatitis B vaccination. There is a clear pattern to hepatitis B vaccine reaction symptoms, just as there was a clear pattern associated with the DPT vaccine reactions, but unlike DPT vaccine where most symptoms usually occur within a few days of vaccination, hepatitis B vaccine reaction symptoms can take many days or weeks to develop and include fevers that come and go, open skin lesions and rashes, severe joint pain and head pain, loss of vision, muscle strength and memory and crushing, debilitating fatigue which leads to chronic disability.

We have had reports of liver cancer developing in small children following hepatitis B vaccinations. There are families with two or three members who have become disabled after hepatitis B shots. Tragically, for newborns and babies under 2 months of age, a hepatitis B vaccine reaction can end in death.

When parents look to the medical literature for answers, they find few studies looking into hepatitis B vaccine reaction reports. None deal with newborns. Most of the studies look at vaccine efficacy, not vaccine safety.

A 1994 study by the Institute of Medicine, mandated by Congress under the National Childhood Vaccine Injury Act, found that there have been no large controlled observational studies or clinical trials investigating clinical reports of arthritis, Guillain-Barre Syndrome,

transverse myelitis, optic neuritis, multiple sclerosis, and other central demyelinating disease or sudden infant death syndrome after hepatitis B vaccination.

What, then, will be the scientific criteria used to either award or deny children compensation for their hepatitis B vaccine-associated injuries under the Federal Vaccine Injury Compensation Program?

Serious questions remain about the quantity and quality of the scientific evidence used by Federal health agencies to license this vaccine for use in children and, in 1991, to recommend that all newborns receive their first dose just 12 hours after they take their first breath.

Last Tuesday, I filed two detailed Freedom of Information Act requests with the FDA and the CDC to make this information a matter of public record. We hope this will lead to better public understanding of current standards used to license this first recombinant DNA vaccine and then recommend all newborn infants and children be required to use it. I will provide copies of what I receive from the CDC and the FDA to you, and I submit my FOIA requests as part of the record.

Families with vaccine-injured children are trying to cope with the knowledge that they tried to do the right thing. They did what public health officials and doctors told them to do. Most of these children were exceptionally bright, healthy, and robust at the time of vaccination.

They received a hepatitis B shot, and something went horribly wrong. In some cases, they were coerced into having more hepatitis B shots, even in the face of severe reactions because the push for a 100 percent vaccination rate has all but eliminated the right to informed consent when it comes to vaccination in America.

This information sheet on hepatitis B produced by the Centers for Disease Control in compliance with safety provisions in the National Childhood Vaccine Injury Act does not come close to meeting the informed part of informed consent.

Parents who want to make educated hepatitis B vaccine decisions for their children often are threatened when they even ask to delay vaccination if the child is sick. The lack of informed consent protections in mass vaccination programs is leading to fear and mistrust of the whole vaccination system.

Bottom line, what we are hearing parents tell us is: show us the science and give us a choice. So we come before you today to ask for, first, an investigation into Federal health agency licensing and policymaking standards applied to the recombinant hepatitis B vaccine; and, second, consideration of special congressional appropriations to fund nongovernment, nonindustry conducted scientific research to identify genetic and other high-risk factors for reacting to hepatitis B vaccine; and, third, the institution of informed consent protections in current vaccine policies.

Again, thank you, Chairman Mica and members of the committee, for demonstrating leadership by acknowledging these vaccine safety concerns, which is the first important step toward addressing them in a way that will save lives. You have listened and we are very grateful.

[The prepared statement of Ms. Fisher follows:]

FROM : NVIC FAX NO. : 2025479870 May. 17 1999 07:30AM P2

NATIONAL VACCINE INFORMATION CENTER

512 W. Maple Avenue, #206, Vienna, VA 22180
(703) 938-0342 Fax: (703) 938-5768
http://www.909shot.com

SUBOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES
U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON GOVERNMENT REFORM
MAY 18, 1999 HEARING ON HEPATITIS B VACCINE
Testimony by Barbara Loe Fisher, Co-founder & President
National Vaccine Information Center

Thank you Mr. Chairman and Members of the Committee;

My name is Barbara Loe Fisher and I am the President of the National Vaccine Information Center, formerly known as Dissatisfied Parents Together, which I co-founded in 1982 with parents whose children had been injured or died from the adverse effects of the DPT vaccine. Our non-profit organization represents tens of thousands of Americans, including families affected by vaccine reactions, health care professionals and parents. We are working to prevent vaccine injuries and deaths through public education and to institute safety and informed consent protections in vaccination programs.

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I think what is important at the end of the day is to acknowledge that we are all here because we love our children and want to protect them from harm. And we need to find ways to protect them from vaccine injury and death while we create public health policies designed to protect them from the ravages of disease. There is no reason why we cannot accomplish both of these goals if we embrace the principle that every child's life is important and no child is expendable.

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When parents look to the medical literature for answers, they find few studies looking into hepatitis B vaccine reaction reports. None deal with newborns. Most of the studies look at vaccine efficacy, not vaccine safety. A 1994 study by the Institute of Medicine, mandated by Congress under the National Childhood Vaccine Injury Act, found that there have been no large controlled observational studies or clinical trials investigating clinical reports of arthritis, Guillain Barre Syndrome, transverse myelitis, optic neuritis, multiple sclerosis and other central demyelinating disease, or sudden infant death syndrome after hepatitis B vaccination. What, then, will be the scientific criteria used to either award or deny children compensation for their hepatitis B vaccine associated injuries under the federal vaccine injury compensation program?

Serious questions remain about the quantity and quality of the scientific evidence used by federal health agencies to license this vaccine for use in children and, in 1991, to recommend that all newborns receive their first dose just 12 hours after they take their first breath. Last Tuesday, I filed two detailed Freedom of Information Act requests with the FDA and CDC to make this information a matter of public record. We hope this will lead to better public understanding of current standards used to license this first recombinant DNA vaccine and then recommend all newborn infants and children be required to use it. I will provide copies of what I receive from the FDA and CDC to you.

Families with vaccine injured children are trying to cope with the knowledge that they tried to do the right thing. They did what public health officials and their doctors told them to do. Most of these children were exceptionally bright, healthy and robust at the time of vaccination. They received a hepatitis B shot and something went horribly wrong. In some cases, they were coerced into having more hepatitis B shots even in the face of severe reactions, because the push for a 100 percent vaccination rate has all but eliminated the right to informed consent when it comes to vaccination in America.

The information sheet on hepatitis B, produced by the Centers for Disease Control in compliance with safety provisions in the National Childhood Vaccine Injury Act, does not come close to meeting the informed part of informed consent. Parents, who want to make educated hepatitis B vaccine decisions for their children often are threatened when they even ask to *delay* vaccination if the child is sick. The lack of informed consent protections in mass vaccination programs is leading to fear and mistrust of the whole vaccination system.

Bottom line, what we hear parents saying is: "Show us the science" and "Give us a choice." So we come before you today to ask for: (1) an investigation into federal health agency licensing and policymaking standards applied to the recombinant hepatitis B vaccine; and (2) special congressional appropriations to fund non-government, non-industry conducted scientific research to identify genetic and other high risk factors for reacting to hepatitis B vaccine; and (3) the institution of informed consent protections in current vaccine policies.

Again, thank you Chairman Mica and members of the committee for demonstrating leadership by acknowledging these vaccine safety concerns, which is the first important step toward addressing them in a way that will save lives. You have listened and we are very grateful.

Mr. MICA. I thank both of you for your testimony.

Ms. Fisher, you just testified that you felt the vaccine information sheets handed out on hepatitis B are inadequate as far as disclosing risks and benefits. What more can we do, or what more should we do, or what information should be included would be my first question?

The second is, there are 16 States now that do allow sort of an opt-out. How would you go about changing that since you have a State-to-State requirement?

Ms. FISHER. First, I would just like to read that the mild problems that are listed on this are soreness at the injectionsite and mild to moderate fever. The only severe problems listed are serious allergic reaction, and it says very rare.

There is no description here of the kinds of symptoms that we have heard today.

Mr. MICA. As far as severe, that is all that is on there?

Ms. FISHER. Right. Serious allergic reaction they say is very rare. They describe serious allergic reaction as difficulty breathing, hoarseness, et cetera, which are symptoms of anaphylaxis. Anaphylaxis occurs within a very short time period after a vaccination is given.

So the people who testified today, who told you about these symptoms, they would be candidates for revaccination according to this vaccination sheet; and, in fact, this is part of the problem.

We have heard from so many people who are being forced and threatened that they have to go forward with hepatitis B vaccinations, even after they have experienced fevers that come and go, skin lesions all over their body, severe joint pain, symptoms that—autoimmune symptoms and neurologic symptoms, and they are being ignored.

Because there is this push for a 100 percent vaccination rate, these people are not being screened out. And they are not being given full information, and the doctors are not being given full information about what to look for after a hepatitis B vaccination.

The manufacturers, frankly, in their product insert, have more of a description about some of the reactions that have been associated with the vaccine than this sheet.

What I am concerned about, this sheet was mandated under this compensation program, and we fought very hard—the parents who were involved in the creation of the system, of which I was one, fought very hard for the safety provisions.

And one of the safety provisions was that parents would get proper benefit and risk information prior to vaccination so they would know how to make informed decisions and also so they could monitor their children following vaccination for signs of a reaction so that revaccination would not take place and more serious reactions would occur that would end in disability and death; and we feel this is woefully inadequate.

Mr. MICA. Ms. Thiel, do you want to respond?

Ms. THIEL. Physicians have access to the drug insert. If they are giving the vaccination, they should be aware of those reactions.

Also, the CDC puts out a publication called MMWR which identifies the fact that there should have been informed consent. There has been a great deal of effort on the part of the hepatitis B immu-

nization programs and on the Internet to identify the fact that they should be asking the parents to sign consent forms.

The Hepatitis Foundation International created a booklet that would go home with the consent forms to identify the importance of the liver, the importance of the vaccine, and some things parents should be concerned about. This has been an effective way of informing the parents of the benefits of the vaccine.

Mr. MICA. What about the question of inadequate research that has been raised here today? Do you all have a position on that, Ms. Fisher?

Ms. FISHER. First of all, there are two kinds of research that need to be done: basic science research that will look at biological mechanisms for hepatitis B vaccine-induced injury or death, which would include looking at what happens at the cellular and molecular level in the human body after the vaccination is given.

The other concern is that this vaccine is often given with other vaccines. Part of my Freedom of Information Act request is that the CDC and the FDA go over the different studies that we would like to see that hopefully were done before this vaccine was recommended in 1991 for universal use in all children, particularly newborns. That would include such things as how many children were involved in these studies, the time periods for followup of vaccine adverse events. In the manufacturers' product insert, they list 4 to 5 day followup for studies that were used to license this vaccine, and yet the reactions we are seeing are taking sometimes longer than 4 to 5 days to occur. So have we missed in those studies, all of the people who testified here today? How good are those studies? Did they include racial diversity of infants and children enrolled in them?

Particularly in light of what Dr. Dunbar said, if we have genetic predisposition here, if there are certain genotypes who are more susceptible to reacting to this vaccine than others and we have only done these studies in certain genetic populations, we don't really know what is going on. And when we give this vaccine and we mandate it and we haven't done the studies prior, it is an experiment and we cannot afford to do that.

I think the FOIA requests are important to take a look at—how was this vaccine licensed and policy made? But also, is the system that we use good enough or should we be raising these standards?

Mr. MICA. Ms. Thiel, has your group taken a position as far as opting out of these vaccinations?

Ms. THIEL. We feel very much if a person has an objection to being vaccinated, they have that right. Of course, it is going to be a problem if you get a lot doing that. You are going to have more exposure to other children if they are not vaccinated.

Mr. MICA. But your group has basically supported the opt-out ability?

Ms. THIEL. Right.

Mr. MICA. One of the other questions that has come up in this hearing and also prior to the hearing is a review of the 1986 law and the access to compensation through that law for those who have some type of vaccine-related adverse reaction.

You were involved in some of that, the development of that legislation, and I guess of monitoring, Ms. Fisher?

Ms. FISHER. Yes.

Mr. MICA. How do you feel about how that is working?

Ms. FISHER. We are extremely disappointed in how this compensation program is being implemented. In fact, it is tragic.

Those of us who came to the table in good faith in the early 1980's to work with Congress and work with the vaccine manufacturers and work with the American Academy of Pediatrics feel like we have been betrayed because three out of four children are being turned away from this system. And because all of the work we did, for example, to set up the table of compensable events for DPT vaccine injury and death so that this system wouldn't be like a trial and you wouldn't have to show the same type of proof and it wouldn't be expensive and traumatic—HHS came in and they gutted it.

They gutted the provisions for awarding compensation for DPT vaccine injuries, and there is almost nothing now presumed to be associated with DPT vaccine.

We were promised that it would be a fair alternative to the tort system, and we feel like we have been betrayed. And the fact that there is $1 billion in the trust fund is a disgrace because there are children out there who need that money because they have done what they were told to do by doctors and public health officials; and they are out there coping and suffering with vaccine injuries, and nobody is helping them because all the resources of HHS and Justice are brought against these plaintiffs.

Justice represents Secretary Shalala in these cases, and it is not a level playing field. I think it is—we absolutely oppose the using of any of that billion dollars for anything other than compensating these children. The money for these studies needs to come out of the billions of dollars that are being given to HHS to fund new vaccine development and to set up tracking systems to track children in order to enforce vaccination and to promote vaccination.

We have got to do a better job of looking at the existing vaccines that we have before we put other vaccines on the market, and we have to do a better job of taking care of the children who pay the price and are our casualties of our public health programs. Our children deserve no less.

Mr. MICA. Thank you. Ms. Thiel, have you observed the operation of the compensation fund, and do you have any comments?

Ms. THIEL. Well, I think it could be improved. I think we have to look at the fact that we have saved so many children and adults from the tragedies of this disease by having this vaccine that I think we have to continue.

When you understand that we have given 10 million doses of the vaccine this year with a small number of adverse reactions that are very serious. I think we have to weigh the benefit to the masses against the unfounded concerns expressed.

For years we were promoting vaccination for high-risk populations, mentioned earlier. This was an abysmal failure because we were not reaching those at high risk, many in urban areas.

These are the children that are probably going to participate in high-risk activities. How can we protect them? We have to protect them when they are accessable, which is in the school system or requiring immunization before entering school. Otherwise, they will

be missed. People continue being infected, with many developing serious cirrhosis of the liver and cancer.

Children as young as 8 years of age have developed cancer of the liver having acquired this disease from their mothers, at the time of delivery. The baby's mucus membranes, in their eyes, nose, mouth, and genitals are exposed to infected blood through the birthing process. Because their immune systems are not fully developed, they have a 90 percent chance of developing the serious consequences of hepatitis B.

There are major social factors related to hepatitis B infection. If, as a teenager, they become infected and go through the chemotherapy treatment and fail, they are going to remain infectious for the rest of their life. They must be concerned about infecting their sex partners if their partners are not vaccinated or immune.

I think Barbara Hahn was very fortunate that her family did not become infected, because she was very careful of any blood or body fluid exposure that she had for her family. We also know that families living in the household with someone who is chronically infected is at higher risk of acquiring hepatitis B.

I use the analogy in 1 teaspoon of blood for the AIDS virus, there are about 5 to 10 particles of the AIDS virus compared to 500 million of the hepatitis B virus. This gives you an idea of how infectious this disease is. Even blood on a dry surface can cause the transmission of hepatitis B to others.

Ms. FISHER. I would like to say something to you Ms. Thiel, and I thank you very much for supporting the ethical concept of informed consent. I think this is really, really important because as you know, as a parent, you love your child more than anyone ever could. And when a child dies from a disease or from a vaccine, it is you, the mother and the father who lives with the consequences of that, and that is why the ethical principle of informed consent that is applied to every other medical procedure in this country that carries a risk of injury or death is so important to be applied to vaccination.

We are not calling for the elimination of vaccine laws. We are calling for flexibility within the laws, a humane application of the laws. We are asking for the right to exercise conscientious belief exemption if we believe our children are at great risk of having a reaction.

I come from a family of serious autoimmune disorders. My mother has lupus. I have one child who has reacted and has disabilities from a vaccination. How can the State possibly ask me to take a risk with another—a vaccine like this one—when I know that my children could either die or have autoimmune disorders from getting this vaccine?

Parents have got to have the right to have the information and then make informed decisions for their children. Every parent wants their child to be healthy. They don't want their child to die from a disease or a vaccine. We have to believe that parents love their children.

Ms. THIEL. I believe that we also have to receive informed consent. We also have to give them the information so they know how serious this disease can be to help them make an appropriate deci-

sion and not just respond emotionally to some of the misinformation they have been hearing about the adverse reactions.

Ms. FISHER. I totally agree with you.

Mr. MICA. Ms. Fisher, you advocated several specific recommendations. One was increased licensing standards; is that correct?

Ms. FISHER. That's right.

Mr. MICA. What are you talking about specifically?

Ms. FISHER. The reason that I filed very detailed FOIAs with the CDC and the FDA on this was I was hoping—I don't know the answer to that question. I was hoping that the committee would help us get those answers and do a review of the licensing procedures and of the policymaking procedures.

Mr. MICA. The other item you recommended was nongovernment studies. But if it is a recommendation to us, it is going to involve government moneys and we have a pretty—well, we have a pretty complex manner of funding studies that was made that way to keep the studies independent from undue outside influence. How can we have a nongovernmental study financed by government—I mean, do you have something specific in mind?

Ms. FISHER. I am not really knowledgeable——

Mr. MICA. And then get an independent study. I think you are questioning the independence of these studies? Again, I don't see how we can accomplish that recommendation since it is government funding, the studies—unless you have some protection and barriers.

Ms. FISHER. I am not knowledgeable about the grant structure at NIH, for example; but I understand there are some grants that are more independent. They are given to scientists, and they are more independent from control by the CDC or the NIH.

I don't know exactly what they are called. But I understand that there are grants available where the—the problem is who is going to be on the peer review committee? Bonnie Dunbar has applied twice for an NIH grant to look at genetic predisposition to hepatitis B vaccine reactions. She has been a vaccine developer for 26 years. She knows what she is doing.

You don't see these grants being given out to scientists who want to look at adverse effects. The grants are given out to develop new vaccines and look at the efficacy of vaccines, but not to look at clinical reports of adverse events to vaccines.

The public is very suspicious of having industry and government be in total control of these scientific studies. And so, if there was a way to get the funding, and then have some autonomy. So yes, of course, to publish you have to be peer reviewed. I don't have the answers, but I would be happy to work with the committee to find one.

Mr. MICA. Thank you. In conclusion, did either of you have any final recommendations, anything additional legislatively or administratively that we can promote to help address some of the problems we have heard described today? Ms. Thiel.

Ms. THIEL. In response to——

Mr. MICA. This is additional.

Ms. THIEL. The advisory committees that review the grants that are coming through have lay people on them—they are not just

physicians who are reviewing these grant requests. They have very strict criteria to assess whether they are qualified and worthy of the funding that they receive. I think that there is a good review system there.

Mr. MICA. Ms. Fisher.

Ms. FISHER. We just touched on a few of the problems with the compensation program, the implementation of the National Childhood Injury Act, and I would just hope that we would have another opportunity to look at that program and talk about the issues surrounding that program.

Mr. MICA. Thank you.

Well, I would like to thank both of our panelists and everyone who participated today, our various witnesses, for their participation.

As I said, we will leave the record open for 30 days. I have never extended the record that long; but since there is so much interest in this subject, we will accommodate additional interest for the record, and anyone interested should contact the subcommittee on Criminal Justice, Drug Policy, and Human Resources with their submission. Without objection, so ordered.

There being no further business before the subcommittee, I will call this meeting adjourned, and I also will make an announcement here. There was a request for press availability after the hearing, and I will make a very brief statement here rather than go out to the Triangle.

This meeting is adjourned.

[Whereupon, at 2:34 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

PROVE **Parents Requesting Open Vaccine Education**

awn Richardson, President
P.O. Box 1071
Cedar Park, TX 78630-1071
(512) 918-9661
prove@swbell.net

Problems with Hepatitis B Vaccine Policy Implementation from a State Perspective:
A Case For Nationwide Immunization Conscientious Exemptions & Informed Consent Laws
May 18, 1999

To the members of the Criminal Justice, Drug Policy and Human Resources Subcommittee of the U.S. Congressional Committee on Government Reform,

Regarding the hearing on the Hepatitis B vaccine on May 18, 1999, please accept the following comments as written testimony to become a part of public record and considered in your investigation. My name is Dawn Richardson. I am a mother, a citizen of the United States, and the president and founder of the Texas-based grassroots support organization Parents Requesting Open Vaccine Education (PROVE). **I sincerely believe the concerns being investigated today stem from a much larger problem of an inhumane and inflexible "one-size-fits-all" vaccine policy machine designed to lucratively compensate drug companies while intimidating and persuading parents and health care providers into accepting the sacrifice some of our precious children in the name of protecting the majority.**

I am urging this committee to please do everything within your power to move us toward more humane and flexible vaccine exemption laws nationwide with the requirement that all parents are educated about the risks as well as the benefits of vaccines and that all parents have the final legal right over what drug is injected into, swallowed, or inhaled by their child. Please don't wait to become passionate about this subject until you or someone you love is hurt or killed by a vaccine that you were told was supposed to keep you healthy.

Currently, only 16 states have conscientious or philosophical exemptions available from mandatory vaccination laws. **It is insane that in this country a mother has the legal right to kill her unborn child in an abortion but in 34 states we have state laws that prevent a mother from making a conscientious decision to protect her child from a medical procedure that she believes carries an elevated risk of injury or death for her child.**

When parents hold a deep conviction that their child has a greater risk of being harmed by a vaccine, especially for a child with a family history of vaccine reactions, autoimmune and neurological disorders, or other health conditions which may genetically predispose their children to reacting, and the parent lives in one of the 34 states without a philosophical exemption, the vaccine is still unconscionably legally forced. This is the reality that parents in 34 states must live with every day. There are not even any genetic or other lab screening tests available to identify and exempt which children will react to vaccines. Parents in Texas, for example, who do not have a local doctor who is willing to bear the pressure and opposition that comes with writing a yearly medical exemption or who do not belong to or follow a religion opposing all immunizations are legally required to put their child in harms way with specific doses of a vaccine at very specific times in order to receive a public education and not break the law.

According to National Vaccine Advisory Committee figures released by the Texas Department of Health in an open records request to PROVE, the national averages show that less than 0.64% of parents take any kind of vaccine exemption for their child and that 98% of all kindergartners nationally are fully immunized. The bottom line that the numbers bear out is that IF THE CHILD IS TRULY AT RISK FOR A DISEASE WITH HIGHLY PROBABLE SEVERE CONSEQUENCES FOR THE CHILD, and IF A VACCINE IS PROVEN SAFE AND EFFECTIVE, and IF THE CHILD IS NOT AT AN ELEVATED RISK FOR A REACTION, the vast majority of parents will have their child immunized. Parents love their children and don't want their child to suffer needlessly from anything whether it is a vaccine preventable disease or a vaccine reaction. The problem lies in the fact that public health officials and vaccine manufacturers, as shown clearly with what has happened with the Hepatitis B vaccine, are militantly pushing universal vaccination regardless of an individual child's risk for the disease and they are tolerating unacceptable levels of vaccine reactions. The miniscule numbers of exemptions taken show that the availability of conscientious choice exemptions in all 50 states would not be a detriment to vaccination rates for highly communicable and highly debilitating diseases. We are clearly talking about a small minority of parents that want the flexibility to delay or decline a dose of a vaccine to protect their child from a health policy encouraged by the CDC and enforced by states that has little regard for the individual child.

I believe it is the basic human right of all patients to choose their health care provider and their modes of treatment and prevention. It is my experience that parents are capable of making informed decisions about the health care of their children and must not be placed in a position in which exercising a conscientious objection to the administration of any vaccine to protect their child from harm means breaking the law. The16 states that currently allow for conscientious choice exemptions are AZ, CA, CO, ID, LA, ME, MI, MN, NM, ND, OH, OK, UT, VT, WA, and WI. It is time for all states to have these exemptions because any vaccine can sometimes cause permanent injury or even death. The National Vaccine Injury Compensation Program has paid out over one billion dollars in damages to families for injuries and deaths caused by the core set of mandated vaccines in less than 10 years.

The significance of the legal right to conscientious choice exemptions is dramatically increasing because vaccines like the Hepatitis B vaccine are being required for all regardless of the risk to an individual. For example, according to CDC surveys, in 1996, there were only 279 cases of Hepatitis B reported in children under 14 in the entire United States. That same year, there were 872 reports of serious injuries and 48 deaths occurring in children under 14 who received the Hepatitis B vaccine with other vaccines, and 214 reports of serious reactions and 13 deaths in children under 14 receiving the Hepatitis B vaccine alone reported to the FDA's Vaccine Adverse Event Reporting System. Yet, starting August 1, 1998, Texas kindergartners were required by law to be fully vaccinated against Hepatitis B. Parents whose kindergarten children don't fit the disease high risk profile of I.V. drug use or promiscuous sex have NO ability to delay or decline the vaccine based on their conscientious analysis of risks vs. benefits. This is significant because 10% of all children born in the United States each year are born in Texas. I am continually contacted by families who absolutely do not want this vaccine given to their child and can't understand why in the United States of America they don't have the right to say no.

Additionally, new vaccines are being developed in proliferation. At various stages, from clinical testing to recent licensure to universal recommendation, are vaccines for diarrhea, Strep throat, Lyme disease, ear infections, and sexually transmitted diseases including Herpes and AIDS. While these vaccines hold promise for many in the high risk categories, **parents should always be able to evaluate their child's risk of contraction of these and any other diseases for which vaccines are available, the sequelae of the disease, and the side effects of the vaccine and then be protected legally to make an informed consent decision for their child. The harsh reality is that in 34 states this is impossible.** The MANUFACTURER/ACIP/AAP vaccine machine makes federal recommendations which translate into inflexible state mandates for all children with little-to-no education about vaccine side effects. It is horrific that the casualties are just accepted as a necessary sacrifice.

Vaccines have protected millions of children from highly communicable deadly and debilitating diseases like smallpox and polio. But they are also powerful drugs that provoke a complex immune response that sometimes goes wrong and injures or kills a child, so they need to be respected and not used indiscriminately. There is no research being done into the cumulative effects of all these vaccines together on a baby's developing immune system. With that in mind, let's please reserve vaccine mandates for diseases of the caliber of smallpox and polio. Chickenpox is not smallpox, and diarrhea (rotavirus) is hardly a lethal killer in the United States. These along with the Hepatitis B vaccine are available to any parent in the United States who wants them for their child - they do not need to be forced.

When parents learn the risk factors for contracting Hepatitis B and they hear that reaction reports are continually being denied and dismissed, they really question what is going on. Also, I am concerned that if drug companies and health officials continue on their recent trend of demonizing generally mild childhood illnesses like varicella (chicken pox) and rotavirus (diarrhea) with the hopes that state implemented vaccine mandates will create an unlimited supply of customers boosting profits, that when a disease evolves in our society of the likes of smallpox or polio, distrust of the system is going to push parents and health care providers away from it just when they may need it the most. It is like "the boy who cried wolf." The forced use of the Hepatitis B vaccine is unquestionably adding fuel to this fire.

Resentment and anger is building in parents around the country toward health officials who presume to care more for their children than their parents. It is the parents who must care for their children, nurture their development, soften their defeats and cheer their accomplishments throughout the children's lives. **Bureaucrats come and go without even the slightest knowledge of a child's hopes and dreams or how lives are shattered and destroyed when a vaccine goes wrong. I ask you: who is more qualified to determine what's best for an individual child? Do minor children belong to the government or to their parents? Your answer to these question will probably determine your resolve to take the necessary steps to get immunization conscientious exemptions and informed consent laws available for every U.S. citizen.**

No parent should be forced to sacrifice their child. All our children, including MY child, deserve the opportunity to live a long healthy life. **It is time that the definition of public health in the United States of America is changed to accommodate a community of healthy individuals where EVERY person is important and NOBODY is expendable.**

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STATE OF ALASKA

TONY KNOWLES, GOVERNOR

DEPT. OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

P.O. BOX 110610
JUNEAU, ALASKA 99811-0610
PHONE: (907) 465-3090
FAX: (907) 586-1877

May 17, 1999

Representative Patsy Mink
Criminal Justice, Drug Policy and Human Resources Subcommittee
Committee on Government Reform
United States House of Representatives
B-373 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Mink:

As Director of the Division of Public Health in Alaska, I have had ample opportunity to see the potentially devastating effects of infection with hepatitis B virus (HBV). Not so long ago, the incidence of acute HBV for Alaska Natives was the highest in the United States.

Historically, southwestern Alaska had the heaviest incidence of new infection. Prior to implementation of a HBV immunization program in 1983, more than 2 of every 1,000 HBV carriers in this section of the state developed serious adverse events as a result of HBV infection, including liver cancer and end stage liver disease resulting in death or the need for liver transplantation. After introduction of the HBV immunization program, the incidence of acute disease in southwestern Alaska went from 201/100,000 in 1982 to 0 in 1993. And in the 15-year period from 1986-2000, it is projected that almost 4,700 new HBV infections and 6 deaths from acute, fulminate HBV infection were prevented.

The value of preventing HBV infection is even more compelling on a national basis. Hepatitis B is an extremely serious disease, resulting in an estimated 4-5,000 deaths each year in the United States due to cirrhosis and liver cancer. Annually, there are approximately 8,400-19,000 hospitalizations and 140-320 deaths among persons in the United States with symptomatic infection (approximately one-half of all persons infected.)

In Alaska, we recommend that ALL children from birth through 18 years of age be immunized against HBV. Before routine infant hepatitis B immunization began, approximately 30,000 infants and children were infected in the United States each year, and the Centers for Disease Control and Prevention estimates that one-third of the *chronic* HBV infections in this country come from infected infants and young children. The majority of these infections occur among children of mothers who are not infected with HBV and thus would not be prevented by perinatal hepatitis B prevention programs.

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Another important reason we vaccinate children is the protection this will provide against exposure to HBV infection when they become adolescents and adults. While most HBV infections occur among older adolescents and young adults, vaccination of persons in high risk groups has generally not been a successful public health strategy. If we wait until they are older, we may be too late; we will have lost our best opportunity to prevent infection. Additionally, when a child acquires hepatitis B infection, it is more likely to become chronic with potentially severe consequences.

HBV infection is acquired by exposure to blood or body fluids from an infected person, and it is approximately 100 times easier to transmit than is HIV, the virus that causes AIDS. Blood and body fluid exposure, while more frequent among some "high risk" groups, occurs among persons of all ages and social or ethnic groups. There is no effective treatment for hepatitis B infection – prevention is the only option. This provides a rationale for recommending universal childhood hepatitis B vaccination.

We take concerns about possible adverse effects of hepatitis B vaccine very seriously. But it is important to weigh the benefits outlined above compared to any risks associated with the vaccine. More than 20 million persons have received hepatitis B vaccine in the United States and more than 500 million persons have received the vaccine worldwide. The most common side effects from hepatitis B vaccination are pain at the injection site and mild to moderate fever.

Serious side effects reported after receiving hepatitis B vaccine are very uncommon and may represent coincidence rather than causation. However, carefully controlled scientific studies are underway to examine whether vaccination is associated with serious neurological disease in a small number of people. There is **no** confirmed scientific evidence that hepatitis B vaccine causes chronic illnesses, including multiple sclerosis, chronic fatigue syndrome, rheumatoid arthritis, optic neuritis or other autoimmune disorders.

Thank you for your consideration of this information as you review the value of hepatitis B vaccine. We must ensure that we use everything in our arsenal to protect our population against the serious impacts of this disease. Given the frequency and severity of HBV infection, the benefit of vaccination far outweighs any known or potential risks.

Sincerely,

Peter M Nakamura by kp

Peter M. Nakamura, MD, MPH
Director, Division of Public Health

University of Medicine and Dentistry of New Jersey
Robert Wood Johnson Medical School

May 17, 1999

Representative Patsy Mink
Criminal Justice, Drug Policy and Human Resources Subcommittee
Committee on Government Reform
United States House of Representatives
B-373 Rayburn House Office Building
Washington, D.C. 20515

Dear Honorable Patsy Mink:

I am writing to inform you about the benefit and safety of the hepatitis B virus (HBV) vaccine. As a pediatrician, I can attest to its benefit in preventing hepatitis B infection in infants. Before the routine immunization of infants, about 30,000 infants and children were infected each year. About one third of all chronic hepatitis B infections in the U.S. come from infected infants and young children. The vaccine has helped tremendously in reducing this burden of disease.

More than 20 million people in the U.S. and 500 million worldwide have received the HBV vaccine. Studies show that the common side effects are mild including pain at the site of the injection and mild to moderate fever. Serious side effects are uncommon. Active surveillance for adverse events have shown no association between HBV vaccine and neurologic conditions such as seizures or Guillain-Barre. There is no confirmed evidence that HBV vaccine causes multiple sclerosis or chronic fatigue syndrome. Ongoing surveillance for adverse events continues in association with HBV vaccine as well as other routine immunizations.

I strongly urge you to support the continued use of this highly effective vaccine to prevent HBV infection from occurring in infants and children who are at the greatest risk of developing chronic hepatitis B infection. The benefits from this vaccine far outweigh the risks. I hope you will act in the best interest of our children and for the good of the health of the general public. Thank you for your consideration of this most important issue.

Yours truly,

Patricia N. Whitley-Williams, M.D.

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May 17, 1999

Representative Patsy Mink
Washington, DC 20515

Dear Representative Mink:

As you are about to attend the May 18 subcommittee to discuss the safety of the hepatitis B vaccine, I hope you will take a moment to consider this please. I think this is a very important vaccine, and that protection it provides far outweighs the cries of a small group of vaccine opponents.

I am a local health department registered nurse, and my job title is communicable disease coorrdinator. I work day in and day out with clients infected with hepatitis A, B and C. Hepatitis B is such a difficult disease for many people, and is so very costly to the health care system in general. Hepatitis B is a reportable disease in my state, and therefore immense time is spent in working with infected individuals, their close contacts, and to test and immune exposed persons when identified to prevent them from becoming ill.

For instance, today I am working with a 19 year old diagnosed with acute hepatitis B. Exposure has occurred to two intimate partners during the time disease may have been likely transmitted. Had these partners received hepatitis B vaccines prior to this exposure, the extended time and cost it will take to hopefully prevent their illness would certainly have been worthwhile! One of the partners (age 15 years incidentally) will need a special immunization, in addition to the usual hepatitis B vaccine, that is extremely difficult to obtain, and in addition, may likely cost over $500 (five hundred dollars). What an immense savings could have been made had this individual previously received the hepatitis B vaccine series. And yes, although rare in this day, persons with hepatitis B may expire from hepatitis B with what is called fulminant hepatitis; such a death occurred last year in a neighboring county in my state to a young adult.

I encourage you to become aware of how important this vaccine is, and know how significant it is to prevent this serious illness with a simple and safe product, hepatitis B vaccine. As a cancer survivor myself, it is also such an important issue to become aware that the hepatitis B vaccine is indeed a cancer preventing vaccine. Anyone familiar with hepatic carcinoma, which can be a complication of unresolved hepatitis B virus infection, and the agonizing end stages that occur, must certainly agree prevention would have been important and very worthwhile.

My precious twelve year old son received the hepatitis B vaccine series as a sixth grader last year. I would not dare he miss that protection. Please do the right thing and remember the good things, (and they are many), that vaccines do; please do not be adversely influenced by those who feel victimized by *rare* and *sensational* events.

Thank you for considering my convictions.

Sincerely,

Joyce Hawkins

Joyce Hawkins

Patsy Mink
Criminal Justice, Drug Policy
and Human Resources Subcommittee
United States House of Representatives
B-373 Rayburn House Office Building
Washington, DC 20515

May 17, 1999

Dear Representative Mink:

I understand that you are having a hearing on hepatitis B vaccination tomorrow, stimulated by stories concerning reactions. The hepatitis B vaccine is one of the most effective vaccines we have, and it would be a pity if you allowed unsubstantiated complaints to damage a newborn vaccination program that could wipe out the disease within 20 years.

Yours sincerely,

Stanley A. Plotkin, M.D.

Stanley A. Plotkin, M.D.

Representative Patsy Mink
U. S. House of Representatives
Washington, D. C. 20515
fax: 202 225 4987

Dear Representative Mink:

I would like to express my concern about the meeting of the Criminal Justice, Drug Policy, and Human Resources Subcommittee, reviewing claims of adverse reactions to the hepatitis B vaccine. I hope that the Subcommittee does not take any action which would jeopardize progress in immunizing the public against hepatitis B virus infection, for several reasons:

1. *Hepatitis B is one of the worst infectious disease problems in the U. S.*
For example, there were more acute hepatitis B cases reported (10,416) than of all the other standard vaccine-preventable diseases combined (8,785 for diphtheria, measles, mumps, pertussis, paralytic polio, rubella, tetanus, and haemophilus influenzae invasive disease). This figure of 10,416 is really just the "tip of the iceberg," as it does not count the even greater number of chronic cases of liver cirrhosis and liver cancer. Over a million people in the U. S. chronically carry the virus, able to transmit it to others. Over 4,000 die each year from hepatitis B virus infection. These figures are available in:

"Summary of Notifiable Diseases, United States, 1997" in the *Morbidity and Mortality Weekly Report*. 46(54), Nov. 20, 1998, in tables E, F, and G.
"Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination" *Morbidity and Mortality Weekly Report*. 40 (RR-13), Nov. 22, 1991.

And in CDC's Web site at: www.cdc.gov/nip/
and at: www.cdc.gov/ncidid/diseases/hepatitis/b/index.htm

2. *Adverse events after a vaccination are not necessarily caused by the vaccination.* For example, I once heard of family who brought their daughter to the clinic, and questioned the doctor thoroughly about the safety of vaccinations. After the parents discussed it, they decided to get their daughter vaccinated. Just as the nurse went to draw the vaccine into the syringe, the child had convulsions. If they had vaccinated the child only a few minutes earlier, she would have had the convulsions after the vaccination. The parents might have concluded that the vaccination caused the convulsion, and reported the episode to the Vaccine Adverse Events Reporting System (VAERS). For this reason, the VAERS and any stories of events after vaccination should be viewed not as conclusive information, but as data needing further analysis.

3. *The hepatitis B vaccines are hundreds of times safer than natural infection with the virus.* Dozens of well-controlled clinical trials have been done with the hepatitis B vaccines, following the vaccinees for twelve years now, and are still studying them into the future. Among these thousands of people, and the millions vaccinated routinely, only rarely have serious adverse events followed hepatitis B vaccination. Studies of these events have not proven they were caused by the vaccinations. In contrast, if an infant gets the hepatitis B virus, there is a 90% chance he or she will become chronically infected. Among those chronically infected, about 25% will die of a disease caused by the virus infection. (For a thorough study of these issues, see "Major adverse reactions to yeast-derived hepatitis B vaccines - a review" *Vaccine*. 16(4): 329-334.)

4. *Forty-six nations have hepatitis B infant vaccination coverage rates higher than the U. S.* Among the 77 nations reporting hepatitis B infant vaccination coverage rates to the World Health Organization or in technical journals, the U. S. rate of 84% is tied for forty-seventh, behind nations in every continent and region of the world. Some of these nations are much less prosperous and technologically developed than the U. S. Part of the reason the U. S. is behind is the publicity generated by people

campaigning against vaccines. Meanwhile, millions of children in other nations are getting vaccinated and protected against this deadly disease.

5. *We can almost eliminate hepatitis B transmission.*
In a couple generations, hepatitis B virus transmission will probably be almost eliminated in many nations. Will it be eliminated in the U. S., or will we allow it to continue killing thousands of Americans? You can have a strong influence on the result.

Sincerely,

Robert Vryheid

Robert Vryheid, PhD, MPH
3714 Fairway Dr.
La Mesa, CA 91941-8051
tel./ fax: 619 697 1467

Phyllis L. Phelps, R.N., B.S.N.
Home: 409 East Market Street
Warrensburg, MO 64093
(660)429-55540
Work: Warrensburg High School Nurse
1411 South Ridgeview Drive
Warrensburg, MO 64093
(660)747-2262
email: whsnurse@mailcity.com

Representative Patsy Mink
Criminal Justice
Drug Policy and Human Resources Subcommittee
Committee on Government Reform
United States House of Representatives
B-373 Rayburn House Office Building
Washington, D.C. 20515

May 17, 1999
Subject: Hepatitis B Vaccine Congressional Hearing: Helping or hurting children?

Dear Representative Mink,

Please support parental informed consent and exemption for vaccinations, particularly Hepatitis B vaccine. Currently there is no long term study done on the effects of the Hepatitis B vaccine. Parents should not be forced to submit their children to a vaccine that was intended for high risk individuals (Hep-b is a blood-transmitted pathogen transmitted through sexual intercourse or sharing needles).
The basic human right to choose, or decline medical treatment should NOT be taken away. Please consider the children's safety and the risks involved with the immunizations currently being used. Thank you for your time and consideration on this matter.

Respectfully yours,

Phyllis L. Phelps

Phyllis L. Phelps

May 14, 1999

Representative Patsy Mink
Drug Policy and Human Resources Subcommittee
Committee on Government Reform
U.S. House of Representatives
B-373 Rayburn House Office Building
Washington, DC 20515

Dear Representative Mica,

It is my understanding that you will be hearing testimony regarding the safety of the Hepatitis B Vaccine. I would like you to know just how critically important the current vaccine program is.

Although often deadly, hepatitis B is not recognized by the general public as having devastating, and potentially deadly, consequences. As a clinical pharmacist working in a large teaching hospital, I see on a daily basis the catastrophic outcomes of patients with hepatitis. This illness takes a huge financial toll on our health care system, and an incalculable personal toll on the patients and their families. With the hepatitis B vaccine, we have the capability of decreasing the numbers of people affected by this infection to a minimum. However, we can achieve this only with a widespread vaccination program that ensures that everyone is protected.

As a nation, we have been able to nearly eliminate polio from our medical experiences, but we have done so only because of a concerted effort on the part of the government and society. Vaccination is a social responsibility that we as citizens bear. We are able to bear that responsibility because the risks associated with vaccination are far outweighed by the risks of the diseases we prevent.

Please listen to the experts on vaccine safety. We need to continue on the path of prevention.

Sincerely,

Veronica Moriarty, Pharm.D.
Drug Information Center
Spartanburg Regional Medical Center
Spartanburg, SC 29303

NACCHO
1100 17th Street, NW, Second Floor
Washington, DC 20036
(202) 783-5550 (202) 783-1583 (Fax)

National Association of County and City Health Officials

By fax: 225-4987

May 17, 1999

The Honorable Patsy T. Mink
United States House of Representatives
Washington, DC 20515

RE: Hearing on Effectiveness of Hepatitis B Vaccine
House Subcommittee on Criminal Justice, Drug Policy and Human Resources

Dear Congresswoman Mink:

The National Association of County and City Health Officials (NACCHO) has respectfully requested that this letter be included in the record of the Subcommittee's May 18, 1999 hearing on Hepatitis B vaccine.

NACCHO represents the nearly 3000 local public health departments, in cities, counties and townships, who work on the front lines to protect and promote the health of their communities. We support the recommendations of the Centers for Disease Control and Prevention concerning the use of Hepatitis B vaccine routinely for infants and adolescents. Liver disease due to the Hepatitis B virus has been a serious public health problem, causing chronic infection in an estimated 1.25 million people in the United states, and 4,000 to 5,000 deaths annually from Hepatitis-B related chronic liver disease or liver cancer. The strategy of vaccinating only persons thought to be at risk for Hepatitis B infections due to occupational exposures, sexual activity or illicit drug use, has not been successful. Moreover, CDC estimates that one-third of the chronic Hepatitis B infections in the United States come from infected infants and young children.

We believe that the benefits to the health and safety of the public from routine use of Hepatitis B vaccinations are great and that there is no current evidence that justifies turning away from a public health strategy that will prevent a large toll of human suffering and save lives. We also support continuing epidemiologic surveillance to measure the effects of Hepatitis-B related disease and to detect any previously undetected risks of the vaccine, so that individuals and health professionals can make judgments and recommendations based on all available information.

Thank you for your consideration of our views.

Sincerely,

Ralph D. Morris, MD, MPH

Ralph D. Morris, MD, MPH
President

Date: 5/17/99

To: **Representative Patsy Mink**
Phone: 202-225-4906
Fax: 202-225-4987

From: **Mothering Magazine**
Peggy O'Mara
Phone: 505-984-6293
Fax: 505-986-8335

Pages:

Subject:

Dear Representative Mink:
We have been covering the issue of childhood vaccinations for 20 years here at *Mothering*, the magazine of natural family living. We are concerned about the high rate of adverse events associated with the hepatitis B vaccine and hope that you will take seriously the concerns of the families who are affected by the mandate for this vaccine.

Here is a news bulletin on hepatitis B that we published in our May/June 1999 issue. We also publish a book called *Vaccination: The Issue of our Times*. For more information on our coverage of vaccinations or to receive a complimentary copy of our book or our magazine, please fax, call, or e-mail me at PeggyO@mothering.com

Thank you for your consideration.

Most Sincerely,

Peggy O'Mara
Editor and Publisher

Editor's Choice: Web Sites to Help You Learn More

THESE HOMEPAGES ALL ADDRESS IMPORTANT TOPICS RAISED IN RECENT ISSUES OF *MOTHERING*

www.oneday.net
A Web site dedicated to the international "One Day in Peace, January 1, 2000" campaign. Over 700 organizations in 120 nations have sent in letters of support for 24 hours without violence around the globa. (See *Mothering* 90, page 36.)

www.christianparent.com
Promotes breastfeeding and attachment parenting as compatible with a Christian life. (See *Mothering* 93, page 68.)

www.organichub.com
An on-line resource for locating organic food and merchandise of all kinds. (See *Mothering* 93, page 42.)

www.HolisticMed.com
This site focuses on alternative treatments to ADD/ADHD. Also has an e-mail discussion list. (See *Mothering* 93, page 78.)

allergy.mcg.edu
Site of the American College of Allergy, Asthma & Immunology. You can take a Life Quality test to help determine if you have asthma, or obtain a list of asthma screening sites. (See *Mothering* 87, page 34.)

Bulletins

Hepatitis B Vaccine: More Dangerous than the Disease?

Photography Tim Dock Mahler

The National Vaccine Information Center (NVIC) released figures earlier this year showing that the number of hepatitis B vaccine-associated adverse events and deaths reported in US children under the age of 14 is exceptionally high, significantly outnumbering the reported cases of hepatitis B disease in that same age group.

Independent analysis of raw computer data generated by the government-operated Vaccine Adverse Event Reporting System (VAERS) confirms that in 1996, there were 827 serious, adverse events reported to VAERS in children under 14 who had been injected with the hepatitis B vaccine. In contrast, during that same period there were only 279 reported cases of hepatitis B disease in children under 14.

Hepatitis B is primarily a bloodborne adult disease. At highest risk are IV drug users and people with multiple sex partners. In 1991, the CDC recommended that all infants receive the first dose of hepatitis B vaccine before discharge from the hospital, even though the only newborns at risk for hepatitis B are those born to infected mothers.

Ironically, only 15 states require mandatory hepatitis B screening of all pregnant women, while 35 require children to have three full doses of hepatitis B vaccine for admittance to daycare or school.

In October 1998, France became the first country to end hepatitis B vaccination requirements for schoolchildren, after reports that many children were developing chronic arthritis and symptoms resembling multiple sclerosis following the administration of the vaccine.

In the US, some experts are worried about the effects of the still-mandatory injections here. Bonnie Dunbar, PhD, a Texas cell biologist and vaccine researcher, says, "It takes weeks and sometimes months for autoimmune disorders such as rheumatoid arthritis to develop following vaccination. No basic scientific research or controlled longterm studies into the side effects of this vaccine have been conducted on American babies, children, or adults."

To learn more, contact the National Vaccine Information Center, 512 W. Maple Avenue, Suite 206, Vienna, VA 22180, 703-938-0342, 800-909-SHOT, www.909shot.com; and the Vaccine Adverse Events Reporting System, Department of Health and Human Services, PO Box 1100, Rockville, MD 20849-11, 800-822-7267, www.fda.gov/cber/vaers.htm

Alternative Medicine Grows Up and Goes to Harvard

The status of alternative medicine is steadily rising. Need proof? This year, the National Institutes of Health's (NIH) division of Complementary and Alternative Medicine has been elevated from an "office" to a "center" and its budget more than doubled, from $20 billion in 1998 to $50 billion this year.

Meanwhile, Harvard University's School of Medicine has begun several month-long, undergraduate courses on alternative medicine and a three-day annual course on alternative medicine for physicians. Someday, perhaps, there will be an advanced Harvard degree in homeopathy.

Massachusetts Citizens for Vaccination Choice
P.O. Box 1033
East Arlington, MA 02474-0020
phone: (781)646-4797
e-mail: MCVCHQ@juno.com

Representative Patsy Mink
Criminal Justice, Drug Policy and Human Resources Subcommittee
Committee on Government Reform
United States House of Representatives
FAX: 202-225-4987

May 17, 1999

Dear Representative Mink:

I am writing to you regarding tomorrow's hearing that will address the many issues surrounding the safety and use of the hepatitis B vaccine in the United States. Thank you for your willingness to look openly at these issues. I am hopeful that a full congressional investigation will follow.

Massachusetts Citizens for Vaccination Choice is a not-for-profit education and advocacy organization representing hundreds of families in Massachusetts who support the rights of citizens to make informed vaccination decisions. In Massachusetts alone, there were 570 hepatitis B vaccine-related adverse reaction reports made to the Vaccine Adverse Event Reporting System (VAERS) between 1990 and 1998. There were 6 deaths, 155 emergency room visits, and 40 hospitalizations. It is worth noting that the FDA has found that *only 10% of doctors report adverse reactions.*

Given that most infants and children are not at risk of contracting this disease, and that the safety and effectiveness of the vaccine is highly questionable, government mandates should be immediately halted and the right of parents to make informed decisions regarding this vaccine should be upheld.

Sincerely,

Debbie Bermudes, OTR/L
Executive Director

TESTIMONY OF WALTER S. KYLE

HEARING ON THE SAFETY OF HEPATITIS-B VACCINE - MAY 18, 1999

CONGRESSMAN JOHN MICA, CHAIRMAN

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES OF THE UNITED STATES CONGRESS COMMITTEE ON GOVERNMENT REFORM

I, Walter S. Kyle, make the following statement to the best of my knowledge information and belief:

My name is Walter S. Kyle, I practiced law in the area of vaccine related injuries from 1978 through 1997. My primary practice involved polio vaccines in civil litigation, but I handled several different types of cases under the National Vaccine Compensation Act.

I comment as a concerned parent who has children subject to the Hepatitis-B immunizations under threat of exclusion from public school.

In civil practice the reported decisions of *Loge v. United States* 662 F.2d 1268(8th Cir. 1981) and *Schafer v. American Cyanamid*, 20 F.3d 1 (1st Cir. 1994) are generally the most often quoted of my work. There are also several reported decisions in LEXIS which pertain to the National Vaccine Compensation Act cases which I handled. A 1997 article in *Boston* Magazine summarizes my background. (Ex. 1).

In March 1992 I wrote an article which appeared in *Lancet*, Simian retroviruses, polio vaccine and the origin of AIDS, (339:600-601), which discussed some of the evidence I had gathered that linked specific monovalent pools of vaccine made in the United States to the outbreak of the AIDS epidemic. In spite of repeated requests to the regulatory agency involved in the release of the identified vaccine monopools, (under FOIA), data regarding these vaccine s has been withheld from me and others.

I have a long history of dealing with scientists at the Centers for Disease Control and feel that they intentionally obfuscate, mislead and cover up vaccine reactions in order to promote the national vaccine programs. The testimony before you clearly showed their ploy when CDC, in essence, admitted that nothing more than a medical records review and a VAERS data analysis was done, in following up infant deaths associated with Hepatitis-B vaccine (a phenomenon not associated with Hepatitis-B in infants.

As a degreed engineer in two disciplines, I have long felt that epidemiology was the garbage basket of science. What CDC has become adroit at doing is cooking numbers to suit their vaccine policy. This is "voodoo science" but the witch doctors are the ones treating our

children. No healthy infant has a "medical history" so the death of the healthy ones can be eliminated from consideration by the flick of a computer key under the CDC's investigational policy.

In 1991 I was one of three attorneys appointed to serve in the capacity of representing people who had suffered adverse reactions to the Salk polio vaccine. We concluded that indeed there were continued and ongoing paralytic reactions to the Salk polio vaccine in spite of CDC statements to the contrary and Salk's testimony before Congress that such reactions never happened.

My investigation showed that, to a reasonable degree of certainty, that CDC knew of such reactions from the outset of the Salk immunization program and endeavored to cover them up. This position continued through the time that the National Vaccine Compensation Act was written and the failure of that agency to come forward with the relevant information clearly shows that it is at conflict with itself in its dual role of both promoting vaccines and reporting adverse reactions to them.

From my role as an attorney in the matter of *Loge v. United States*, I have the distinct impression that the agencies (Bureau of Biologics and Centers for Disease Control) involved in the release of vaccines and the reporting of adverse reactions to them have historically felt that specific safety regulations pertaining to release of polio vaccines were in fact discretionary. I know of at least one case of vaccine induced paralytic polio that CDC recognized as such but intentionally refused to report it as an adverse reaction to the vaccine.

The government employees who deal with the polio vaccine also deal with the other vaccines, I assume in much the same manner.

When DTP came under scrutiny in the late 1970's, NIH conducted a study in Los Angeles. (Cody-Baraff). Although the study was to be a thirty day follow up of vaccine reactions, when several children died in 3-5 days after immunization, the researchers arbitrarily stopped the reported reaction time as 48 hours post immunization and terminated the study. Even at this shortening of the reaction time, the reaction rate in the 48 hours post immunization was 1:1,750.

An inspector general needs to be appointed to oversee the way NIH spends its money. I believe it is the only agency that lacks such oversight.

It now appears that CDC and the American Academy of Pediatrics have implemented a medical treatment plan for infants which is designed to exclude any scientific proof of vaccine reactions. In short, nurses are giving immunizations without taking any child history and before physicians examine the child on the date that the immunizations are given. Hence there will never be any credible scientific evidence or medical record that the child was well prior to the immunizations so a valid comparison can be made to post immunization results.

In 1983 the French government eliminated the Sabin oral polio vaccine from routine immunizations in France. That eliminated domestically

SK 4/5/99

arising cases of polio in France. Although the same live vaccine was the major cause of polio in the United States since 1971, the live oral polio vaccine has never been removed as a vaccine for use in this country although the recommendation has finally been made to switch to the improved Salk vaccine which the French use.

CDC wanted the live polio vaccine because it was known to spread polio viruses from the infant recipients to others within thirty days of immunization. Mothers of the children were the most commonly paralyzed victims even though the mothers never consented to immunization for themselves. This was a long standing stealth immunization program.

I know that it is politically incorrect to challenge the manufacturers of vaccines or to question the people who insist on 100% immunization.

Based on an historical knowledge of the treatment legitimate scientists have received from the power circle which controls vaccine standards, safety and release, I question the moral and ethical standards of the scientists who sit on the Advisory Committee on Immunization Practices due to so many having long-standing economic links to vaccine manufacturers - a billion dollar business.

One of your witnesses, Dr. Samuel Katz, now head of the American Academy of Pediatrics was the "go to guy" for Lederle in 1971 when the continued production of its polio vaccine in African Green Monkey kidney cells was made an issue by Pfizer which had developed a vaccine using human diploid cells. (See the attached internal memorandums of Lederle, Ex 2).

Pfizer promoted the concept that use of the human diploid cells was an advance that would eliminate the risk of transmission to humans of undetectable simian viruses assumed to exist in the monkey cells used to make the polio vaccine. Katz apparently *knew* that could not happen.

Although the Academy of Pediatrics initially appeared to endorse this concept, intervention and a concerted press effort by Lederle and Bureau of Biologic's officials thwarted the switch. The BoB "assumed" that the quarantine of monkeys for six weeks would assure that there were no extraneous viruses in the monkeys if they did not get sick while in captivity. Katz was sure the Lederle vaccine was safe, as made.

Fourteen years later, using techniques discovered in the methodology developed to identify Human Immunodeficiency Viruses, the African Green Monkey - the monkey used since 1963 to make polio vaccine in the United States - was found to be a natural host for Simian Immunodeficiency Virus which did not make that monkey sick.

The discovery of such extraneous monkey viruses in polio vaccines did not warrant their rejection because the BoB's standard for release of live oral polio vaccine permitted release if the extraneous viruses (or its DNA) were not known to cause harm in humans. Of course no one knew what HIV was in 1977-78. See Exhibit 3.

Katz was wrong then and he is wrong again.

s/SK 4/15/99

As a new parent, knowledgeable of the actions of several of the men and women who have failed in their statutory duty (28 USC Sect. 262 (d)) to "insure the continued safety and purity" of polio vaccine, I should not be forced to immunize my infant with Hepatitis-B vaccine for the sole purpose of eliminating the risk of that disease in certain high risk sub groups of the population.

The CDC is extremely disingenuous when it comments that "there is no conclusive scientific proof that the Hepatitis-B vaccine causes reactions". The facts are, as I understand them, that there is no conclusive scientific proof that the Hepatitis-B vaccine is either safe or effective in infants.

Would any physician in his or her right mind inject the same dosage of vaccine, in a legitimate trial, into an eight pound infant as is injected into a 180 pound adult? I suggest that it would be only one who is paid to assure efficacy by someone who knows that efficacy is the only standard required for licensure.

Is it not obvious that the "fix" is in - that safety is not a major issue in vaccine licensure? Look at Neal Halsey's record (along with Sam Katz's ardent support) on the EZ Measles vaccine. If a French scientist had not stood up to them and exposed it in *Lancet* (after Halsey began trials in the United States) - they would have stuck our children with that outrage also.

It is manifestly unfair for the government to dictate to parents a vaccine schedule when it makes no concerted effort to check or follow up or report adverse events associated with vaccinations.

Only after the duty to follow up adverse vaccine events is placed in the hands of competent people whose mission is to link medical conditions with vaccine administration, not as the current mission appears to be, "risk management" that overlooks many adverse events, should anyone feel safe with entrusting their child care to a group of people in Washington whose life revolves around pharmaceutical industry contracts and NIH grants tailored to promote the politically correct concept that vaccines are absolutely safe.

History has shown that no vaccines are completely safe and CDC's history with Hepatitis-B vaccine shows that competent and complete testing and follow through has not been undertaken by that agency.

If you wish to resolve this problem, then you must, at the very minimum, fund attorney's who have an economic incentive to discover the faults with the vaccines and scientists whose careers will not be jeopardized by questioning vaccine safety.

When the vaccine compensation act was initiated the Pharmaceutical Companies were at severe risk of being bankrupt from the litigation associated with the vaccines. After removal of the civil discovery process in the Vaccine Compensation Act, the internal memorandums which can cripple a company have been eliminated from the litigation process

WDK 4/5/99

and the "lack of scientific evidence" to which the CDC alludes in its press release concerning this hearing does not necessarily not exist - it is unnecessarily not available.

I respectfully suggest the following changes be made:

- The agency which undertakes the licensure, safety testing and/or promotion of vaccines should be separated from the agency charged with the duty to investigate and analyze vaccine reactions.

- The problems with the vaccine injury compensation program could be remedied if the civil practice mechanism of discovery is instituted with the various drug manufacturers having the status of "parties" to the Court Claim's actions in return for their continued protection under the Act. The present vaccine compensation system is a total failure, in large part, due to the lack of a responsible agency to aggressively pursue reporting and analysis of adverse reactions to vaccines and the claimants' inability to discover any internal scientific data known to the manufacturer and the government regarding the vaccines.

- The attorneys who undertake such litigation should be paid promptly and continuously throughout the prosecution of a vaccine related case.

- Several prominent attorneys have been "squeezed out" of the vaccine compensation program by overzealous government defense attorneys who object to and delayed the prompt payment of legal and expert witness fees. Attorneys who handled these cases at the initiation of the program appear to have been targeted and eliminated. Full compensation for their services should be mandated in order to have them return to this area of litigation and fees equivalent to fees under the FTCA should be awarded retrospectively.

- Congress should seriously consider the nationalization of vaccine manufacturing in light of the push to immunize every child in the country under a program which puts no liability on the makers of the vaccines. If the infants and children of this country have their immunization decisions made in Washington, without any benefit of local medical care, treatment, or intervention (a communistic approach) then the people have a right to assure that no company profits from their taking such a risk, (an equally communistic approach).

Signed under the pains and penalties of perjury on June 15, 1999.

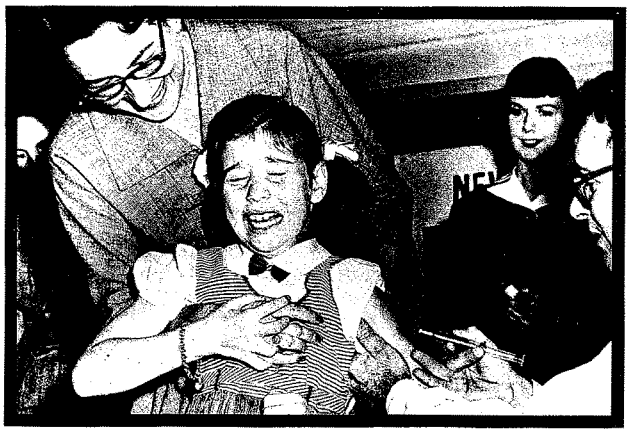
Walter S. Kyle 6/15/99

Walter S. Kyle

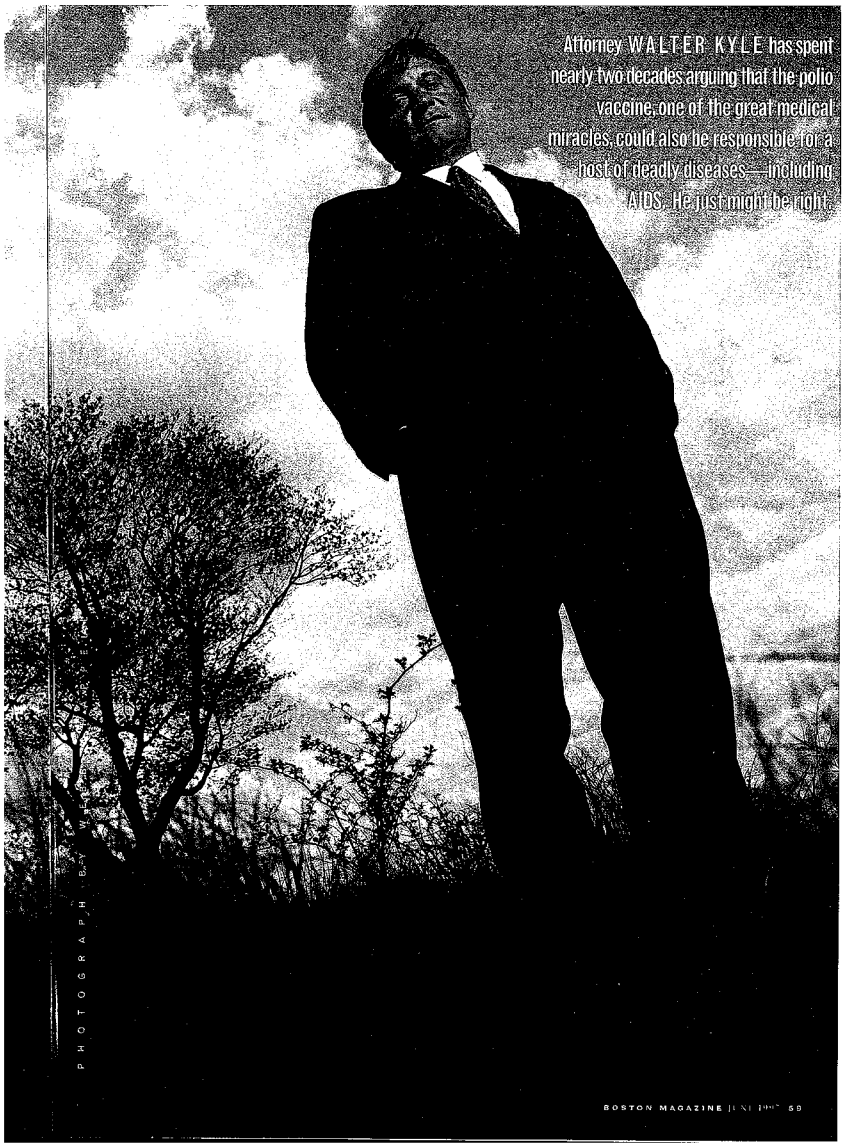
THE LONELY CRUSADE OF WALTER KYLE

By Debbie Bookchin and Jim Schumacher

DIRECTLY ABOVE THE GIFTED HAND, an upscale antiques and crafts store in the center of Hingham, a black and gold sign neatly mounted on the white clapboard of an immaculately kept Colonial house announces the offices of Walter S. Kyle, Attorney at Law. At first blush, Walter Kyle seems to blend perfectly into the backdrop of Hingham's amalgam of suburban chic and historic elegance. He is a handsome and affable 47-year-old Arkansas transplant whose soft-spoken and gentlemanly bearing suggest ease and comfort. His tidy office is tastefully turned out: a small cherry desk adorned with an antique brass faux-gas lamp, leather chairs, striking vermilion drapes, newly hung Williamsburg Collection wallpaper, and Persian-style rugs covering polished pine floors.



THE CURE: Almost everyone born before 1955 remembers the swath of terror that polio cut through the American psyche.


Attorney WALTER KYLE has spent nearly two decades arguing that the polio vaccine, one of the great medical miracles, could also be responsible for a host of deadly diseases—including AIDS. He just might be right.
PHOTOGRAPH BY
BOSTON MAGAZINE

"ASK ANY MOTHER if she would approve of her child being given a vaccine that was potentially contaminated with monkey viruses," Barbara Loe Fisher says of the polio vaccine. "I think she would tell you, 'No, thank you.'"

On a glass-encased shelf sits a gold-framed, inscribed photograph of Kyle and his son Robert standing with President Clinton in the Oval Office; nearby sits another of Kyle standing directly behind Clinton as he gives a speech in New Hampshire during the 1992 primary. Clinton, who told *Boston Magazine* he has known Walter Kyle "most of his life" and is "grateful for his friendship," tapped Kyle to serve as his New Hampshire field director during the 1992 presidential race. Dressed in a conservative blue suit that fits snugly over his athletic frame, Kyle could easily be mistaken for a smooth and prosperous lawyer, at home in the corridors of power.

Yet Kyle has devoted most of his career to a single-minded and iconoclastic pursuit that has earned him no love in Washington or in the boardrooms of America's pharmaceutical giants: attacking the polio vaccine. The vaccine is one of modern medicine's most revered miracles; but Kyle has borne witness to its darker side. Not only can the vaccine itself cause paralysis and death by infecting recipients with polio, but Kyle says there is plenty of reason to believe that it may be the repository for a variety of monkey viruses that can cause disease in human beings. That is because all polio vaccine produced for consumption in this country is grown on the kidney tissues of monkeys, which are notorious reservoirs for all kinds of viruses. He believes that federal health regulators have at times allowed contaminated batches of vaccine to be distributed to infants and children in this country. He has even hypothesized that one possible source of the AIDS virus was through contaminated polio vaccine.

The Food and Drug Administration (FDA) counters that the vaccine is free of all known monkey viruses. Kyle believes he has evidence to prove otherwise. In three undisclosed locations in the Boston area, Kyle, in the course of 20 years of litigation, has collected more than 100,000 pages of internal drug company memoranda and government documents. He says the internal memos paint a damning picture of a vaccine production process rife with contamination problems and a government that doesn't seem to care. "Why would anyone think it's okay to give American kids a vaccine that might be contaminated with monkey viruses?" says Kyle. "But that's exactly what's been going on with the polio vaccine. For 40 years they've been engaged in a massive experiment with our children. Every parent should be angry."

TODAY IT IS EASY TO FORGET how deeply the fear of polio gripped the nation during the first half of this century. But almost everyone born before 1955 remembers the swath of terror the disease cut through the American psyche. Parents would reach into a crib to pick up their infants and, to their horror, find that overnight their legs had turned limp and lifeless. Polio could take the most robust and athletic children and reduce them to weakened cripples, condemned to a lifetime on crutches or worse, entombment in an iron lung. Polio didn't single out the poor and sickly; it struck healthy, middle-class kids and adults too. It was unpredictable. No one seemed to know how the disease was spread, so no one knew how to avoid it. In the epidemic of 1916, the first of almost four straight decades of annual epidemics in this country, 27,000 people were paralyzed and 6,000 died. As recently as 1952, 58,000 people contracted the disease. Every summer, as polio epidemics worsened throughout the 1940s and early 1950s, parents prayed their children would be spared. Polio had become a national scourge. Deliverance from it could not come soon enough.

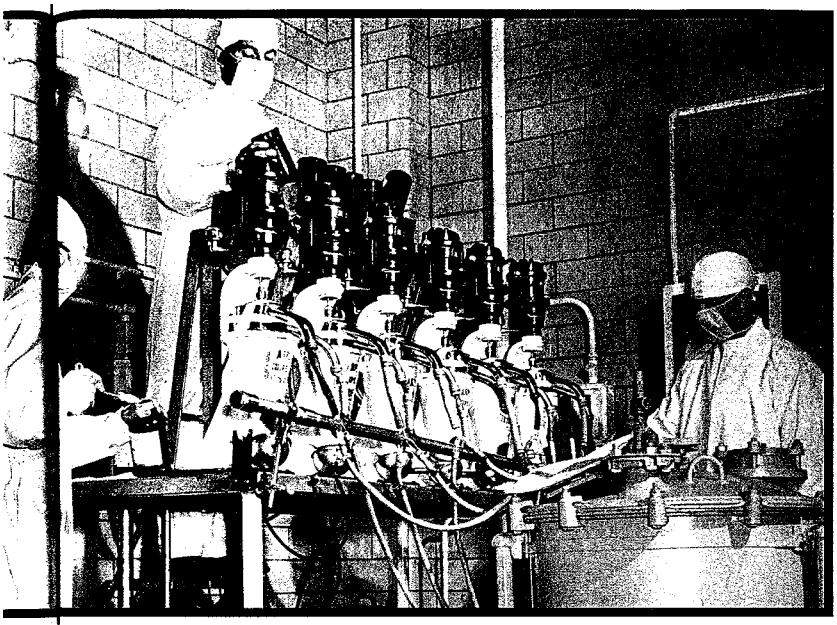
When after extensive research in the early fifties a young, unknown microbiologist from the University of Pittsburgh named Jonas Salk developed a vaccine, he became an instant American hero. On April 12, 1955, the 10th anniversary of the death of Franklin D. Roosevelt, perhaps the most famous American polio victim, church bells rang throughout the land to celebrate the success of the trials of Salk's vaccine and its availability for massive immunization. Between the inactivated Salk vaccine and later Albert Sabin's "live" oral vaccine, polio was completely eradicated in this country by the late seventies. The success of the polio vaccine has stood as a singular achievement that is universally regarded as an unparalleled triumph of American know-how over what was as close to a plague as this country had ever known.

In 1977, when Walter Kyle was preparing to take the Arkansas bar exam, the last thing on his mind was the polio vaccine. The second in a family of overachievers (his two sisters both practice law, one in Texas, the other in Arkansas; a brother is a neurosurgeon) and a proficient pilot, Kyle had planned to pursue aviation law. He recalls that he used to fly seaplanes for Chalk's International to Bimini (before Gary Hart made it famous with Donna Rice aboard the yacht *Monkey Business*) after graduating from the University of Miami in Coral Gables. At Miami, Kyle received degrees in mechanical and electrical engineering, and then spent two years testing autopilot systems by pushing planes to their maximum speeds and taking them into a dive to see if they would crack up before he could recover.

After he'd had his fill of engineering feats, Kyle returned home to attend law school at the University of Arkansas in Fayetteville, where his old friend Bill Clinton and Bill's new wife, Hillary, were two of his professors. (Kyle recalls that the future First Lady was "more intimidating" in the classroom than her husband.) Two weeks after graduating, Kyle took the bar exam, skipping the lengthy bar preparation course most students consider prerequisite. He already had a job lined up with a law firm in Ft. Lauderdale.

Then the wife of one of his plane mechanics suddenly became paralyzed—a victim of what doctors call "contact" polio. Like almost 3 million Americans each year, she had brought her infant son to his pediatrician for a routine polio immunization. And like those other Americans she had no idea that her son's ingestion of the live oral vaccine held any danger for her or her child. But three weeks after he received the vaccine, she became permanently paralyzed from the waist down. The statistical risk of paralysis from the vaccine is considered negligible, but each year 8 to 10 people in the United States contract polio after receiving the oral vaccine or, as in the young mother's case,

Debbie Bookchin and Jim Schumacher are freelance writers who live in Vermont.



PANDORA'S BOX: Above, workers in 1955, processing the polio vaccine. Kyle believes the continued use of monkey tissue in making the vaccine has exposed millions of Americans to many simian viruses.

after being exposed weeks later to the poliovirus in the stools of a recently vaccinated child. In 1963, the United States had switched from an inactivated injected vaccine and began to use the live virus vaccine. One reason the country began using the live vaccine was to increase the number of people being immunized in this fashion.

When Kyle learned that government policy included this kind of deliberate exposure of care givers to the deadly virus, he was outraged. "These people were innocents whose lives were ruined all because of a massive government program to innoculate people with a live virus without their consent," he says. "I thought it was a travesty." One day after passing the bar exam, he signed up his first case, agreeing to represent the woman and her family against one of the world's largest drug manufacturers, Lederle Laboratories, now known as Wyeth-Lederle Vaccines and Pediatrics, in Radnor, Pennsylvania, the nation's only manufacturer of live polio vaccine.

Kyle took his paralysis case to a well-known tort attorney, Henry Woods, now an Arkansas federal judge. On the day they were to start the trial, the two men won a sizable settlement from Lederle for their client. As far as Woods was concerned, the case was over. Not so Kyle. In 1979 he filed suit against the federal government on behalf of his paralyzed client, claiming not only that the government had failed to follow its own regulations to ensure that the vaccine was safe for people in close proximity to those innoculated, but that it was an invasion of a constitutional right to privacy for the U.S. government to expose people to the virus without their knowledge or consent. When the U.S. Court of Appeals for the Eighth Circuit, in St.Louis, agreed with Kyle that the government could be held liable on certain claims just like any private citizen, Kyle significantly advanced the rights of anyone harmed by vaccines to sue the government for negligence. Since then he has been involved in nearly 100 claims on behalf of vaccine-damaged clients.

Far from prospering from these claims, Kyle has often not been paid for his vaccine work and has found that he has to devote increasing amounts of his time to more garden variety tort law to make ends meet. But even if they haven't made him rich, his vaccine litigations have secured him a minor place in legal history. In 1988, the United States Supreme Court cited his 1981 case in a landmark decision recognizing the rights of any vaccine-damaged individual to sue the federal government for failure to follow its own regulations. "He has touched a lot of people through his work," says Clinton. "He has always been hard working, determined, and compassionate."

IT WAS DURING HIS INITIAL case that Kyle received his first big batch of internal documents from Lederle. *(Continued on page 93)*

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(Continued from page 61)

In his discovery requests, Kyle had asked for Lederle's neurovirulence-testing data—the tests that ensure the vaccine won't cripple anyone. In response, he received a flood of documents and noticed that many contained references to "adventitious agents." Memo after memo documented Lederle's problem with the agents. Says Kyle, "It became obvious that what they were talking about was unwanted live monkey viruses that they couldn't get rid of." The realization piqued his curiosity.

Kyle started setting aside every document that mentioned adventitious agents. When he later turned to analyze them, he realized that the memos were describing a witch's brew of contaminants, including simian measles, foamy viruses, simian virus 40 (SV40), adenoviruses, and simian cytomegalovirus, known to scientists by its acronym SCMV. The Lederle memos dated from the early sixties to 1987 show that these adventitious agents had been plaguing the process of manufacturing vaccine for decades, forcing Lederle to discard what would have become millions of doses of vaccine.

Kyle cites a 1983 memo describing an internal company study of 13 years of vaccine production. The memo documents that Lederle was forced to junk almost half—43 percent—of all vaccine-in-production largely because of viral contamination problems. The memos show Lederle also had other contamination issues. A 1977 memo reports that even though the vaccine manufacturing process was supposed to be sterile, bacterial contamination forced the rejection of a large amount of vaccine-in-production. An internal company investigation found that mold, yeast, and strep were living in the company's air duct system.

As Kyle continued to collect Lederle memos, he realized that they mentioned one specific "adventitious agent" again and again: simian cytomegalovirus. According to Kyle's documents, simian CMV and CMV-like agents have proved to be a chronic problem for Lederle, which frequently had difficulty keeping the virus out of monkey-kidney-tissue preparations—the so-called harvests of poliovirus-containing fluids from the kidney tissues. Kyle believes the virus or its DNA has almost certainly made it beyond the vaccine-in-production stage and into some doses of the final vaccine released to the public, a charge that Lederle denies.

SCMV is a member of the herpes virus family. Its human counterpart, human cytomegalovirus, can cause retinal and gastrointestinal disorders and malaise. It is considered quite dangerous to infants or people with compromised immune systems. HCMV easily infects if it is ingested orally. If SCMV were present in oral polio vaccine, something officials from the Food and Drug Administration adamantly deny, it would be, they acknowledge, a cause for serious concern.

Lederle, which sells 16 million to 20 million doses of the vaccine each year, most of it to the U.S. government, insists all monkey tissue it obtains is tested and screened for adventitious agents before it is used for vaccine production and that it "strictly adhere[s]" to FDA regulations. Doug Petkus, a Lederle spokesman, asserts that the screening process used by Lederle is designed to insure that the vaccine be free of all foreign viruses, including SCMV. Another Lederle spokesperson, Audrey Ashby, maintains that "monkeys contaminated with cytomegalovirus have never been used for oral polio vaccine production."

But internal company memos from 1972 suggest that for many years SCMV-infected monkeys were used. In August 1972, Ronald Vallancourt, a veterinarian who was head of Lederle's polio production, described a study the company had undertaken with the FDA to examine how widely SCMV contaminated monkey tissue. In a memo titled "Cytomegalovirus Contingency Plan," Vallancourt noted that the joint study had found all 11 monkeys examined harbored the virus. Worse, he noted, 7 of the 11 infected monkeys "would have passed our existing test standards," an acknowledgment on Vallancourt's part that the monkeys would have been found suitable for vaccine production. Vallancourt concluded that the 1972 study suggested that SCMV "has been present in our environment for at least as long as the poliovirus vaccine has been produced. Therefore, all substrate [kidney tissue] used to this date have conceivably been 'contaminated.'"

> Kyle believes that the simian counterpart to HIV, or possibly even an HIV progenitor, may have been released in millions of doses of polio vaccine in the seventies.

The possibility of vaccine contamination was apparently of no concern to federal health officials at the time. As far back as 1968, a Lederle official had boasted that Roderick Murray, the head of the federal agency then charged with vaccine safety, had "agreed" with the company "that the adventitious agents . . . are of little consequence for an oral preparation in that such a large experience exists with the use of oral polio vaccine without any evidence of trouble related to these agents." Kyle's memos indicate that government health officials never followed up on the joint SCMV study. In one 1972 memo, Vallancourt even observed: "Cytomegalovirus . . . is not being tested for at this time. For a manufacturer, and especially a regulatory agency, to accept this situation can only be judged a dichotomy but it has its basis in the fact that this agent is extremely cell-associated and cannot end up in the final vaccine." Kyle disputes Vallancourt's conclusion, focusing instead on Lederle's failure to test for SCMV. "If they weren't testing for this virus at least until after 1972, and they admit the monkeys were all contaminated, then Americans got contaminated vaccine," he says.

In 1973, Vallancourt informed his superiors at Lederle that federal officials had never again raised the subject of the SCMV contamination since the completion of the joint study the previous year. In another 1973 memo, he predicted that "our CMV problem will be pushed further and further into the background." Vallancourt was right, as underscored by the resignation of a government scientist named Kendall O. Smith, an electron microscopist, who in 1968 had first discovered widespread SCMV contamination of commercial African green monkey kidney tissues—the exact type used for polio vaccine manufacture. In a 1969 paper published in the *Journal of the National Cancer Institute*, Smith noted that SCMV often escaped detection by conventional methods and warned that existing testing protocols were inadequate. Smith quit the FDA in disgust over the agency's failure to react to the virus. In 1972, he told the journal *Science* that he found it "unforgivable" that federal regulations governing polio vaccine production had not been changed to ensure more thorough screening against the virus. Those regulations are essentially unchanged today.

BARBARA LOE FISHER is a five-foot-one-inch, 49-year-old Washington, D.C., mother-turned-activist who heads the National Vaccine Information Center (NVIC), headquartered in Vienna, Virginia. From the organization's airy, second-story office just outside the Beltway, she and cofounder Kathi Williams have long pushed for greater government disclosure of the little-studied deleterious effects of vaccines upon some recipients and for parents to be allowed to make informed decisions about what vaccines their children receive. The notion of live monkey viruses in the polio vaccine strikes Fisher as alarming and par for the course, at the same time. "Our organization is very concerned that there seems to be so little interest on the part of the government about the issue of exposing millions of children to viruses and other biological agents from other species," she says. "Nobody knows what the long-term impact might be."

Fisher notes that as recently as 1995, Swiss scientists found evidence that the live

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measles-mumps-rubella vaccine, grown on cell cultures of chicken embryos, might be contaminated with avian leukosis virus, which can cause a leukemia-like illness in birds. As long as the polio vaccine and a handful of others are to be mandated for every child, the government has an obligation to prove they are free of contaminants, she says. "Ask any mother if she would approve of her child being given a vaccine that was potentially contaminated with monkey viruses," she says of the polio vaccine. "I think she would tell you, 'No thank you.'"

Cecil Fox was a senior scientist with the National Institutes of Health for 18 years until 1991. There he did cancer research and became a prominent AIDS researcher who discovered that the virus that causes AIDS could live outside the bloodstream and in the lymph nodes. Fox has been concerned about the polio vaccine for many years. He takes issue with Vallancourt's 1972 assertion that since SCMV is "cell-associated" it could not end up in the final vaccine, arguing that fluids containing CMV-infected cells are notoriously difficult to clean up. "Saying it's cell-associated is taking a great leap of faith," he says. "There's no good way of cleaning up a cultured medium or liquid in which a fair amount of CMV has been present. You may be able to filter out all the infected cells, but that doesn't mean that the liquid is no longer infectious."

Although he remains a supporter of the oral polio vaccine, he cautions that continued reliance on monkey kidney tissues for vaccine production carries risks. "There's no way to ensure purity. All you need is one virus in one cell," he says. The use of monkeys, he says, is "a Pandora's box: The risk is that there are still monkey viruses that have not yet been discovered that can be transmitted to humans."

Fox is particularly concerned about the inactivated vaccine, which he believes holds far greater risk than the oral vaccine for transmitting monkey viruses to humans, because it is injected directly into the body. Fox's concern is of renewed interest because the Centers for Disease Control and the Massachusetts Department of Public Health have recently recommended using inactivated vaccine for some of the four recommended childhood doses of polio vaccine in response to concerns about polio caused by the live vaccine. Fox stresses that for many years the original Salk vaccine—an injected vaccine—may have been contaminated with up to 60 different monkey viruses, which he has referred to as the "crabgrass" of the polio vaccine.

At least one of these viruses, simian virus 40 (SV40), was not always killed by the formaldehyde used to inactivate the Salk vaccine. Between 1954 and 1963, up to 98 million Americans were exposed to SV40 through the polio vaccine. By 1963, all vaccine manufacturers had switched to African green monkeys, a species that is not infected with SV40; and all stocks of contaminated polio vaccine were no longer on the market. Long presumed harmless, SV40 genetic material has recently been discovered in some human brain, bone, and lung cancers. Scientists speculate that it is an oncornavirus, a cancer-causing virus, but that it may take years to cause certain cancers. Fox, who now heads a Gaithersburg, Maryland, research firm, says SV40 highlights the dangers associated with monkeys. "When you inject ground-up monkey guts into children, all kinds of things can happen."

MEDICAL MIRACLE: Jonas Salk created the vaccine that freed the world from the horrors of polio.

Kyle speculates that the government was reluctant to get tough on Lederle's SCMV problem because it feared running out of vaccine. In fact, Vallancourt noted in his "Cytomegalovirus Contingency Plan" that the company held all the cards should the government decide to crack down on CMV: "Unless and until Pfizer's Diplovax [a rival vaccine] is in abundant supply, the FDA cannot risk Lederle being off the market."

Kyle also believes that Lederle's SCMV problems likely did not end 25 years ago. The 1983 memo, which had documented that the company had tossed almost half of its vaccine-in-production because of contamination problems, cited SCMV as the top culprit. Kyle has also collected hundreds of pages of Lederle's monthly reports on poliovirus harvests. The reports document that SCMV continued to torment the vaccine manufacturer well into the 1980s. From October 1980 to March 1981, SCMV was particularly vexing, forcing the company to reject 65 percent of its harvests. A January 1981 report complained: "Rejections of harvest produced in October, November ... and December ... have been very high—11 in a row ... and 13 of 14 overall. An unidentified viral agent, strongly resembling or presumed to be cytomegalovirus, is the cause."

In 1986, Lederle was forced to scrap 16 percent of all harvests because of SCMV. As recently as 1987, the last year for which Kyle has information, Lederle documented that it had discarded 30 percent of all its poliovirus harvests during the first half of the year, 8 percent because of SCMV contamination.

FDA OFFICIALS DISMISS the possibility that the polio vaccine released to the public could be contaminated by SCMV or any other known monkey virus. In a lengthy interview, William Egan, a chemist and deputy director of the FDA's Office of Vaccines Research and Review, and two of his subordinates asserted that the oral polio vaccine is, and has been, free of foreign viruses since SV40 contamination ended in 1963. But as a senior FDA official later clarified: "We can't screen for something we don't know about. We maintain it's free of viruses we

know how to protect from." Many of the scientists contacted for this article who work with monkeys, including Ronald Desrosiers, professor of microbiology and molecular genetics at Harvard Medical School and chairman of the microbiology division of New England Regional Primate Research Center, believe that only a small fraction of the viruses harbored by monkeys have been identified. Desrosiers once described use of monkey tissue in polio vaccine preparation as "a ticking time bomb waiting to explode."

According to Peter Reeve, a virologist and associate director of the FDA's division of viral products, the FDA ceased its own testing for viral contaminants more than 15 years ago. "There was no more point in putting time or effort into getting negative results," Reeve said. "It became clear that it was not necessary to repeat the [manufacturer's] tests because there was a lot of time and money involved." Lederle continues to check for viral contaminants according to the FDA requirements, which place the obligation of testing products on the manufacturer. The FDA itself conducts only routine virulence tests in its effort to minimize vaccine-associated polio.

Kyle says the disclosure that the FDA has suspended its own testing is an example of what he characterizes as the "incestuous relationship" between the agency and the drug companies it regulates. Fisher from the NVIC is also angered by the news, which she says proves her point that the polio vaccine receives little scrutiny because of its sacred-cow status. "They're supposed to be the watchdogs," she says. "But the reality is that they have such a cozy relationship with the drug companies that they are much too lax in regulating the vaccine. They have no business allowing manufacturers to use any sort of animal tissue if they can't guarantee its safety."

Could monkey viruses from the oral polio vaccine have infected people? W. John Martin, a professor of pathology at the University of Southern California, announced in 1995 that he had isolated a virus that was closely related to SCMV from the brains and peripheral blood of two people with neuropsychiatric diseases. Writing in a peer-reviewed journal, *Clinical and Diagnostic Virology*, he posited that the likely source was contaminated doses of the oral polio vaccine. Gary Hayward, a renowned herpes virus expert at Johns Hopkins University, has confirmed that the genetic sequences Martin has sent him are very close to those of an African green monkey cytomegalovirus. "The virus he's working with is not from baboons, or chimpanzees or rhesus. It's definitely from an African green monkey-like species," says Hayward. Martin's work has not been replicated and no one knows today whether Martin's hypothesis—that SCMV or an SCMV variant could be related to chronic fatigue syndrome and other immune-depressive diseases—has

Walter Kyle

any basis.

Martin says his belief that monkey viruses could be playing a role in human disease stems from his own experience testing vaccines at the FDA in the late seventies. He recalls being suspicious of viral DNA in a batch of vaccine and seeking permission from his superior to test it further. Permission was denied, and the agency released the batch containing millions of individual doses.

Martin's story is confirmed by a colleague from the time, G.S. Aulakh, a scientist who recalled that his superiors at the FDA rejected Martin's efforts to test the contaminant. "Nobody tested to see if it was harmful or not," Aulakh recalls. He adds that he has not seen or spoken to Martin since the two men worked together nearly 20 years ago, but his memory of his boss's brush-off is the same. "They told me the testing would scare the people, and it's not in the interest of the American people and this organization to do it," Aulakh says. A postscript: A few years later Martin's superior retired from the FDA and took a job as a senior vice-president with American Cyanamid, the parent company of Lederle.

HARLAND WINTER is a pediatric gastroenterologist who holds multiple staff positions at Children's Hospital, Massachusetts General, and Boston Medical Center. He is an associate professor at the medical schools of Harvard and Boston University. In his home, Winter has a reproduction of an ancient Egyptian papyrus drawing of a person with a polio-withered leg, a reminder that polio has afflicted mankind for millennia. Now polio is near extinction worldwide. But he echoes other clinicians when he says that fear of monkey viruses shouldn't scare people from the vaccine. "I think it would be terrible if people became so concerned about taking vaccines that polio would return," he says.

Susan Lett, medical director of the immunization program of the Massachusetts Department of Public Health, explains that even though the Western Hemisphere was declared polio free in 1991, the possibility of exposure to the virus always exists until the disease is wiped out. "The risk for that happening is declining based on rapid advances in other countries," Lett says, but she adds that people should continue to make sure their children are vaccinated. She says the CDC has never provided her with any data indicating the current vaccine contains dangerous contaminants. "We are all committed at every level to having the safest vaccines available," she says.

For his part, Kyle contends he is not anti-vaccine. What bothers him is the pattern he feels his memos reveal. "There's no reason American kids should be exposed to dangerous viruses because of government sloppiness and indifference," he says. Kyle believes that lax regulation of the vaccine has not only exposed Americans to SCMV and other monkey viruses but possibly to a far greater danger—AIDS. He believes that SIV (the simian counterpart to HIV, the human virus that causes AIDS) or possibly even an HIV-progenitor may have been released in millions of doses of polio vaccine in the seventies.

SIV infects up to 50 percent of African green monkeys in the wild. But since it is asymptomatic in the monkeys, Kyle believes infected African greens would not have been excluded from vaccine production prior to the discovery of the virus in 1985. Since then, all monkeys used to make vaccine have been tested for the virus.

Kyle focuses principally on one lot—2 million to 3 million individual doses—of vaccine released in 1977. The FDA was so concerned about the lot that its release was delayed for an unprecedented 20 months. FDA scientists had discovered the batch, listed as "Lot 3-444," might contain retroviruses (SIV and HIV are retroviruses). Although no one at the time knew about the existence of AIDS, the possibility the vaccine could contain retroviruses prompted the agency to send micrographs—photographs taken through an electron microscope—of suspected viral material found in the batch to three electron microscopists at the National Institutes of Health for review.

> "It's in the best interests of the drug companies not to do anything," says a prominent scientist "Until somebody like Walter Kyle raises enough hell, it's going to continue that way."

Though the scientists were unsure about the identity of the material, the FDA decided the lot was free of contaminants and released it for public consumption. Kyle says that far from making a definitive determination concerning the vaccine's safety, one NIH scientist, in a memo to the FDA, worried about the possibility of retroviruses in the vaccine and warned of the potential for cross-species transfer of viruses. Kyle speculates that Lot 3-444 and perhaps others may have been contaminated with SIV or an HIV progenitor.

It was after he had received and reviewed the extensive documentation on Lot 3-444 that Kyle began research that led him to posit an alternative source for AIDS in North America. In the seventies, some clinicians were administering repeated doses of the oral vaccine to gay men in California and New York as an unorthodox cure for herpes lesions. Kyle believes that the live virus, which normally would pass through the gut in children without adverse effect, found access to the bloodstream in gay men as a result of the open lesions and sexual activities. Kyle believes that when the HIV-like virus entered the blood stream, it began its deadly work.

Kyle's theory, far from being dismissed, was published in 1992 by *The Lancet*, one of the most prestigious medical journals in the world. Partially in response to Kyle's claims, this past year FDA scientists tested samples from 12 lots of old polio vaccine for the presence of HIV and SIV. The results, they say, were negative. Howard Urnovitz, a Berkeley microbiologist who is founder and science director of the Chronic Illness Research Foundation, has reviewed the FDA study. He says even if HIV or SIV were not found, the finding of other markers associated with nonpolio viruses is significant. "What's shocking is that there is a polymerase DNA [an enzyme characteristic of a retrovirus]," Urnovitz says. "Because these are vaccines that should only contain [the poliovirus which is] an RNA virus. What it tells us is that they have no idea what's spilling over into the vaccine."

John Coffin, a Tufts professor of molecular biology and microbiology who serves as a senior editor of the highly respected *Journal of Virology*, feels Kyle's AIDS theory "doesn't make a great deal of sense." Like many other scientists, Coffin believes the likely source for the AIDS virus in humans is chimpanzees, not African green monkeys. He observes that the polio vaccine has a 40-year safety record that is "well established" and believes that the vaccine is completely safe as far as retroviruses are concerned. Nonetheless, Coffin says, there is always a possibility of cross-species viral contamination when animal tissues are used. "By continuing to grow the vaccine on monkey tissues, there clearly is a discernible risk," he says. "It would make a lot of sense to move away from monkey tissue."

That view is shared by a number of scientists, including Jonathan Allan, a virologist and internationally known AIDS researcher at the Southwest Foundation for Biomedical Research in San Antonio, Texas. Allan is a supporter of the polio vaccine and says he has no reason to believe it is contaminated. But he agrees that continued use of monkey kidney cells for polio vaccine production is foolhardy.

"There's a lot of scientific evidence that points to the possibility that monkey viruses that typically cause little or no disease in their natural hosts can have disastrous consequences when they jump ship into humans," says Allan, who was a vocal dissident on an FDA panel that approved the baboon bone marrow transplant for AIDS patient Jeff Getty in 1995. In a 1996 *New York Times* op-ed essay, he castigated the FDA and CDC for "muddled" priorities, saying,

"Once a virus invades the human population it is nearly impossible to eradicate it." Allan, like many other scientists interviewed for this article, believes the United States should abandon the use of monkeys and join countries such as Great Britain and Canada that have used more expensive cloned human cells to produce oral and inactivated polio vaccine for many years.

RECENTLY, WALTER KYLE has begun to turn his attention to the many new unexplained diseases that have arisen in the second half of this century. What if some are connected with viral contaminants in vaccines? In Kyle's very first vaccine case, Lederle argued that his client had become paralyzed by a polio vaccine that would not have affected any normal person because she was immuno-compromised in some fashion. Kyle says it was the other way around, and he was angered that the drug company engaged in what he calls a classic "blame the victim strategy." His client was fine until she was exposed to the vaccine. "My thought was there was some agent—monkey viral contaminant—that transmitted transient immune deficiency," he says. "That's why she got paralyzed."

Now Kyle is having tissues and blood samples from clients who have unexplained immune system disorders tested, searching for clues that they may be harboring in their blood monkey virus sequences that came from the polio vaccine. Kyle admits it's a chilling idea that millions of Americans could be walking around with monkey viruses, but given what he knows, it hardly seems far-fetched. What is scarier to him is the continued use of monkeys to manufacture the polio vaccine and continued government indifference. "Why do we continue to take risks with our children when the rest of the world abandoned monkeys a long time ago?" he asks in frustration. "When are we going to wise up?"

Today, even as more and more scientists recognize that there are safer alternatives, Americans continue to have no choice when it comes to polio vaccine: both the oral and injected vaccines available in this country are exclusively grown on monkey kidney cells. Pasteur Mérieux Connaught manufactures an inactivated vaccine from monkeys for U.S. consumption but produces the vaccine on clean cloned human cell lines for Canadian use. Cecil Fox maintains that, despite all the problems associated with monkeys, there is no financial incentive for vaccine manufacturers to give them up.

"It's easy. We've done it for a long time, so we keep on doing it," he says. Fox doubts that U.S. policy will change in the near future, even though the technology exists to readily make a vaccine safe from all contaminants. "It's in the best interests of the stockholders of these companies not to do anything," he says. "Until somebody like Walter Kyle raises enough hell, it's going to continue that way." **B**

American Academy of Pediatrics
1801 Hinman Avenue
Evanston, Illinois

November 29, 1972

Julius J. Weinberg, M.D.
1800 Grand Avenue
Waukegan, Illinois 60085

Dear Doctor Weinberg:

In reply to your note of November 22, 1972 I can inform you that the Committee on Infectious Disease has discussed the relative merits of the amount of polio virus vaccine grown on human diploid cells vs. growth on monkey kidney cells. It is the felling of the Committee that this vaccine probably has some slight advantage over the old vaccine because the complete elimination of the risk of transmission of the simian virus.

The new vaccine has been approved by the Division of Biologics, and I suspect this method of manufacture will gradually replace the other method. However, the inability to obtain the new vaccine should not deter the practitioner from going ahead and continuing to use the vaccine produced on monkey kidney cells.

I am sure the Red Book, which is due for release early next year, will discuss this matter in the section on poliomyelitis vaccine.

Very truly yours,

Stanley L. Harrison, M.D.
American Academy of Pediatrics

12/1/72
1. Dr Sam Katz - Washington to call

(25)

EXHIBIT 2

Biological Section - November 29, 1971

Mr. R. A. Schoellhorn

American Academy of Pediatrics--
Pfizer's Human Diploid Cell Vaccine

Mr. J. H. Rose
Mr. G. J. Sella, Jr.
Dr. W. M. Sweeney
Mr. D. Wallis

Mr. J. Rose's Memo Dated 11/16/71

I contacted Dr. Sam Katz, Chairman of the American Academy of Pediatrics Committee, about our concern of statements supporting diploid cell vaccine over our current monkey kidney. Dr. Katz told me he was contacted by the DBS to attend a committee meeting on December 3 to learn of the new diploid vaccine and that he would not be in attendance, but has recommended another committee member. He did not volunteer his name.

I told Dr. Katz we were concerned about statements of endorsing the vaccine over monkey kidney and he responded, without reservation, that this would certainly not be the case, would not be in the best interest of the public health, and certainly would have no foundation for such an endorsement. In fact, he said they may do nothing more than inform the Committee that an additional vaccine is now available.

I directed the conversation in the area of antibody titers to infants six months of age. He said he considered this to be absolute nonsense since the antibody titer has no relationship to the protection of the infant.

I told him I would be happy to come down to see him and other committee members with a great deal of information regarding the safety and efficacy of polio vaccine. He said such information should be cherished but certainly is not necessary since there is no question in the Committee's mind that this vaccine has been and will continue to be a safe vaccine.

I thanked him for listening to me, we exchanged pleasantries, and the conversation ended.

I recommend we do not contact Dr. Katz further on this subject since it will simply prove to be annoying.

PJV:mr

Paul J. Vasington

75

CYANAMID 312-869-4255

Pearl River November 15, 1971

Dr. P. J. Vasington

Mr. S. A. Flaum
Mr. R. Oppenheimer

Pfizer Human Diploid Cell
Polio Vaccine

We received a report on Thursday, November 11, 1971 that earlier that week a Pfizer salesman had contacted various members of the City of San Francisco Health Department and made two important "claims" for their new vaccine.

1. That the American Academy of Pediatrics will endorse and recommend the diploid vaccine in preference to the monkey kidney cell vaccine.

2. That the diploid vaccine provides higher antibody titers, particularly in children under 6 months of age, than does the monkey kidney material.

In checking on statement "1" I had Sander Flaum call Mr. Jack Lynch, Director of Public Information for the American Academy of Pediatrics.

Mr. Lynch in turn contacted Dr. Stanley L. Harrison, ~~Chairman of Committee on Infectious Diseases~~ Chairman of Committee on Infectious Diseases, American Academy of Pediatrics. Lynch responded that according to Dr. Harrison, "several members of the Committee are enthusiastic about the diploid cell vaccine and the possibility does exist that the Committee will recommend the diploid vaccine following its license by the D.B.S.".

BERKOWITZ & EDERLE

Mr. Flaum then secured an opportunity for Lederle to present comments to the Committee prior to the Committee taking any action.

The commercial importance of seeing that the Academy Committee does not take action to recommend the diploid vaccine cannot be overstated. We need them to at the very least remain neutral.

I believe that you and I should meet with Dr. Harrison as soon as possible and, if indicated, arrange to meet personally with the full Committee. In preparation for such a confrontation it would be valuable to have the support of the DBS. Could we count on Dr. Kirschstein reiterating the comments per the attached article (Infectious Diseases, August 1971)?

I understand you will be in Washington on November 17 and 18. If you can, another contact with Dr. Kirschstein could help clarify their position and perhaps shed some light on the marketing advantages that Pfizer might be expected to use to promote their vaccine.

Let's discuss the situation on Friday, November 19.

John Rose

JR:F
Attach

THE MEDICAL LETTER
a non profit publication
on Drugs and Therapeutics

Published by The Medical Letter, Inc., 56 Harrison Street, New Rochelle, N. Y. 10801

Vol. 14, No. 16 (Issue 354) August 4, 1972

DIPLOVAX — A NEW ORAL POLIO VACCINE

An oral polio vaccine prepared in human cells has now been licensed by the Division of Biologics Standards. Promoted as "A new biological advance" under the trade name Diplovax (Pfizer), it incorporates the three types of live, attenuated Sabin strains used in the oral vaccines available for the past decade in the United States. Like the older polio vaccines that are prepared in monkey kidney cells, Diplovax is effective in conferring immunity against paralytic polio. Recommendations for use of Diplovax are the same as for other oral polio vaccines; three doses are recommended by the United States Public Health Service for previously unimmunized children and adolescents and for adults traveling to areas where polio is epidemic or occurs regularly (Morbidity and Mortality, Suppl., June 24, 1972). In infants immunization should begin at six to 12 weeks of age. Generally the first two doses are given six to eight weeks apart and the third dose eight to 12 months later. A booster dose is indicated at the time of entrance to school, when there is a threat of an epidemic, and before travel to an endemic area. Since poliomyelitis is now rare, immunization during pregnancy is seldom indicated. When exposure to the disease is likely, however, pregnancy is not considered a contraindication to use of the vaccine.

SAFETY OF LIVE POLIOVIRUS VACCINES — When live poliovirus vaccines were first introduced, there was concern that the attenuated vaccine virus could revert to a virulent state and invade nervous tissue. Extensive experience with Sabin strains propagated in monkey kidney cells suggests that vaccine-associated paralytic polio occurs less often than once per million doses in adults and even more rarely in children. Theoretically, the virus might revert to virulence more readily after propagation in human cells, but polio vaccines prepared in human cells have already been used extensively in Yugoslavia, Sweden, the U.S.S.R. and the United Kingdom without causing polio.

The cells used for vaccine virus propagation can be contaminated by other viruses that could be transmitted to vaccinated persons. In one known incident, the SV40 virus, which causes cancer in hamsters, was inadvertently injected into many people who received the Salk vaccine. No increase in malignant disease is known to have resulted, and 17 years of experience with polio vaccines produced in monkey kidney tissue provide some reassurance that these vaccines are safe. The surveillance techniques used, however, might not detect an increase in ma-

lignancies among vaccinated individuals, and there is no way of knowing whether 17 years of surveillance is long enough.

PREPARATION OF VACCINES - Advertisements for Diplovax criticize polio vaccines prepared in monkey kidney tissue because "...at least 20 viruses can be present in monkey kidneys and...more than 1,000 monkeys may be used for each batch of vaccine." Although most of the monkeys are used for safety testing (contrary to the implication of the advertisement), the presence of other viruses is a source of concern. The monkey kidney cells are used for propagation of viruses only once and are discarded; each batch of vaccine, therefore, has a new potential for serious contamination. Screening cells for viruses is an arduous process, and there has been controversy over whether the Division of Biologics Standards has been sufficiently rigorous in its requirements for screening.

Diplovax is prepared in a human cell strain that originated from a fetal lung fibroblast. The strain has been maintained for years in tissue culture, permitting long-term observation of its characteristics. Extensive examination has revealed no evidence of contaminating viruses, but, as with monkey kidney cells, viruses that are not detectable with present techniques conceivably could be present.

CONCLUSION - Diplovax is a new oral polio vaccine that is prepared in human cells. It is probably less likely to be contaminated with other viruses than are the monkey kidney cells used for previously available polio vaccines. The new preparation appears to be as effective as older oral polio vaccines in protecting against paralytic polio. Ten vaccine experts who are consultants to The Medical Letter were asked to choose between Diplovax and vaccines prepared in monkey kidney cells; five chose one and five the other.

RHEUMATOID FACTOR TESTS

Rheumatoid factors are antibodies to human immunoglobulins that may be present in the serum of normal adults, but occur more often and in greater quantity in adults with rheumatoid arthritis. Rheumatoid factors are rarely demonstrable in children even in the presence of juvenile rheumatoid arthritis. Many serologic methods for detecting these factors are on the market but none provides an ideal test that is completely specific yet sensitive enough to detect every patient with rheumatoid arthritis.

MATERIALS USED IN TESTS - Most rheumatoid factor tests use either red blood cells or inert particles (latex, bentonite, charcoal) coated with human or rabbit immunoglobulin G (IgG). The bond between the particulate carrier and the IgG coat may be immunologic (an antigen-antibody reaction) or nonimmunologic.

FALSE RESULTS - Rheumatoid factors have been demonstrated in 10 to 50 per cent of patients with such apparently disparate conditions as tuberculosis, cancer, upper respiratory infections and syphilis, as well as in young women taking oral contraceptive pills and healthy individuals over the age of 60. Slide tests frequently give false positive, doubtful or "borderline" results and some false negative results as well. Both slide and serial serum dilution tests using freshly prepared

INTEROFFICE CORRESPONDENCE

Pearl River
Biological Production - August 23, 1968
OFFICE BLDG/FLOOR RMS DATE

COPY TO Mr. S. S. Alston
Dr. F. E. Fontaine
Dr. H. D. Piersma
Mr. E. J. Scoble
Dr. P. J. Vasington

SUBJECT: Meeting at DBS on August 21, 1968

REFERENCE: Present: From DBS - Dr. R. Murray
From Lederle - I. S. Danielson

I told Dr. Murray that there was some concern at Lederle about a possible requirement barring the use of African green monkey kidney as the substrate for the growth of attenuated polioviruses. I mentioned that the fear of possible contamination of the vaccine with the Marburg virus has subsided since it has been shown that a monkey infected with this virus will die within seven to ten days and will never survive the required six-week isolation period. Secondly, I mentioned that I had reported to Lederle that he (Dr. Murray) had stated that the adventitious agents that Dr. Kendall Smith is presumably demonstrating by his techniques are of little consequence for an oral preparation in that such a large experience exists with the use of oral polio vaccine without any evidence of trouble related to these agents. Dr. Murray agreed with both of these reports.

I then asked whether a vaccine produced in human diploid cells, such as WI-38, would be considered for licensing. The answer was "Yes." He said that regulations are being developed to cover the use of human diploid cells for vaccine production. These proposed requirements will be available in draft form within the next few weeks.

If the substrate for virus growth is changed to WI-38, five consecutive lots of each type will be required before licensing. Some clinical work will be required but probably it will not be extensive.

I reviewed the floor plan of our normal tissue culture production area and proposed that we use one of the laboratories across the hall from the one used for African green tissue scheduled for vaccine production. He saw no objection to this plan provided that this laboratory is used only for WI-38 while this line of cells is being produced.

I. S. Danielson

ISD:mr

331635

EXHIBIT 3

THE LANCET

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ORIGINAL ARTICLES

SHORT REPORTS

EDITORIALS

STROKE OCTET

CLINICAL PRACTICE

VIEWPOINT

BOOKSHELF

NEWS and COMMENT

NEWSPAPER

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causes of primary hypercholesterolaemia.[8] The identification of more patients with FDB should enable further studies to define the influence of diet and hypolipidaemic drugs on circulating LDL particles in these patients. Meanwhile our results indicate that lovastatin appears to reduce total and LDL cholesterol as effectively in patients with FDB as in those with other forms of primary hypercholesterolaemia.[8-11]

This work was supported in part by a grant from the L. K. Whittier Foundation and by National Institutes of Health grants HL 28399 and RR 334. We thank Mr Stephen J. Russell and Mr Scott R. Thatcher for *Msp*I analyses.

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VIEWPOINT

Simian retroviruses, poliovaccine, and origin of AIDS

WALTER S. KYLE

Scientists recognised the problems of undetectable simian viruses in poliovaccines in the 1950s when live SV-40, discovered in all Salk inactivated vaccine, appeared in Sabin's original seed strains. As an attorney I was prompted to seek out documents from US government and vaccine manufacturers by a medicolegal case of paralysis in a contact of a vaccinee. When that case was settled my background as a graduate electrical and mechanical engineer prompted my continued scientific inquiries. These have led to a hypothesis on the origin of AIDS.

In 1976 tests on of some monopools of live poliovaccine detected type C RNA viruses. After an almost two year study by the US Bureau of Biologics one such monopool was released in 1977, under an amendment to the manufacturer's licence, held by Lederle, permitting up to "100 organisms"/ml in the final vaccine. Such virions were associated with reverse transcriptase activity in the vaccine and when passed into other cell lines, but no retrovirus recognised at that time was detected and they were assumed to be harmless in small quantities. Poliovaccine has a sterling safety record but that very safety led to non-approved uses of the vaccine for treatment of herpetic lesions. What I propose is a link between HIV-related retroviruses from the African green monkey in poliovaccine lots, the use of this vaccine by homosexuals in a manner unanticipated when the vaccine was licensed, and the onset of the AIDS epidemic in the United States.

Some ten years ago simultaneous outbreaks of Kaposi sarcoma and serious opportunistic infections began to be reported among homosexual men, especially in New York City, San Francisco, and Los Angeles. In 1982 the US Centers for Disease Control concluded that the coincidence of Kaposi sarcoma and *Pneumocystis carinii* pneumonia "strongly suggests the occurrence of a single epidemic of underlying immunosuppression in homosexual men".[1] In the following year the cause of this acquired immunodeficiency syndrome (AIDS) was found to be a novel retrovirus which we now know as HIV. The cause of AIDS might have been identified but the source had not. Subsequently Essex and colleagues reported that the African green monkey, the species used in the production of most live poliovaccine in the US, was a reservoir of simian immunodeficiency virus (SIV).[2] 30–70% of these monkeys in the wild carry this virus and it does them no harm; however, SIV does cause "simian AIDS" in the African macaque. The harmlessness of SIV in green monkeys indicates that monkeys carrying such a virus would not be excluded from vaccine production because they would show no obvious signs of illness. SIV has some virological and biological properties in common with HIV. However, HIV (or HTLV-III or LAV) was novel in that it was not thought to be endogenous in man and could be distinguished from the then known animal retroviruses by techniques such as nucleic acid hybridisation. Similarly the US government's tests in 1976–77 on virions from poliovaccine lot 3-444 established them as unlike any of the known type-C viruses (retroviruses), and the vaccine was released for use provided it contained fewer than 100 organisms per dose and did not contain viruses "known to be harmful to man".

Presumably the regulatory authorities concluded that the presence of any such monkey virus would not affect man because there would be no transfer from the digestive tract to the lymph and blood systems and because there was no reason to suspect inter-species transfer. At that time this

ADDRESS: PO Box 332, Franconia, New Hampshire 03580, USA.

must have seemed correct, otherwise there would surely have been an outbreak in the child recipients of the vaccine. We need to remember that HIV is not thought to be transmitted via tears or urine, for example—indeed it is not perceived to be as infectious as hepatitis B virus, and a few (50–100) organisms per dose of vaccine would not be expected to affect the children taking it. This implies that if the "single epidemic of immunosuppression" began around 1977–78 and stemmed from the African green monkey, it impacted on heterosexuals and male homosexuals differently, because of differences in the type of sexual contact or in the rate of exposure to the virus or its progenitor.

I suggest that the key lies in the use of poliovaccine, contaminated with small numbers of type-C retroviruses, for the treatment of herpetic lesions, a sexually transmitted condition the prevalence of which in homosexual men is indicated in the early case-reports of those who died from AIDS. In 1974 Adolph Tager proposed[3] live oral poliovaccine for the treatment of recurrent herpes, and multiple poliovaccine doses given monthly were suggested by clinicians in New York and California.[4] The doses used for this purpose would have exceeded the "100 particle per dose" safety limit and could have provided a point source for infection that spread to sexual contacts. Other adults would also have been exposed to the putative progenitor HIV at that time, hence the need to speculate that this virus either survived passage through the gastrointestinal system because of the rate of exposure and/or bypassed it because of the nature of the sexual activity.

Was there, therefore, no concern about extraneous viruses in live poliovaccine? A series of memoranda from 30 years ago shows that there certainly was. Indeed some manufacturers who were invited to make the live vaccine declined for this reason, Merck & Co being an example.[5] Regulations brought out in the 1950s[6] referred to the exclusion of "viable" microbial agents, but a simian virus might not be considered viable in man. These regulations apparently differed from the National Institutes of Health proposed restriction on the inclusion of simian viruses unless they had been proved not to be harmful to man. In 1972, after discovery of 80–110 nm viruses in its production fluids, Lederle implemented a "cytomegalovirus contingency plan" in a response to regulations requiring additional testing for extraneous viruses. The discovery of unknown type-C particles in poliovaccines would not therefore necessarily have led to their elimination from released vaccine lots. Interpretation of the regulations allowed for a wide discretion, and even though the neurovirulence regulations were not strictly followed it did seem that a very safe product was being produced and used without significant reactions in the United States. A 1980 statement from the commissioner of the FDA implied that the only microbial agent that could be released within poliovaccine lots would be type C retroviruses.[8] Since (at least up to 1985) the regulations did not insist on tests for such viruses, their presence is highly likely.

What was the viral agent? In 1976, Phillip McGrath, director of electronmicroscopy at the US Bureau of Biologics (BOB), recorded that three samples of Lederle poliovaccine lot 3-444 contained, besides large numbers of 18–28 nm polioviruses, spherical particles 80–100 nm in diameter resembling oncornaviruses. A rough estimate put their number at between 1000 and 100 000 per ml vaccine. By 1977 some oncornaviruses had been shown to cause leukaemia and tumours in laboratory animals. An important characteristic was their possession of RNA-directed polymerase or reverse transcriptase. This large subfamily of the retroviruses consists of four types, A-D, and most of them are C-type viruses 80–110 nm wide with a central core inside the envelope. In 1975 Dr John Petricianni and Dr J. B. Milstein of BOB described a simple, rapid screening test for type-C RNA tumour viruses, based on a sensitive reverse transcriptase assay.[8] In 1976, Milstein reported such activity in lots 3-444, 1-212 and others. Importantly, reverse transcription exhibited by one vaccine monopool was also exhibited by the particle within it when grown into other cell lines. The discovery of suspect particles, specifically C-type RNA retrovirus, in 3-444 and in other lots prompted extensive testing of lot 3-444 by the Food and Drug Administration. Indeed the length of time this vaccine lot was held (20 months) was unprecedented. The US government set up a special committee to test and consult on the vaccine and the agent within it but eventually BOB permitted its release. An agent capable of genetically transmitting RNase-sensitive RNA copying ability would not be released today—or permitted for use in multiple doses by males with a homosexual lifestyle. The manufacturer's position, one that was accepted by the government of the day, seems to have been that any such organisms would stay within the intestinal system of the child since this was an oral vaccine; there was no known harmful effect for man and the microbe would not remain viable. Some companies developed alternative methods of poliovaccine manufacture (eg, in human diploid cell lines) but at that time Lederle released press statements extolling the safety of poliovaccine made in the African green money substrate. It seems the years of safety in vaccine production led both manufacturers and government to overconfidence—yet they had recognised one extraneous agent (cytomegalovirus) some years earlier and had done nothing further to test for them (see above).

My hypothesis that the virus particles found in those vaccine lots were HIV (or some variant) can be tested by analysing stored samples by the polymerase chain reaction. Reverse transcriptase analyses of released vaccine have shown up positive for such simian viruses up to 1985, and a critical look should now be taken at all such vaccines. If US government laboratories have already done PCR tests on stored samples of the incriminated lots of poliovaccine which remain, the results should be made public.

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The HEPB Initiative is a project founded and organized by a coalition of community members and students from Boston University School of Medicine, Boston University School of Public Health, Harvard College, Harvard Medical School, Harvard School of Public Health, Tufts University School of Medicine and Tufts University School of Public Health. It is supported by the Asian Health Collaborative, Beth Israel Deaconess Medical Center, The Boston Schweitzer Fellows Program, Massachusetts Medical Society, Merck & Co., Sharewood Clinic and South Cove Community Health Center.

Uniting Professional Schools and the Community
The HEPB Initiative • c/o 260 Longwood Ave, Room 244 • Boston, MA 02115

June 9, 1999

Congressman Elijah Cummings,
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Governmental Reform and Oversight
B-373 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Cummings,

On the behalf of the communities in which we serve, the Hepatitis B Education and Prevention Boston Initiative (HEPB Initiative) would like to submit testimonial in support of the hepatitis B vaccine and vaccination programs targeted at the Asian Pacific Islander (API) population.

The HEPB Initiative is a three year old community-service organization founded by Boston area professional students. Our outreach and prevention program includes collaborations with local community health centers, medical centers, professional schools, and government agencies including the Department of Public Health and the Health Care Financing Administration. We are presenting our project and data at the HCFA/CDC Adult Immunization Conference this summer in Dallas.

Our founder, Leslie Hsu has included her own very personal testimonial. Also enclosed are data from the CDC regarding the prevalence of hepatitis B in Boston and data from our own patients.

While issues have come up regarding the vaccine, the benefits of the vaccine easily outweigh the risks, especially in the API population where the rates of hepatitis B are 10-20 times higher than any other group. We encourage you to the support of the hepatitis B vaccine and catch-up immunization programs in at-risk communities.

Thank you for your time. Please feel free to contact me if you have any questions.

Sincerely,

John K. Su
Executive Director

The Hepatitis B Education and Prevention Boston Initiative

Uniting Professional Schools and the Community

John Su, Executive Director
260 Longwood Ave., Room 244 Boston, MA 02115

Visit us at www.hepbinitiative.org

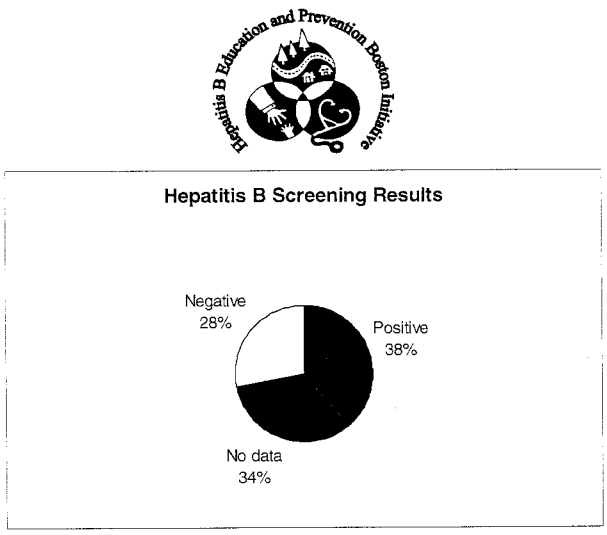
The following data was gathered from patients seeking **free hepatitis B screening tests and vaccines** provided by the **Hepatitis B Education and Prevention (HEPB) Initiative**, an organization composed of medical and public health students in Boston.

The HEPB Initiative was **founded in 1997** and received its patients in March 1998. Since then, it has provided screening tests and vaccinations to nearly **230 patients**.

The HEPB Initiative provides the screening tests and vaccinations at **South Cove Community Health Center** and **Sharewood Project**, both of which are located in the **Chinatown neighborhood of Boston**.

The latest statistics compiled by the CDC on the incidence of hepatitis B in the Greater Boston area (graphs are included) indicates that **Asians and Pacific Islanders are nearly twice as likely to be infected by hepatitis B than Caucasians**.

Our patient profile indicates that those needing a vaccine are often **young adults who do not speak English and do not have medical insurance.**


Hepatitis B Education and Prevention Boston Initiative
Hepatitis B Screening Results
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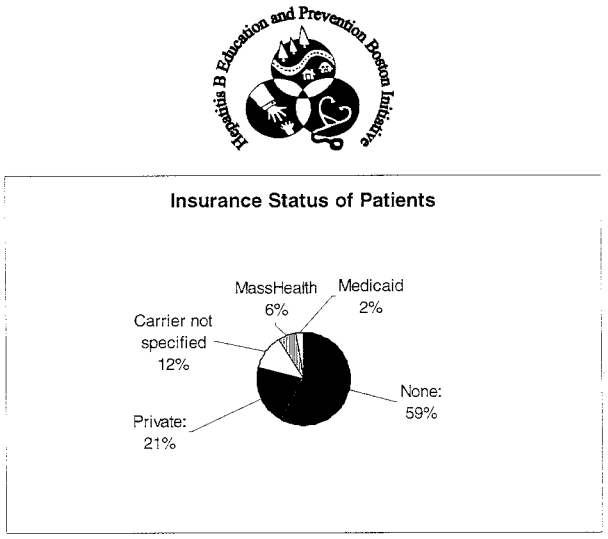
28%
Positive
38%
No data
34%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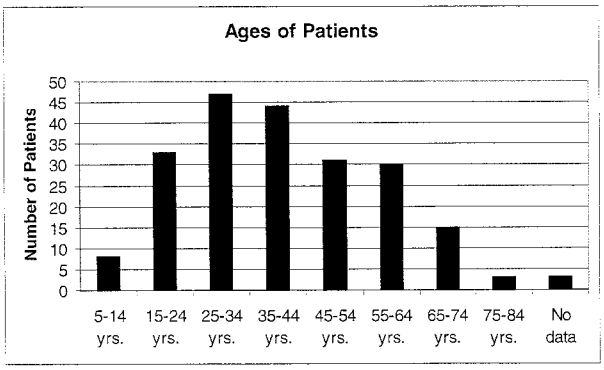
Medicaid
2%
Carrier not
specified
12%
None:
59%
Private:
21%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Number of Patients
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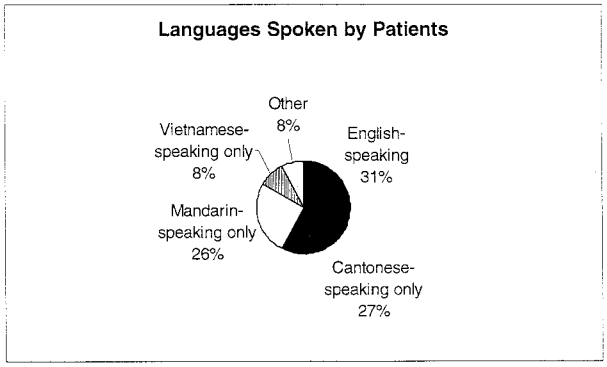
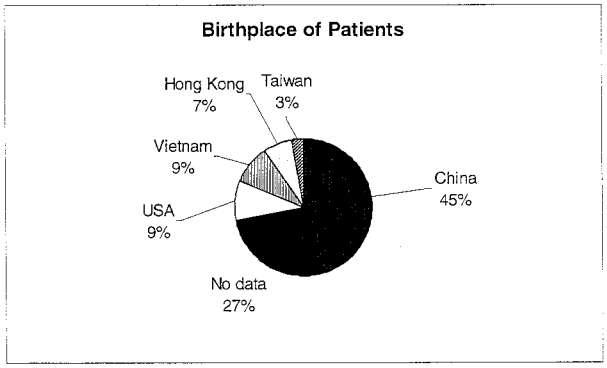
45
40
35
30
25
20
15
10
5
0
5-14 yrs.
15-24 yrs.
25-34 yrs.
35-44 yrs.
45-54 yrs.
55-64 yrs.
65-74 yrs.
75-84 yrs.
No data


Languages Spoken by Patients
Other
8%
Vietnamese-
speaking only
8%
English-
speaking
31%
Mandarin-
speaking only
26%
Cantonese-
speaking only
27%


Birthplace of Patients
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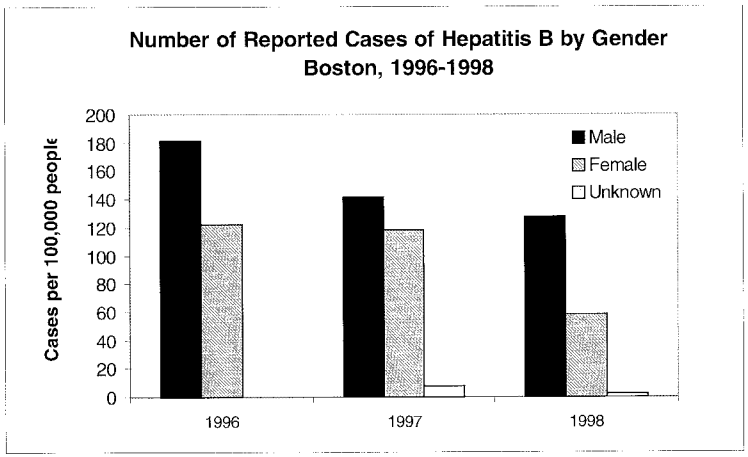
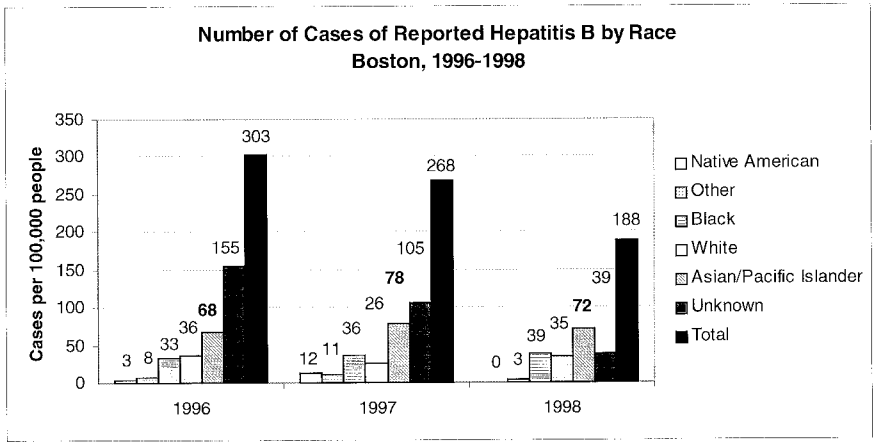
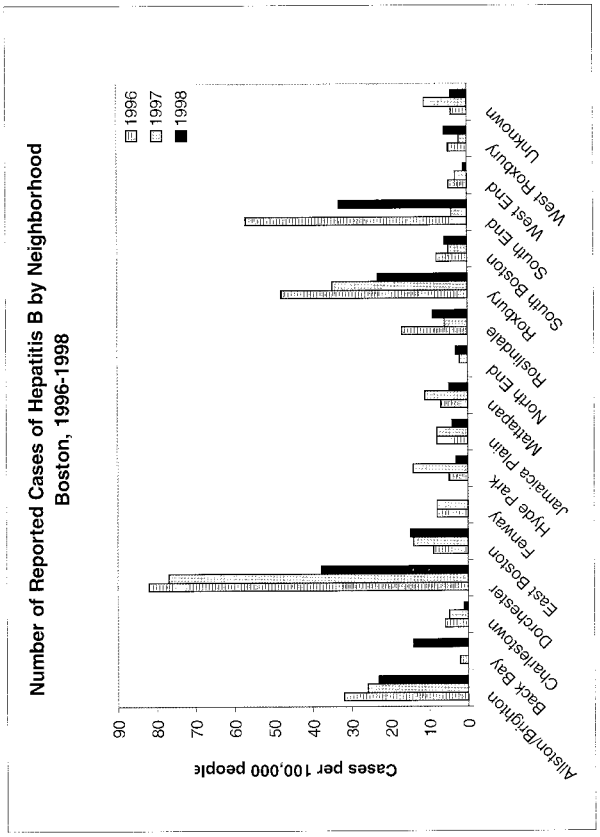
7%
Taiwan
3%
Vietnam
9%
China
45%
USA
9%
No data
27%


Number of Reported Cases of Hepatitis B by Gender
Boston, 1996-1998
Cases per 100,000 people
200
180
160
140
120
100
80
60
40
20
0
1996
1997
1998
Male
Female
Unknown

Source: CDC


Number of Cases of Reported Hepatitis B by Race
Boston, 1996-1998
Cases per 100,000 people
350
300
250
200
150
100
50
0
3
8
33
36
68
155
303
12
11
36
26
78
105
268
0
3
39
35
72
39
188
1996
1997
1998
Native American
Other
Black
White
Asian/Pacific Islander
Unknown
Total

Source: CDC


Number of Reported Cases of Hepatitis B by Neighborhood
Boston, 1996-1998
1996
1997
1998
Cases per 100,000 people
0
10
20
30
40
50
60
70
80
90
Allston/Brighton
Back Bay
Charlestown
Dorchester
East Boston
Fenway
Hyde Park
Jamaica Plain
Mattapan
North End
Roslindale
Roxbury
South Boston
South End
West End
West Roxbury
Unknown

Source: CDC

Testimony of Leslie D. Hsu, MSPH
Co-founder of Hepatitis B Education and Prevention in Boston Initiative

Dear Representative Cummings,

Hepatitis B (HBV) strikes without mercy and with great discrimination. At age 20, I watched helplessly as both my 18-year-old brother and mother died from HBV. Here is my testimony in support of the HBV vaccine and its great service to public health.

American dreams shattered. Both my parents came to the United States to study graduate school and pursue their American dream. They worked very hard to raise two children with much love and support. Yet despite all the sacrifices they made to give their children the best education and best medical care, my brother, John, woke up one day with great pain in his side. That pain turned out to be liver cancer, and that was the first time we heard about HBV. The whole family was tested for the first time, and we were simply told that all of us had been exposed to the virus and that only my father and I developed antibodies.

Families and friends destroyed. Within 3 years of discovering HBV, I lost both my brother and mother. During that time, I discovered that many family friends had died of liver cancer and many friends were fighting liver disease as well. According to DHHS, "Between 1990-1995, the average incidence rate for Asian Americans was 200 per 100,000, which was seven times higher than the average for African Americans and 30 times the average rate for Caucasians."

Pain and suffering beyond imagine. What is most disturbing about HBV is that it is a silent killer. There are no symptoms, no warning! We never had a chance. Having engaged in none of the activities that lead to HBV infection, the questions that torment us even today is where we got exposed to the virus? My mother, diagnosed only one month after my brother's death, died not only from liver cancer but mostly from the guilt that perhaps she might have transmitted HBV to her children at birth (this is the most common mode of transmission for Asians). And yet, all of this pain, all of this suffering, could have been avoided simply with a vaccine!

I have, since these tragedies, channeled my grief towards setting up the Hepatitis B Education and Prevention Boston Initiative (HBI); a medical and public health student initiated mass media campaign that provides free screening and vaccinations. Though my life will never be the same, I am doing everything in my power to save other innocent lives by educating others about the importance of getting screened and vaccinated. The Hepatitis Branch at the CDC estimated in 1995, that 55,000 Asian American and Pacific Islander (AAPI) children will be infected with HBV, 14,000 will develop chronic HBV infection and 3,000 will die from liver cancer. They also projected cost savings of $100-500 million if all AAPI children are vaccinated. In light of the gravity of these predictions, I urge all of you to please guarantee that the vaccine will always be available for hundreds of thousands who can be saved.

Sincerely,

Leslie D. Hsu, MSPH
Harvard School of Public Health, 98

UNITING PROFESSIONAL SCHOOLS AND THE COMMUNITY

www.hepbinitiative.org

HEPATITIS B EDUCATION AND PREVENTION BOSTON INITIATIVE

Mission Statement

The Hepatitis B Education and Prevention Boston (HEPB) Initiative is devoted to diminishing hepatitis B viral infection in Greater Boston by launching an age and culturally sensitive mass media and educational outreach campaign towards Asians and Pacific Islanders and by providing free hepatitis B screenings and vaccinations with minimal access barriers for all individuals.

The HEPB Initiative is also committed to providing its members with meaningful experiences in community service and public health promotion.

History

- *October 1996:* At the Asian Pacific American Medical Student Association (APAMSA) National Conference held at Harvard Medical School (HMS), the idea for a nationwide hepatitis B screening and vaccination program was presented by the Community Health Committee.
- *January-February 1997*: Founders of the HEPB Initiative, students from Harvard Medical School (HMS) and Harvard School of Public Health (HSPH), met with the Asian Health Collaborative and South Cove Community Health Center (SCCHS) in Boston Chinatown as well as local department of public health officials to identify needs of community and explore collaborative efforts. The HEPB Initiative was born to meet these needs.
- *March-April 1997*: Founders established an executive team of students from Boston University School of Medicine (BUSM), HMS, HSPH, and Tufts University School of Medicine (TUSM) to continue assessing community needs, meet with potential collaborators nationwide and research possible funding sources.
- *May 1997*: The HEPB Initiative's first hepatitis B education session was held at SCCHC. Mini-health fair and surveys assessing mass media outlets and knowledge of hepatitis B were distributed to Vietnamese-American teenagers. The project was introduced at Ebert Community Service Day at HMS and the project was subsequently awarded seed money.
- *Summer 1997*: Beth Israel Deaconess Medical Center donated 400 screenings for HEPB Initiative participants at South Cove. Merck & Co. donated 600 doses of vaccine. Committee members met with South Cove to discuss the possibility of using the health center as a screening and vaccination site and began to develop outreach materials.
- *October 1997*: The HEPB Initiative was featured in *Focus* and *Rounds*, and was presented at the HSPH Community Partnership Day. The "Fusion" benefit dance raised $3300 for the project. Committee members met with TUSM to discuss the possibility of using Sharewood Project as a screening and vaccination site.
- *November-December 1997*: Protocols for the screening and vaccination clinic at South Cove were established and volunteer manuals were written. It was established that federally-funded Vaccines for Children would be used for eligible participants. South Cove agreed to cover the cost of vaccinating 200 patients free of charge in addition to those who qualified for the Free Care program at South Cove.
- *January 1998*: A mass media campaign was launched by the HEPB Initiative in Chinatown.

- *Spring 1998*: Volunteers for the clinic are trained. SCCHC opened its doors to HEPB Initiative activities.
- *Summer 1998*: The HEPB Initiative received substantial financial support from the Health Care Financing Administration (HCFA) and the Massachusetts Medical Society.
- *October 1998:* Sharewood Project opened its doors to HEPB Initiative activities. South Cove Community Health Center is now open for HEPB Initiative activities twice a month in four-hour sessions.
- *November 1998:* The HEPB Initiative received a second donation of 600 vaccines from Merck & Co.
- *March 1999:* A hepatitis B Kick-Off Event was held by HCFA featuring the outreach and education efforts of the HEPB Initiative and its collaborators. The project supports the U.S. Department of Health and Human Services' the Asian American Pacific Islander Initiative.
- *Spring 1999:* Over a hundred and fifty patients have received screenings and vaccines through our project. Countless others have been educated through health fairs, workshops, outreach materials, and presentations.

  The collaborations with the clinics continue to evolve and solidify, and mass media and education campaigns remain an integral part of the project. Volunteers are professionals in the community or students at BUSM, Boston University School of Public Health, Harvard College, HMS, HSPH, TUSM, and Tufts University School of Public Health. The HEPB Initiative considers innovative methods for reaching target populations in Chinatown and strategies for expansion to other communities.

Strategies

- Mass media and education campaigns will be targeted towards the Asian and Pacific Islander community.
- Multiple media channels, including posters, pamphlets and radio and television broadcasts, in Cantonese, Mandarin and Vietnamese will raise general awareness of hepatitis B and advertise the free screenings and vaccinations.
- Workshops targeted towards young people will be held at schools and at youth centers in Chinatown.
- Informational brochures targeting physicians and other professionals in the medical community will be developed to raise awareness of the prevalence of hepatitis B among Asians and Pacific Islanders.
- Free screenings and vaccinations will be offered at South Cove Community Health Center (885 Washington Street, Boston MA 02111) and Sharewood Project (Church of All Nations, 333 Tremont Street Boston MA 02116).
- Follow-up compliance will be encouraged by incentives provided by local sponsors of the HEPB Initiative.

HEPATITIS B EDUCATION AND PREVENTION BOSTON INITIATIVE

What YOU Can Do to Help!

- Spread the word about our program and its services.
- Donate incentives for our follow-up program.
- Donate vaccines and/or screenings.
- Provide financial support.
- Volunteer in the clinic or in educational and outreach campaigns.

Collaborators and Sponsors

Asian American Bank
Asian American Broadcast Network
The Asian Health Collaborative
Ben & Jerry's Ice Cream
BankBoston
Beth Israel Deaconess Medical Center
Boston Lion's Club
The Boston Schweitzer Fellows Program
Boston University School of Medicine
Boston University School of Public Health
Harvard Medical School
Harvard University School of Public Health
Health Care Financing Administration
Massachusetts Department of Public Health
Massachusetts Medical Society
McDonald's
Merck & Co.
Sharewood Project
South Cove Community Health Center
Tufts University School of Medicine
Tufts University School of Public Health

Contacts at the HEPB Initiative

Executive Director		
John Su	(617) 266-7583	jksu@bu.edu
Administrative Director		
Jenise Wong	(617) 432-9259	jcwong@fas.harvard.edu
Director of Outreach		
Peerapong Tantamjarik	(617) 262-5936	ptantamj@hsph.harvard.edu
Director of Materials Development		
Jennifer Chen	(617) 876-6491	jchen2@opal.tufts.edu
Director of Clinic Affairs		
Karen Ho	(617) 524-4144	kho@student.med.harvard.edu

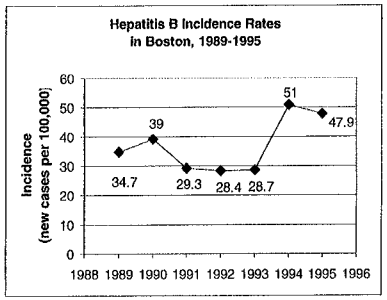
Please send all correspondence to:
HEPB Initiative
260 Longwood Ave., Rm. 244
Boston, MA 02115

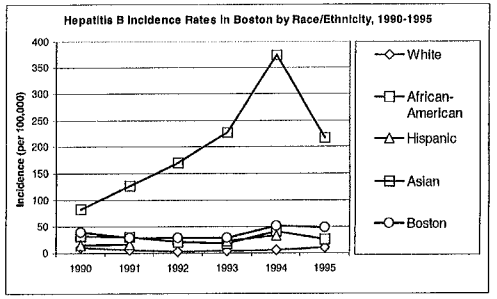
HEPB INITIATIVE FACT SHEET

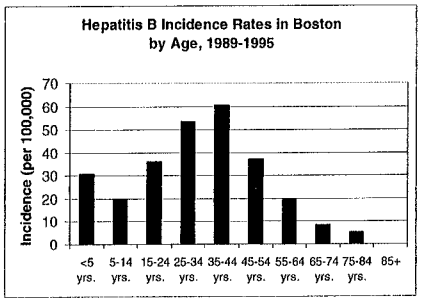
About the Disease

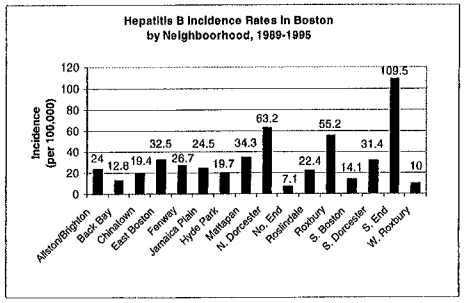
- Hepatitis B is 100 times more infective than AIDS but is easily preventable by a vaccine.
- Hepatitis B can cause life-long infection, liver failure (cirrhosis, cancer) and death.
- 250,000 people in the United States contract the disease annually.
- 5,000 people die from the disease annually.
- In Boston, the average annual incidence rate (per 100,000 people) for 1990-1995 was a striking 199.9 for Asians, 28 for Blacks, 16.7 for Hispanics and 6.6 for Caucasians.
- Asians are 25 times more likely to get hepatitis B.
- There is NO EFFECTIVE CURE for hepatitis B.
- The vaccine is administered in 3 doses: the second and third doses are given one month and three months, respectively, after the first shot.
- Vaccination programs form the integral part of decreasing incidence and spread of the disease.

BOSTON HEPATITIS B STATISTICS

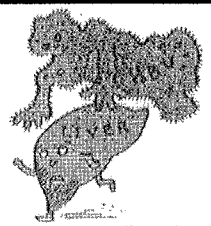








What is Hepatitis B?



Hepatitis B is a serious liver disease caused by a virus. The virus can enter the bloodstream, attack the liver, and cause severe illness, even death! In some cases, the virus can remain in the body for a lifetime and cause ongoing liver damage-including liver cancer.

How do kids get Hepatitis B?

- From mother to child at birth
- Sharing gum or food
- Sharing personal items, such as toothbrushes and razors
- Contact with blood, body fluids, open sores, or cuts
- Sharing needles for ear or body piercing, tattooing, and drug use

So what should you do?

To find out if you have Hepatitis B...
GET SCREENED!!

To protect yourself against Hepatitis B...
GET VACCINATED!!

Talk to your parents, school nurse, or doctor about getting vaccinated. If you are **24 years old or younger** you can get free screening and vaccination for Hepatitis B at South Cove Community Health Center.

FACT: Hepatitis B is 100 times more infectious than AIDS.

FACT: Hepatitis B virus infection rate of Asians in the US is as high as 13%, more than 25 TIMES compared to the overall US rate of 0.5%.

FACT: Hepatitis B is easily preventable with a safe and effective vaccine.

Which kid has Hepatitis B?

Symptoms
- Yellowish skin and eyes
- A bloated belly that hurts
- Loss of appetite
- Wanting to vomit
- Fever
- Extreme tiredness
- Dark-colored urine
- A rash all over the body

Symptoms
- None

Answer: BOTH

Both may have the Hepatitis B virus. Some infected people never feel sick (they are carriers). They can still infect others and develop severe liver disease later on. Most kids who have the virus don't know it because they don't feel sick.

PUBLIC HEALTH

Students to Launch Boston Program Against Hepatitis B

A coalition of public health and medical students concerned about the high rate of hepatitis B in Boston's Asian community will launch a free screening and vaccination service in October, thanks to vaccines donated by Merck & Co. and screenings in conjunction with Beth Israel Deaconess Medical Center.

Hepatitis B is an incurable disease that may cause liver failure and death, but an effective vaccine is available. The virus is present in blood and other body fluids and can spread by sexual contact, needle sharing, maternal transmission, and unsterile equipment used for body piercing and tattooing. An estimated 250,000 people in the U.S. are infected annually. Nearly 5,000 die each year.

The disease is especially prevalent in populations from Southeast Asia, China, the Pacific Islands, and several areas of Africa and South America. In Boston, which has a large Chinese community and is a popular area for Southeast Asian refugees, the average annual incidence (per 100,000 people) between 1990 and 1995 was nearly 200 for Asians, while only 28 for blacks and less than 7 for whites.

Led by Leslie Hsu (HSPH '98) and Michael Tran (HMS '00), students from Harvard Medical School, the Harvard School of Public Health, Tufts University School of Medicine, and Boston University Medical School formed the Hepatitis B Education and Prevention in Boston (HepB) Initiative in February 1997. Their initial research indicated that Asian teenagers and young adults are at especially high risk. Many have not been vaccinated despite recent immunization programs, and they are likely to engage in risky behaviors that spread the virus. So the HepB organizers decided to target Asian high school students and young adults for education, screening, and vaccination.

The members of the HepB Initiative are, front row (l to r): Michael Tran (HMS) and Leslie Hsu (HSPH); middle row: Cassandra Lee (BUMS), Cassandra Kelleher (HMS), Emily Tsai (HMS), Lucy Shum, and Annabel Chen (HMS); back row: Joyce Ho (HSPH), Tom Sun (TUSM), Nerissa Concepcion (HMS), Emerson Lin (HMS), and Jim Cheung (HMS). Missing is Jeanie Chou (HSPH).

A Key Donation

Tom Vernon, HMS '64, executive director of medical and public health affairs at Merck, was impressed by the HepB Initiative's effort to reach a group most at risk. Merck's donation of 600 doses of hepatitis B vaccine will enable the group to offer free vaccinations to 200 uninsured youths through the South Cove Community Health Center and other clinics serving the Asian community. The vaccine is administered in three doses over a six-month period and usually costs about $180. (Screening adds $60.)

Hsu was motivated to form the HepB Initiative by personal experience: she lost both her mother and brother to hepatitis B. "None of us knew what hepatitis B was until it was too late, and I wanted to do something that would stop this disease from hurting others," she says. Encouragement from her HSPH advisers and the support of an Albert Schweitzer fellowship have helped her carry out her vision.

In a short time, the HepB Initiative has achieved its first goal, of locating screenings and vaccinations for the uninsured. Now the group will be soliciting additional monetary and in-kind donations for their second goal, to join community service organizations, such as the Chinatown Coalition, to mount a mass media campaign. This program would educate Asian youths about hepatitis B and tell them about the availability of free screenings and vaccinations for those who do not have medical insurance.

—*Peta Gillyatt*

E CUFF

Q&A with Leslie Hsu, South Cove health center in Chinatown

Leslie Hsu, 24, a graduate student at the Harvard School of Public Health, is working with the South Cove Community Health Center in Chinatown, trying to prevent deaths from hepatitis B. Since Feb. 7, every other Saturday from 1 to 3:30 p.m., Hsu and her project partner, Michael Tran, have been at the Washington Street health center passing out information and conducting a vaccine and screening program. Hepatitis B claimed the lives of Hsu's brother and mother. City Weekly reporter Sandy Coleman recently talked to Hsu, a recipient of the Albert Schweitzer Fellowship.

Q: What is hepatitis B?

A: Hepatitis B is a hundred times more infectious than AIDS. It's a virus infection that affects the liver. What it can do is cause liver damage or liver cancer. About 95 percent of the people who get exposed to the virus develop their own antibodies and are safe. It's the other 5 percent that become carriers and they are the ones at risk. ... There are symptoms, but some infected people never experience these symptoms. ... Usually, there is yellowish skin and eyes, a loss of appetite, fever, fatigue.

Q: How does one get this disease?

A: It's usually passed from mother to child at birth. Asians are about 25 times more at risk than most other races. Other ways are sharing gum or food, sharing personal items like toothbrushes or razors, being in contact with blood, body fluids, open sores, or cuts. And, I guess you can also get it by sharing needles from body piercing or drug use.

Q: Tell me about the work you are doing with regard to hepatitis B.

A: We started a year ago. Our vision was to unite graduate students in Boston with the community towards addressing the high prevalence of hepatitis B, especially among Asians. In the past year, we did a lot of community assessment to figure out what people are doing already in Boston. We found out that what was missing from existing education programs was a screening and vaccination series. So, we worked hard to provide the service for free. In August, Merck Pharmaceuticals donated 600 doses of vaccine for us and Beth Israel Deaconess Hospital donated 400 screenings. Three weeks ago, we started a mass media campaign with pamphlets and posters in Chinese, Vietnamese, and English.

Q: What challenges do you face?

A: The problem with the vaccine is that there are three shots. The second shot is given one month later, the third shot is six months later. The challenge is to try to get the kids to come back. So, we are approaching businesses to locate more free prizes for these kids.

Q: Who is eligible for this program?

A: The service is only available for people 24 years old and younger. We did a lot of research figuring out who was most at risk. Based on that, we've decided to choose 24 and younger. And, they have to be uninsured.

Q. Why are Asians so much more at risk?

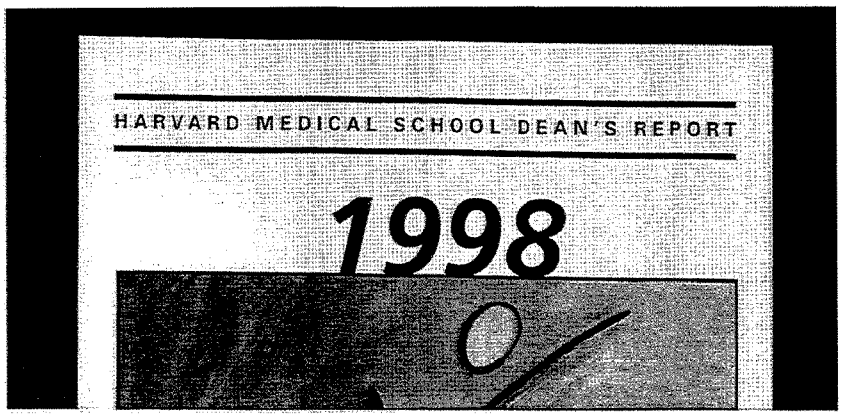
A: A lot of people ask me this question. I'm not sure if there is research on it. ... It's passed easily. ... This virus is epidemic to Asian and African countries. Those countries are more at risk and people emigrate over. ... Many people think it's a sexually transmitted disease, so it is something that you don't talk about. My mom and my brother got hepatitis B and passed away from liver cancer. There were no symptoms. We always had this burning question: Where did it come from? We speculate that when my mother was in Taiwan, they used the same needle to vaccinate all the children.

My brother was diagnosed in 1991; he passed away in '93. My mother got liver cancer a month after my brother passed away and she passed away in '94. My father and I have antibodies. ... I don't want to scare people, but I lost half my family. ... Get vaccinated. It's safe and you don't have to worry about it ever again.

Q: What are the occurrences of hepatitis B in Boston?

A: In Boston, the average rate per 100,000 from 1990 to 1995 was 199.9 for Asians compared with 28 for blacks, 16.7 for Hispanics, 6.6 for whites. We're offering the service to anybody regardless of race.

▶ *For more information on the Saturday vaccination series, call 1-888-456-4659.*



Initiative Makes Gains Against Hepatitis B in Boston

A coalition of public health and medical students concerned about the high rate of hepatitis B in Boston's Asian community, together with the South Cove Community Health Center, have received a $48,000 grant from the Health Care Financing Administration to expand their efforts to educate, screen, and vaccinate Asian youths.

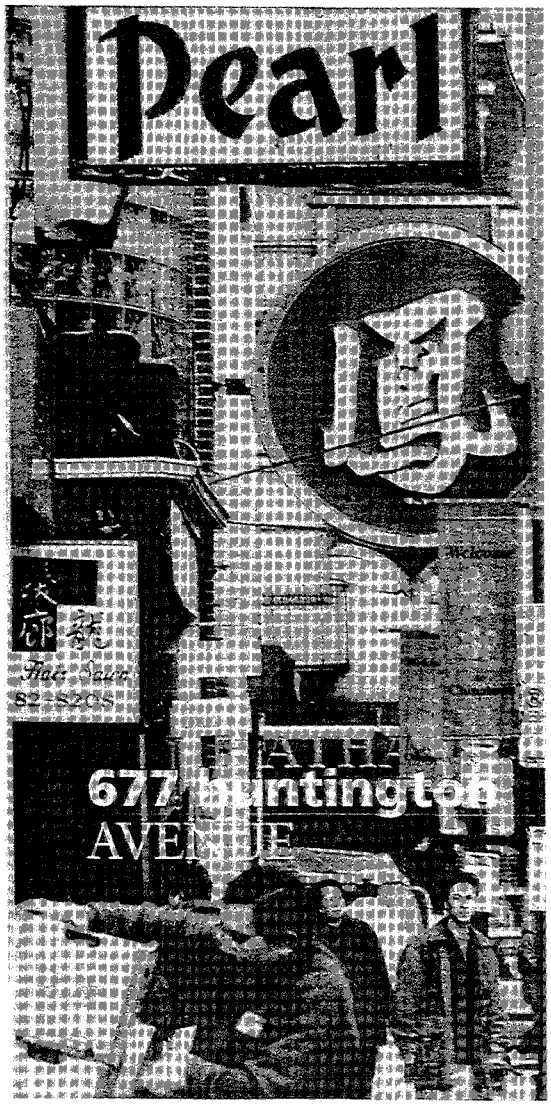
Led by Michael Tran (HMS '00) and Leslie Hsu (HSPH '98), students from the Medical School and School of Public Health, Tufts University School of Medicine, and Boston University Medical School formed the Hepatitis B Education and Prevention in Boston (HepB) Initiative in February 1997.

Last year, the initiative launched a pilot free screening and vaccination service at South Cove Community Health Center thanks to a generous donation of vaccines by Merck & Co. In six months, student volunteers and center staff screened 80 patients for hepatitis B and administered vaccines to half of them. This year, they are launching a mass media campaign and offering screenings at a second clinic.

Hepatitis B is a life-threatening and incurable disease that can cause liver failure and death, but an effective vaccine is available. The virus is present in blood and other body fluids of infected people and can be spread through sexual contact, needle sharing, maternal transmission, and even by unsterile equipment used for body piercing and tattooing. An estimated 250,000 people in the U.S. are infected annually, and nearly 5,000 die each year.

Hepatitis B is especially prevalent in populations from Southeast Asia, China, the Pacific Islands, and several areas of Africa and South America. In Boston, which has a large Chinese community and is a popular settlement area for Southeast Asian refugees, the average annual incidence (per 100,000 people) between 1990 and 1995 was nearly 200 for Asians compared to 28 for blacks and less than seven for whites. ■

Clockwise from top left: James Rosetto, Geoffrey Hsu, patient Michael Mesrobian, and physician Gail Lee



Harvard School of Public Health Review
Spring/Summer 1998

Fighting Hepatitis in Boston's Chinatown

INSPIRED BY GRIEVOUS FAMILY loss and public health's prevention ethos, Master of Science student Leslie Hsu teamed up with Michael Tran, a Harvard Medical School student, last year and set about to organize a free hepatitis B screening and vaccination program in Boston's Chinatown. After a year of many negotiations and much change to the project's original conception as a drop-in center, the program finally got underway earlier this year at the South Cove Community Health Center.

The whole experience has been intensely gratifying, says Hsu. But she has also learned that while the road to a public health program may start with good intentions, it takes a lot more than good intentions to get you there. "Just wanting to do something good is not going to make a project successful. It takes being flexible, establishing credibility, and forming partnerships," says Hsu.

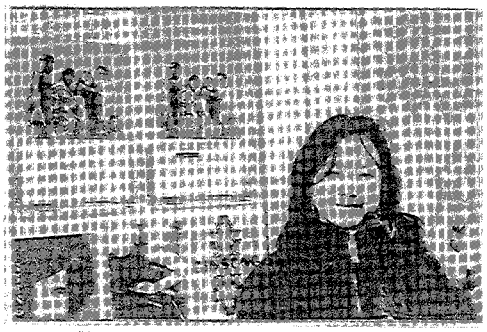
Hsu, a second-year student specializing in health communication in the Department of Health and Social Behavior, lost both her mother and her younger brother to liver cancer caused by a hepatitis B infection. Watching the long struggle of her brother and mother—the harsh and ultimately futile medicine—steered Hsu toward a career in prevention-minded public health. "I was very much a believer in medicine. But prevention is so important. It is so key to just educate people about these problems ahead of time," she says.

In the case of liver cancer, the avoidable problem is hepatitis B

infection. Partly because of some key studies done in the 1970s and early 1980s by epidemiologists at the School, it has now been well-established that chronic hepatitis B infection is a major risk factor for the most common type of primary liver cancer.

The nexus between hepatitis B infection and liver cancer looms as a special threat to the health of Asian and Pacific Islanders in the United States because the hepatitis B infection rates are so much higher in those groups than in the general population. Between 8 and 15 percent of Asian women in the U.S. and Canada are infected with hepatitis B, compared to 2 percent of women in the general population. In Boston, a popular place for Southeast Asian immigrants to settle, the difference is even more striking. For 1990-95, the average annual hepatitis B incidence rate among Asians was 200 per 100,000, which was 30 times the average annual incidence rate of 6.6 per 100,000 for whites and 7 times the 28 per 100,000 rate for blacks.

For Hsu, all of this information incandesced into a clear idea: "It is very simple—all you have to do is get vaccinated. Get these three shots and you never have to worry about this." Hsu and Tran got the ball rolling over a year ago, mobilizing medical and public health students from Harvard, Tufts, and Boston University. They worked on creating a web of different arrangements with community centers, businesses, and pharmaceutical companies. Many hours and meetings later, the result was the Hepatitis B Education and Prevention Boston Initiative, a team of 21 graduate students supported by advisors from the Harvard School of Public Health, Harvard Medical School, and the Boston Schweitzer Fellows Program.



Masters candidate Leslie Hsu at the South Cove Community Health Center, where posters promote the hepatitis B screening project that she helped launch.

Rare is the public health program that doesn't require a fair bit of diplomacy: there are almost always other programs, institutions and interests to work with and navigate around. But as Beverly Wing, project coordinator for the Boston-based Asian Health Collaborative and mentor to the Hepatitis B Initiative, points out, the success of this student-initiated effort was especially dependent on coordinating with others. As Harvard students, they were outsiders in Chinatown, notes Wing, and "they needed an entrée into the community." Also, if the program was to include actual administration of hepatitis B vaccines, they would have to get the help of medical professionals; as students, they couldn't give the shots themselves. Hsu says she had no idea how much negotiation and coordination would be involved in a supposedly "simple" vaccination program.

The time and effort of launching the hepatitis B project has stretched Hsu and Tran, but Wing says these Harvard students stand out for a couple of reasons. "They are such a responsible group," she says, noting how they worked at fine tuning their program, making the needed adjustments and keeping in close contact. Hsu has been remarkably diligent and thorough, says Wing: "Her commitment is so strong. She started this—and she is going to see it through."

Hsu, Tran and the others worked for months to get a donation of 600 doses of hepatitis B vaccine from Merck & Co. They got Beth Israel-Deaconess Hospital to agree to donate 400 screening tests. Their original vision of a kind of hepatitis B drop-in center has been modified somewhat to bi-monthly hepatitis B sessions at the South Cove health center. The target group is people age 24 and under. The students have also now started a "culturally appropriate" media campaign to advertise the program.

Hsu has been working on the hepatitis B project for over a year. She admits to being visited by doubts and frustration along the way. "But I just keep on going back to why I started this program," she says, recalling her mother and her brother. "Even if just three people show up, that keeps three people and their families from suffering from the consequences of hepatitis B—that is what keeps me going."

Children's Hospital of Pittsburgh

Division of Allergy Immunology and Infectious Diseases
Department of Pediatrics
University of Pittsburgh
School of Medicine

3705 Fifth Avenue
Pittsburgh, PA 15213-2583
Ph: (412) 692-7885 *Appointments*
(412) 692-5326 *Eve/Weekends*
Fx: (412) 692-8499
www.chp.edu

E.R. Wald, MD
Division Chief
Ph: (412) 692-7489
wald@chplink.chp.edu

D.P. Skoner, MD
Section Chief,
Allergy & Immunology
Ph: (412) 692-6850
skonerd@chplink.chp.edu

D.M. Kruse, *Manager*
Ph: (412) 692-5930
kruse@chplink.chp.edu

P. Fireman, MD
Ph: (412) 692-7215
firemap@chplink.chp.edu

G.A. Friday, MD
Ph: (412) 692-7232
fridayg@chplink.chp.edu

M.D. Green, MD, MPH
Ph: (412) 692-6111
greenm@chplink.chp.edu

D.P. Greenberg, MD
Ph: (412) 692-7215
greenbd@chplink.chp.edu

J.M. Martin, MD
Ph: (412) 692-7215
martinju@chplink.chp.edu

M.G. Michaels, MD, MPH
Ph: (412) 692-7215
michaem@chplink.chp.edu

D.R. Nash, MD
Ph: (412) 692-7232
nashd@chplink.chp.edu

Betty Angelini, RN, BSN
Allergy & Immunology
Research Nurse Coordinator
Ph: (412) 692-7466
angelib@chplink.chp.edu

Karen Small, RN, MSN, CRNP
Infectious Diseases
Nurse Practitioner/
Research Coordinator
Ph: (412) 692-7356
smallk@chplink.chp.edu

Children's North
2599 Wexford Bayne Road
Sewickley, PA 15143
Ph: (724) 933-3600
Fx: (724) 933-3621

Children's South
1300 Oxford Drive
Bethel Park, PA 15102
Ph: (412) 854-5005
Fx: (412) 692-8814

Children's East
Corporate One Office Park
Building One, Suite 110
4055 Monroeville Boulevard
Monroeville, PA 15146
Ph: (412) 666-3800
Fx: (412) 666-3821

June 15, 1999

Chairman John Mica
c/o Sharon Pinkerton
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
United States House of Representatives
B-373 Rayburn House Office Building
Washington DC 20515

Dear Chairman Mica:

This letter is in reference to the Congressional hearing held on May 18, 1999 before the Subcommittee on Criminal Justice, Drug Policy and Human Resources regarding the safety of hepatitis B vaccine. I was unable to attend the committee meeting, however I would like to express my views on the safety of this vaccine. I am an Associate Professor of Pediatrics at the University of Pittsburgh School of Medicine and the Children's Hospital of Pittsburgh. My training and expertise is in Pediatric Infectious Diseases and in my academic role, I care for patients, conduct research, and teach medical students and pediatric residents. My area of research expertise is with vaccines. For the past 14 years, I have conducted clinical and laboratory-based research with a variety of vaccines including hepatitis B, Haemophilus influenzae type b (Hib), MMR, varicella (chicken pox), diphtheria-tetanus-acellular pertussis (DTaP), and a variety of combination vaccines.

Vaccines are the most cost-effective means we have to prevent communicable diseases in children and adults. Infections that were common in the early and mid 20th Century have been essentially wiped out in the United States and other parts of the world. The eradication of smallpox worldwide and polio in the western hemisphere did not occur by accident. Vaccine programs have eliminated debilitating and lethal diseases such as smallpox, paralytic polio, diphtheria, measles and Hib meningitis. During the past decade, immunization rates have improved in the United States, but even better coverage is needed to prevent outbreaks of certain infections. In reference to hepatitis B, we have not done as well as with other vaccines. For a decade after licensure of hepatitis B vaccine in the United States, we attempted to vaccinate adults considered to be in high-risk groups. Unfortunately, such high-risk individuals do not come to medical attention for routine preventative care, and therefore these individuals are left unprotected. Despite the availability of hepatitis B vaccine, the incidence of hepatitis B infection continued to rise in this country. The incidence peaked in 1985 and then

gradually declined after public health measures to prevent transmission of HIV aided in the prevention of the sexual transmission of hepatitis B. Nevertheless, hepatitis B continues to be a problem in this country. The only practical way to protect individuals is to immunize them before they are unknowingly exposed to the virus as a young adult. Although the true effect of our current childhood universal immunization program will not be seen for another decade, it will be highly effective in preventing the transmission of this virus to innocent individuals. I am sure that you have been informed by others that chronic hepatitis B carriage results in liver cirrhosis and hepatacellular carcinoma in many individuals. The health care costs for these persons, including liver transplantation, are enormous. As with other vaccines that we give to children, hepatitis B vaccine is highly cost effective.

There are a number of misconceptions that opponents of vaccinations would like for you to believe, but are simply untrue. The myths that apply to hepatitis B vaccine follows:

- Myth #1: **Hepatitis B infections began to disappear before vaccination.** As noted above, hepatitis B disease was not declining before vaccination. In fact, it continued to rise after the vaccine was available. This was because our vaccination strategies were not effective. Now that the vaccine is given to most children, we will see a decline in the incidence of hepatitis B infections in the next 10-20 years.

- Myth #2: **Hepatitis B vaccine causes many harmful side-effects, including death.** Vaccine foes frequently site the number of reports to the Vaccine Adverse Event Reporting System (VAERS) as proof that the vaccine causes those adverse events. This is not true. The fact that an individual becomes ill sometime after vaccination is not proof that the vaccine caused the illness. Unfortunately, previously healthy individuals occasionally develop serious chronic diseases whether they receive hepatitis B vaccine or not. For every case of multiple sclerosis reported after hepatitis B vaccine, one can find many more that occurred with no relationship to vaccination.

- Myth #3: **My child is not at risk for hepatitis B disease and therefore my child should not be immunized.** Every child grows up to be a sexually active adult. Unfortunately, some of them grow up to be sexually promiscuous or use intravenous drugs. Parents are not likely to think that their children would ever be at risk for acquiring hepatitis B infection. However, we know that this is not the case.

- Myth #4: **If the authorities cannot refute the causal relationship between hepatitis B vaccine and chronic illnesses, then the vaccine must be guilty.** It is very easy for vaccine opponents to accuse useful vaccines as causing a laundry list of chronic illnesses. It is quite another step to prove that such accusations are inaccurate. Such opponents have decided that the vaccine is guilty until proven innocent. However, I believe that our experience with millions of doses of hepatitis B vaccine tell us that the vaccine is innocent until proven guilty.

- Myth #5: **Hepatitis B vaccine is many fold deadlier than the disease.** To make this point, vaccine foes cite all of the reports to VAERS as proof that the vaccine causes a

great deal of morbidity and mortality among its recipients. An association of events temporally does not mean that one causes the other. They also cite the relatively few number of cases of hepatitis B disease reported to the Centers for Disease Control and Prevention (CDC). Of course, they forget to tell you that only a fraction of the number of cases of hepatitis B disease in the United States are reported to the CDC.

Vaccine opponents site the decision by the French Ministry of Health on October 1, 1998 to suspend routine hepatitis B immunization in adolescents in French schools. As you may know, on the day prior to this decision, the Viral Hepatitis Prevention Board (World Health Organization) concluded that "the data available, although limited, do not demonstrate causal association between hepatitis B immunization and central nervous system demyleinating diseases, including multiple sclerosis. No evidence presented at this meeting indicates a need to change public health policies with respect to hepatitis B immunization". This decision was made after a thorough review of the epidemiology of hepatitis B and multiple sclerosis, ongoing surveillance studies, and reports of adverse events occurring after vaccination. They found no statistically significant association between hepatitis B vaccine and multiple sclerosis. The current age and sex distribution of multiple sclerosis matches the distribution before use of the vaccine, and there is no correlation with vaccine administration. Furthermore, there is no evidence for the biologic plausibility of an association between hepatitis B vaccine and multiple sclerosis. Ultimately, the French Ministry of Health admitted that they were not against immunization of adolescents with hepatitis B vaccine, but they were reacting to a public outcry against school-based immunization programs without parental knowledge or consent. Their decision to suspend immunizations was not based on scientific information, but rather on sociopolitical issues.

In September 1998, Barbara Loe Fisher, President of the National Vaccine Information Center, sent a report entitled, "Hepatitis B Vaccine: The Untold Story" to 55,000 pediatricians and nearly 7,600 state legislators. In this report, she voiced many of the misconceptions noted above. For example, she stated that "hepatitis B is not common in childhood and is not highly contagious". She does not tell you that hepatitis B **is** common in adulthood, it **is** contagious with sexual contact or exposure to infected blood, and the most effective means of preventing the disease is vaccination prior to exposure. She states that "hepatitis B is not a killer for most". Four to five thousand individuals die of the effects of chronic hepatitis B infection annually in this country. I believe that we should do what we can to prevent these deaths. In this document, Barbara Loe Fisher states that in 1996 there were 10,637 cases in the US and only 279 in children. She doesn't mention that these numbers are only a fraction of the true number of cases that occur in the US annually. She states that there is inadequate "proof of long-term safety". The vaccine has been given to millions of individuals in this country for more than two decades (including prelicensure studies). I believe that such data provide excellent proof of long-term safety. She states that hepatitis B vaccine causes lupus, arthritis, Guillian-Barre syndrome, demyelinating neuropathies, transverse myelitis, multiple sclerosis, diabetes mellitus, chronic fatigue syndrome, seizures, autism, autoimmune diseases, and others. She cites case reports of these diseases occurring sometime after vaccination as well as reports of deaths and injuries sent to VAERS. According to her report, hepatitis B vaccine is responsible for nearly every chronic disease for which we have no known etiology. Each time that the association of these diseases with hepatitis B vaccine have been thoroughly evaluated, no causal association has been found.

Dr. Bart Classen has stated that hepatitis B vaccine causes diabetes. He claims that the incidence of diabetes is lowest in countries that give BCG vaccine at birth and the highest incidence in countries that give a variety of vaccines including hepatitis B vaccine at school age. The data from which Dr. Classen derives his conclusions have been analyzed by many other independent investigators. They have found that the incidence of diabetes correlates with the per capita gross national product, per capita calorie intake, child mortality rates and the distance from the Equator. It may be that climate accounts for some of the global differences in the rates of diabetes and it may explain the observation that the incidence of diabetes increases as one moves away from the Equator. Independent investigators found that Dr. Classen used incorrect and inaccurate analytical methods and that ten-year follow up data failed to support his claims.

A number of published studies dispute Dr. Classen's claim that vaccines cause diabetes. For example, 1) in Sweden, diabetics were less likely to have received measles vaccine; 2) in Canada, there was no association between BCG vaccine and diabetes; 3) in New Zealand, there was no association of diabetes with hepatitis B vaccine; 4) in Finland, there is no association of diabetes with Hib vaccine; and 5) the global increase in the incidence of diabetes was not associated with the use of vaccines. On March 20, 1998, The Institute for Vaccine Safety at the Johns Hopkins School of Public Health held a workshop to address concerns raised regarding the relationship between diabetes and immunizations. The workshop panel concluded that 1) both genetic and environmental factors contribute to the risk of diabetes; 2) infections may increase the risk of diabetes in animals and humans; 3) selected vaccines are protective vaccines against type I diabetes in animals but the data in humans are inconclusive; and 4) no vaccines have been shown to increase the risk of diabetes in humans.

In a related issue, Dr. Classen states that the rate of diabetes increased in Pittsburgh, Pennsylvania between 1975 and 1994. He attributes the increase in diabetes to the introduction of Hib vaccine. To support his conclusion, he cites published data from investigators at the University of Pittsburgh and the Children's Hospital of Pittsburgh. I reviewed the original papers and found that Dr. Classen misrepresented the data. Although the rate of diabetes increased during the first five years after the introduction of the Hib vaccine, the rate significantly declined during the next five year period. The rate of vaccination against Hib as well as hepatitis B increased dramatically during the latter five year block and therefore refutes the claim that vaccines contribute to the incidence of diabetes. It is this type of misrepresentation of the data that is so worrisome. Individuals such as Dr. Classen make preposterous claims based on a misrepresentation of the data.

The claims that hepatitis B vaccine causes chronic illnesses is prototypic of similar claims against other vaccines. Dr. Neil Halsey, Johns Hopkins University, has characterized typical "vaccine scares". The characteristics include, 1) a causal link is claimed with a disease of unknown or unclear etiology, 2) the association is claimed by one investigator or a single group of investigators, 3) the association is not confirmed by peers or subsequent research, and 4) claims are made with no concern for loss of confidence in our vaccine programs. Such claims are disturbing to parents because they have no way of knowing who are the "real" experts. Parents have no independent way to judge claims made by vaccine proponents and vaccine foes. The

"controversy" that is propagated by the media tends to inflame the public. Parents become fearful and demand a halt to immunization programs. State governments throughout the US are being barraged by "parent advocacy groups" to relax immunization requirements. A health committee of the Louisiana legislature voted to split the MMR vaccine into three separate shots given over a two year period. Fortunately, level heads prevailed and the Louisiana House narrowly rejected the bill. Such legislation is driven by emotional fears in the community, not scientific evidence. Vaccine opponents claim that vaccines cause harm without any supporting evidence. Depending upon the claim, it may take years for scientific studies to refute such claims. In the meantime, the media latches onto the controversy and propels it to new heights. As we have seen with hepatitis B vaccine, MMR vaccine and others, even after the claims are disproven in multiple studies, the "controversy" never seems to go away.

I hope that you will take into consideration the comments and analyses provided above when assessing the risks and benefits of hepatitis B immunization. There is no question in my mind and the rest of the practicing medial community that hepatitis B vaccine is safe and effective in preventing chronic infection with hepatitis B virus. If hepatitis B vaccine causes any chronic diseases, it must do so at extremely low rates. The long-range benefits of the vaccine clearly outweigh the risks of potential rare adverse events. If you have any questions, please do not hesitate to contact me at (412) 692-7215.

Thank you for allowing me to address the Committee on this important topic.

Sincerely,

David Greenberg

David P. Greenberg, M.D.
Associate Professor of Pediatrics
Division of Allergy, Immunology and Infectious Diseases
Children's Hospital of Pittsburgh
University of Pittsburgh School of Medicine

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P:\david greenberg\hepbletter.wpd

18 May 1999

P K.I.D.S Parents of Kids with Infectious Diseases

U.S. House of Representatives Subcommittee on Criminal Justice, Drug Policy and Human Resources/Hepatitis B Vaccine Hearing

Testimony for the record
PKIDs
PO Box 5666
Vancouver, WA 98668
360-695-0293
pkids@pkids.org

My name is Trish Parnell. I'm the director of PKIDs, a national nonprofit for parents of kids living with chronic, viral infectious diseases. Hepatitis B is one of those diseases, although it shouldn't be. We've had the ability to eradicate hepatitis B with a vaccine since 1982 – make it go the way of smallpox and polio.

Every parent of a child living with hepatitis B will tell you that they'd do or give anything to turn back the clock and have their child vaccinated. It's so simple to prevent, and yet many parents are unaware of the disease and that kids can get it. When I found out my daughter has this disease, the place inside me where I'd laid plans for her perfect, happy life just shattered. It doesn't matter what words I use to describe the feeling, it's impossible to completely understand it if you haven't experienced the same thing with your child. But, as awful as it was to look at her and realize that people were afraid to be around her, that she was in for a lifetime of tests and care or possibly a life shortened by serious illness, none of the emotions I had compared to how I felt when they told me it could have been prevented. There was a vaccine to prevent infection and she didn't get the vaccine.

PKIDs has parents all around this country who have gone through the same thing. We get calls and emails from parents in shock because their kids – of all ages – have become chronically ill with hepatitis B, which causes anything from jaundice and fatigue to cirrhosis, liver cancer, and death.

This disease is not kind to kids. Ninety percent of the babies who are infected at birth or shortly thereafter will become chronic carriers. That percentage slowly reverses as the child ages. A five-year-old has about a 50-50 chance of becoming chronic, and an adult has a ten percent chance. Kids are the ones most at risk from this disease.

According to the Centers for Disease Control and Prevention, there are between 1 million and 1.25 million folks in the U.S. who are chronically infected with this disease -

forty-two percent of whom were initially infected before their 19th birthday. More than half of those infected before their 19th birthday were infected perinatally, or around the time of their birth. These figures don't represent the millions of Americans who've been infected (and therefore were infectious to others), but whose immune systems were able to eventually fight off the disease.

The World Health Organization says that one-third of the world's population, two billion people, have had or do have hepatitis B. This is a mind-boggling number. Of that number, 350 million are chronically ill with this disease. Each year in the U.S., an estimated 200,000 people have new hepatitis B infections, of whom more than 11,000 people are hospitalized, and 4,000 to 5,000 people die.

PKIDs exists because there are lots of families living with chronic, viral infectious diseases. We don't want to see any more children infected. We want them protected through the use of safe vaccines and universal precautions. All of the reputable health organizations in the U.S., and in the world, support the hepatitis B vaccine for its safety and efficacy. CDC figures show that more than 95 percent of children and adolescents, and more than 90 percent of young, healthy adults develop adequate antibody to the recommended series of three doses and are protected against acute hepatitis B as well as the chronic consequences of HBV infection, including cirrhosis and liver cancer.

Already, more than 20 million persons have received the hepatitis B vaccine in the U.S., and more than 500 million persons have received the vaccine worldwide. The CDC's website shows that the most common side effects from hepatitis B vaccination are pain at the injection site and mild to moderate fever. Studies show that these side effects are reported no more frequently among those vaccinated than among persons not receiving vaccine. Among children receiving both hepatitis B vaccine and diphtheria-tetanus-pertussis (DTP) vaccine, these mild side effects have been observed no more frequently than among children receiving DTP vaccine alone.

Hepatitis B is real and it's in this country. One-third of those infected don't know how they became infected. The majority of the 200,000 newly infected each year do not even know they're infected, and may never know. But in the weeks or months before their bodies' immune systems fight off the disease, if they do, they can infect others. It's important to vaccinate the newborns and young children because they're most at risk for chronic illness, and it's important to vaccinate the kids in middle schools because they're becoming teenagers, a fast-growing population for hepatitis B infection.

It isn't necessary to have intercourse to get infected with hepatitis B, it can be transmitted by deep kissing. The mucous membranes in the mouth are thin, and if one person has bleeding in the mouth from gingivitis or other causes, the blood can mix with the saliva and be passed into the other person's mouth where it can enter through their mucous membranes.

These are things you don't think of unless you or someone you love is diagnosed with hepatitis B, then it becomes necessary to educate yourself about the disease. The public can't be protected by identifying those infected. There's no way to know who's infected. If you haven't been vaccinated, you could not be infected on Thursday, and become infected on Friday and not know it. The way to protect yourself and your family is to use universal precautions (assume everyone has an infectious disease and act accordingly), and get vaccinated when vaccines are available.

Trish Parnell

18 May 1999

K.I.D.S
Parents of Kids with Infectious Diseases

U.S. House of Representatives Subcommittee on Criminal Justice, Drug Policy and Human Resources/Hepatitis B Vaccine Hearing

Testimony of Karen/PKIDs

Karen is a member of the Advisory Board of PKIDs, an organization for parents of children with chronic, viral infectious diseases. Her eight-year-old son was diagnosed with hepatitis B five years ago and she would like to relate her family's experience with this virus to the Subcommittee members in order to increase their understanding of how devastating hepatitis B is. She is offering her comments in the hope that by promoting vaccination against this disease, other families will be spared the pain that hers is experiencing.

Chairman Mica, Congresswoman Mink, and members of the Subcommittee:

I'm here today to talk about my family. I won't add to the list of statistics related to immunization issues. I'd like to personalize them, to bring them to a level that you can relate to from the heart rather than from a business, political or clinical standpoint. My husband and I have three young children. One of us became infected with hepatitis B and is now a carrier. The face of this virus is one of our twins.

Although he has no apparent symptoms yet, biopsies at ages 3 and 4 confirmed that he had worsening cirrhosis. He did not respond to a 7-month course of interferon, a form of chemotherapy, and no other treatment has been available for him. He has had cirrhosis long enough that he must be monitored frequently for liver failure and cancer.

Fear

There is a four-letter "F" word from which we try to shield our children. It's something they shouldn't know anything about at such a young age. The word is Fear. Fear of social repercussions, Fear of financial ruin, Fear of sickness, death and loss.

Social Issues

You may have noticed that I have not provided our family name. I can't. The first thing hep B families learn, usually after rejection by friends or family, is to go to extreme lengths to protect their children's privacy. We cannot risk exposing our children's plight on programs like 20/20 to help inform others of the dangers of this disease. We

want to reach out for comfort when we learn our child has an incurable illness, but we can't. Local hospitals offer support groups for parents of children with cancer, but not for hepatitis.

We therefore formed a nonprofit group, PKIDs, or Parents of Kids with Infectious Diseases. PKIDs is determined to not only help families with infected children, but also to educate the public about chronic, viral infectious diseases including hepatitis B. My role as a member of the PKIDs Advisory Board enables me to accomplish my personal goal of ensuring that other families are prepared to deal with the complicated issues related to living with an infectious disease.

Emotional Issues

Parents feel an overwhelming need to warn childcare workers, teachers, Sunday School caretakers, babysitters, playmates and their parents that extra care needs to be taken if our child scrapes his knee, bites or is bitten, or has a bloody nose. We want to tell everyone to *get the shots*, yet we agonize over the negative consequences of "telling" . . . will our child be treated fairly, will he be ostracized on the playground, will we ever find a babysitter? Will he have any friends, or will our child be singled out as the kid to avoid? Will information given to the school nurse in confidence wind up as the topic of conversation at a PTA meeting? There are discrimination and disability laws that guarantee my child a public education, but there are no laws to protect my child's heart.

My husband and I attended a school training meeting with a group of parents. During casual conversation, a mom mentioned that she'd heard that there was a child with hep B in our school district. She went on to tell the other concerned parents that she had visited the school superintendent in an effort to identify the child so that she could better protect her son by isolating the children. We sat paralyzed in silence, waiting for glances to turn in our direction (they didn't!), and all I could think was, *get your kid the shots if you want to protect him*. We supervise our child's play, we coach his soccer games, we are there as much as possible in order to protect *other* people's children. But it's obviously impossible to continue this vigilance as the children grow older. When a neighbor tried to put a bandage on our child's bleeding cut I pushed her away. She thinks I'm overprotective. She has no idea I was protecting *her*. No one else should have to live with this virus. It's preventable.

Financial Issues

We worry about our ability to provide the best care for our child. His interferon treatment cost well over $20,000 and only a portion was covered by insurance. We are self-employed and watched our health insurance premiums triple. Those premiums now exceed our mortgage payment. We can't change carriers because we fear he could become sick or need a transplant during the "pre-existing condition exemption period" with a new policy. If no cure or control is found in the very near future, he will most likely need a liver transplant. We have been warned that transplant and post-transplant care could ruin us financially, and it is only a temporary solution for him. The virus would eventually attack the new liver as well. We wonder whether we will be able to

afford to put our children through college, whether we will ever be able to afford retirement.

Closing

I call this virus IT. Capital I, capital T. Those of you familiar with Stephen King's monster will understand why. IT invades our lives, our thoughts, and our spiritual beliefs, no matter what defenses we erect. I watch my happy children playing and IT reminds me that we will soon have to tell my son that he has a serious illness. Whenever he doesn't feel well, I wonder, "Is this IT?" How long will IT allow him to play the sports he loves? How will IT affect his school performance? The quality and length of my son's life are huge unknowns, but statistics make it difficult to be optimistic. You can all look at your young children and fantasize about their senior proms and weddings. I cannot.

My son is a leader. He is clever, creative, charming. He is very protective of our other children and they look up to him. I fear the effect IT will have on his brothers, worry about how they will deal with his illness, or worse. I fear that I will watch my child die, the worst possible thing that can happen to a parent. No other family should ever have to experience this pain. Three shots can prevent IT.

Hepatitis B is transmitted primarily through blood and sexual contact with infected persons. My child can infect yours by sharing toothbrushes at camp, biting, leaving blood residues on hard surfaces (the virus lives for several days), sports such as wrestling where sores make contact, and so on. There are young, asymptomatic carriers who have not yet been diagnosed. Infected children and young adults will be socializing with and dating your children. I beg you to educate yourselves about the hepatitis virus and disease progression as well. Only then will you be able to make a truly informed decision regarding school immunizations and how to best protect our children.

Thank you for listening.

Karen
Advisory Board

PKIDs
PO Box 5666
Vancouver, WA 98668
877-55-PKIDS
www.pkids.org
pkids@pkids.org

18 May 1999

U S. House of Representatives Subcommittee on Criminal Justice, Drug Policy and Human Resources/Hepatitis B Vaccine Hearing

Testimony for the record

PKIDs
PO Box 5666
Vancouver, WA 98668
360-695-0293
pkids@pkids.org

My name is Sue and I'm a PKIDs mom. My entire family has been devastated by the hepatitis B virus, as both my husband and son are chronic carriers. I am telling my story to stress the dire necessity of having all school-age children immunized against this dreaded but preventable disease, so that you never have to experience what we are going through.

I am very fortunate to have a loving, devoted spouse and three wonderful sons, ages 13, 11, and 7. I would guess that we're a pretty typical family, in that we work very hard as well as play very hard (especially during baseball season!), and maintain a ferociously hectic schedule. Where we're not typical, however, is that both my husband and oldest son are chronically infected with hepatitis B. I contracted the virus while working as a registered nurse in ICU and infected my husband. To this day we haven't a clue as to how, or when, our son was infected.

When this all started several years ago, the doctors we were seeing didn't feel any urgent need to get the boys tested (they told us they didn't test kids) even though we were high risk. They saw three healthy young boys and reminded their paranoid mother that "this was not a casually transmitted disease". The boys were finally immunized when my youngest was an infant.

A long time ago, my husband's liver status deteriorated to a point where he required treatment and was referred to a hepatologist. He recommended that the boys be tested for hep B and we were horrified to learn that our oldest son had this dreaded disease.

We couldn't understand how could this be. There was never any breach of careful technique where my husband was concerned, assuming he's the source of our son's infection.

Everyone in my family is affected by this. My husband failed a trial of interferon and has been on lamivudine for two years. He's had liver biopsies, ultrasounds, and endoscopies, and innumerable blood tests. He had an extensive work-up and is now on the liver transplant list.

Our son has also had a biopsy, several ultrasounds, numerous lab tests and doctor's visits. He's a very adjusted teenager but at times he asks, *why me*? He has many friends, but few know of his hepatitis.

He's an excellent student and scored 26 on the high school ACT tests. He's active in Scouts and *loves* playing sports. He played as a quarterback for one great season before we knew he had hepatitis. Then the doctors told him football was probably the one sport he should avoid because of the contact.

I must sound like the typical bragging mom, but he's a great all-around kid. He looks and acts just like your child, but he's dealing with stuff a normal 13-year-old boy shouldn't have to. It breaks my heart.

I worry every day and pray as he leaves the house in the morning that God keep him safe. I worry about the safety of the other kids if my son should have a blood-involved injury.

We don't know what the future holds for us – the uncertainty doesn't feel good. They say that good things always come out of bad, and while we've always been faithful, I think we've become more so, and that's a good thing. I believe that our family is in God's hands and I get great comfort in that – some days it's all I have. Every night my husband and son bless each other's liver with baby water. That is what comforts them. We just wait, for a future that holds little promise.

Sue/PKIDs

May 16, 1999

Subcommittee on Criminal Justice, Drug Policy, and Human Resources/Hepatitis B Vaccine Hearing

Testimony for the record:

My name is Maureen Kamischke and I am a PKID's mother writing you today on behalf of kids living with the Hepatitis B virus, and the importance and necessity of the vaccine for Hepatitis B.

I am the mother of a nineteen-month old child who is chronically infected with Hepatitis B. Dealing with the Hepatitis B virus is very taxing for both the child and the family. Our little one receives injections of interferon three times per week. One of the few things that eases my mind with regard to her status is the fact that we live in a state which mandates the vaccination of all elementary school age children for Hepatitis B. I would never want anyone to suffer the anguish of having their child infected when a vaccine is readily available to prevent infection.

Please consider the importance of presenting all sides of the vaccination issue by listening to the voices of the PKIDs' parents and others who live with this chronic infection daily. Remember infectious diseases have no prejudices. They infect people of all ethnic backgrounds, religion and social status. Thank you for your time.

Sincerely,

Maureen M Kamischke

Maureen Kamischke

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