conditions set forth by Congress on Federal funding of needle exchange programs have yet been met. We in Congress have crafted a protection to disallow federal funding of needle exchange programs unless the science shows that such programs will not only reduce HIV infection, but also not increase drug use.

Fourth, is Dr. Satcher's position on the survey of childbearing women, the blinded surveys. We have heard already this morning, and we will continue to hear, that opponents of Dr. Satcher have erroneously claimed—and I use the word ''erroneously;'' and I underline it—that the infants known to be HIV positive were sent home without parental notification after being tested specifically for HIV. And this is simply untrue. It is not true.

Again, it takes some understanding of how science today, and the medical community and the public health, obtains baseline data from a population so you will know where you are starting, whether or not interventions work or not, how much of a public health issue it should be.

In this particular case, samples were gathered from left over blood specimens that were taken for standard tests. The rest of the blood is discarded and put over in a cabinet, typically thrown away.

Under this study, all personal identifying information is taken off. But that blood has some useful purpose from an epidemiologic standpoint, from a public health standpoint because we can see what the baseline of something like HIV positivity actually is. The information that was gathered from these surveys of this discarded blood is not labeled, is not attached to an individual—Why not? For reasons of privacy, something that we all respect. We do not want people taking blood from us, having our name attached to it, testing it, and then releasing it to the world. However, those same women were counseled about the benefits of being tested and offered an HIV test that would allow them to know their and their baby's HIV status. The allegation is that this was a secret test. Yet, women were offered and encouraged to be tested and to be aware of their HIV status.

This blind survey was critical. We can look how far we have come and the progress that has been made, in terms of treating HIV infection, with our public health officials, because it was the only totally unbiased way to provide a valid estimate of the number of women infected with HIV as well as their demographic distributions.

Thank goodness we have access to such information. But again, this whole accusation that infants known to be HIV positive were sent home without telling their parents they were being diagnosed with HIV is simply untrue. This survey yielded population-based numbers of the incidence of HIV, not linked to individuals unless they gave their informed consent.

Well, as you can tell, I feel strongly about this position of Surgeon General. I will bring my remarks to a close for this time around. I feel strongly that we need a Surgeon General who can articulate the needs, the challenges of public health, which are inevitably there. We need a Surgeon General who can advise the administration because the administration is making decisions every day that affect the public health whether it be in the area of disease or prevention or managed care, organization and delivery of our health care system.

Secondly, I feel very strongly that Dr. David Satcher is the man for this position. He is a scientist. He is a family man. He is committed to local decisionmaking. He is an educator. He is a spokesperson. He is an eloquent spokesperson. But most importantly, he is committed to his fellow man, to improving the public health.

I look forward to the debate. I hope our colleagues do participate in the debate. And I think that at the end of the day, hopefully, we will get to the truth and the kernels of truth that lie behind all the accusations and ultimately confirm Dr. David Satcher.

Mr. JEFFORDS. Mr. President, I thank the Senator from Tennessee for a well-documented, very thorough and careful examination of the nominee.

I now yield 20 minutes to the Senator from Massachusetts, my esteemed ranking member.

The PRESIDING OFFICER (Mr. SANTORUM). The Senator from Massachusetts.

Mr. KENNEDY. I thank the Senator.

Are we under a time agreement?

The PRESIDING OFFICER. There is no control of time.

Mr. KENNEDY. Thank you.

PRIVILEGE OF THE FLOOR

Mr. President, I ask unanimous consent that two fellows in my office, Caroline Lewis and Diane ROBERTSon, be granted floor privileges for the consideration of the Satcher nomination.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. KENNEDY. Mr. President, I want to join in commending my friend and colleague, the Senator from Tennessee, Senator FRIST, for an excellent presentation. During the consideration of the nominee, he was careful with his questions, probing with his questions, and obviously prepared prior to the time of the nominee's presentation and during the course of the hearings.

I think today we see the result of some very hard and disciplined and informed judgment based upon his evaluation of this extraordinary nominee for the position of Surgeon General and the Assistant Secretary. I listened with great interest to his very detailed description of the great opportunities for this Nation when we gain the service of Dr. Satcher in that position as Surgeon General and Assistant Secretary for Health.

I heard with great interest, again, his response to a number of the allegations, quite frankly, misrepresentations that have been made about Dr. Satcher's record. I must say that I find myself in agreement with his understanding of Dr. Satcher's position, and as to his representation to the committee during the course of the nominee's presentation, and in response to various questions.

I also want to commend the chairman of our committee, Senator JEFFORDS, for the work that he has done in both scheduling Dr. Satcher for the hearings, for the way that the hearings were conducted, the balance and the fairness which is so much a part of everything that he is associated with, and for his compelling statement as well.

I am very hopeful that the Senate will have the opportunity to vote on this truly outstanding nominee in the not too distant future. This position has been vacant for a very considerable period of time. We have an outstanding recommendation by the President, a truly outstanding nominee, an outstanding candidate, an outstanding individual on the issues of public health. The position of Surgeon General needs to be addressed if we are going to be responsive to the concerns of our families in this country. We have had, quite frankly, enough delay on this outstanding nominee. It is time to act.

Mr. President, I commend the leadership for bringing to the floor the nomination of David Satcher to be Surgeon General and Assistant Secretary for Health. Dr. Satcher is extremely well qualified for this position. In fact, his life story is a tribute to the strength and vitality of the American dream. Dr. Satcher was raised on a farm in rural Alabama. He was one of 10 children. His mother was a homemaker and his father was a foundry worker. Neither of his parents finished elementary school, and between them, they never earned more than $10,000 a year.

The defining moment of Dr. Satcher's extraordinary life may well have occurred when he was a toddler. It was then, at the age of two, that he survived a near fatal attack with whooping cough. Although whooping cough had been a leading cause of death among young children in the United States, it would become much rarer by the time he was born. But the vaccine was not available to Dr. Satcher's family. They were poor African Americans living in the rural South. They had limited access to medical care, and none of the white doctors who practiced in the area would treat black patients. Fortunately, Dr. Satcher's father was able to talk a black physician in the area into making a house call and, against all odds, Dr. Satcher survived this dire illness. Largely as a result of this experience, he decided he wanted to become a doctor. He stated that he wanted to ''make the greatest difference for the people who I thought have the greatest need.''

Mr. President, he repeated that during the course of these hearings. Anyone who was in that room at that time

and had an opportunity to listen to Dr. Satcher make that statement and make that commitment would not be on the floor of the Senate now urging rejection of this nominee. His commitment was to make ''the greatest difference for the people who I thought had the greatest need.'' That was a statement made with extraordinary humility. By someone else, it might have a different ring. But when you were there listening to Dr. Satcher make that statement, you could not help but know that he has been committed to that cause over the course of his extraordinary life, and it has been an extraordinary life.

Dr. Satcher's parents wanted their children to get the best education they could as black children attending segregated schools in rural Alabama. Dr. Satcher was valedictorian of his high school class. He was one of only three students, out of a class of seventy, who went on to college.

He attended Morehouse College in Atlanta, which awarded him a full scholarship. He graduated magna cum laude and was elected Phi Beta Kappa.

I have heard comments on the floor that ''the United States is entitled to the best.'' Three out of seventy graduated from his high school and he goes on to college with a scholarship and graduates magna cum laude. We have the best, Mr. President. We have the best in this nominee.

He went on to medical school at Case Western Reserve University, a first-rate, tough medical school. I have had the opportunity to visit that excellent school, and it is one of our best, and it's tough academically, it's vigorous. He was one of only two African American students. He became the first black student to receive a Ph.D. degree and M.D. degree simultaneously.

He was also elected to Alpha Omega Alpha Honor Society. After finishing his residency at the University of Rochester, Dr. Satcher went to Los Angeles to join the hypertension clinic at the Martin Luther King, Jr. General Hospital in Watts. I have had the chance to go to that hospital, and it is right on the firing line, in terms of trying to meet human need. He went on to direct research on Sickle Cell Anemia at the King-Drew Sickle Cell Center there, and he founded and chaired the King-Drew Department of Family Medicine. He opened a free clinic in Watts, in the basement of a Baptist church that he had joined, and he served as its medical director until 1979.

Mr. President, just keep following along this extraordinary life of commitment to others, and of excellence, in terms of the practice of compassion and reaching out to those who are the hardest pressed.

From 1974 to 1979, he taught epidemiology at UCLA, one of the top medical schools. Dr. Satcher then returned to Morehouse College to chair the Department of Community Medicine and Family Practice. In 1982, he became president of Meharry Medical College in Nashville and served in that capacity for 10 years, where he is credited for helping to deal effectively with the college's financial problems.

Whether you are talking about going out into the most difficult areas and opening a free clinic in the bottom of a church and trying to help and assist people, whether you are talking about being in the classrooms at UCLA as an instructor to the brightest minds in our country, whether you are talking about being a college president, he has done it all. He has done it all, Mr. President. But his heart is out there with the underserved people. You can't look at his record, and you can't read about it and listen to him and not understand it.

Since 1992, Dr. Satcher has ably led the Centers for Disease Control and Prevention in Atlanta, the agency responsible for protecting the Nation's health and preventing disease, injury and premature death. In this capacity he has played a leading role in safeguarding and improving the health of all Americans.

In 1992, under Dr. Satcher's leadership, CDC developed and implemented a very successful childhood immunization initiative. Before the initiative, only a little more than half of the Nation's children—55 percent—were immunized. Today, the figure is 78 percent, and vaccine-preventable childhood diseases are now at a record low.

Dr. Satcher would be the first to say: I don't deserve all the credit for this. He would say: I don't even deserve a great deal of the credit, or even a little of the credit.

But he would tell you that he was out there fighting every step of the way with those who do deserve the credit. He was there, and he deserves great credit for this because he made it a priority. It was in terms of not only the availability and accessibility of vaccines, but it was working to try and overcome the kinds of resistance that exists in so many communities locally across this country that he was able to devise strategies to work this through. I find that in my own State of Massachusetts, in a number of different communities, there is a great hesitancy or resistance to move ahead with immunizations for children, for many different reasons—those individuals that have difficulty with the English language and those that have cultural kinds of problems in moving forward, in terms of vigorous vaccination regimes, the repetitiveness in making sure children are going to keep up to speed in terms of the number of times that we have to go back and get these vaccinations. There is a lot of complexity in terms of making sure that children are going to receive those vaccines. But we have gone from 55 percent to 78 percent on his watch. He deserves credit.

Dr. Satcher has also led CDC efforts to deal more effectively with the infectious diseases and foodborne illnesses. Our Nation relies on CDC to provide the rapid response needed to combat outbreaks of disease and protect public safety. Under Dr. Satcher, CDC is implementing a strategy against new and re-emerging infectious diseases, like TB, with better surveillance and detection. Many of us thought we had moved past TB, the time of tuberculosis. Yet, we find pockets of it that still exist in many different communities in this country. It is associated so much with the problems of poor housing, poor sanitary conditions, and generally the problems associated with poverty. We have it in many of our communities. We still have it and we can't forget it, and we should not forget it. We need a doctor that understands the response to recent food poisoning incidents. He has been a leader in developing a new early warning system to deal with such illnesses. He has earned many distinguished tributes during his extraordinary career. In 1996, he received the prestigious Nathan B. Davis Award from the American Medical Association for outstanding service in advancing the public health.

In 1986, he was elected to the Institute of Medicine of the National Academy of Sciences in recognition of his outstanding leadership.

Dr. Satcher is a respected family doctor. Ask those families out there in the Watts area. Ask the families down in the southern parts of our country in rural communities. I think for any of us that took the time to sit through those hearings and listen to him can understand that he has—I suppose the best description is the ''bedside manner.'' There are other words that are more eloquent to describe it. But he has it, and anybody that has ever met him and known him, or talked to him, or, I am sure, have been treated by him would understand and respect him. He is a respected scholar that has been elevated to the most prestigious positions in our country, voted on by those of his peers who understand his scholarship, and he is a respected public leader recognized for his service in public health.

His career has emphasized work in patient care, health policy development and planning, education, research, health professions education, and family medicine. His range of skills and experience, and strong commitment to improving public health make him well qualified to be the country's principal official on health care and health policy issues—America's doctor. America is a healthier nation today, and it is healthier in large part because of Dr. Satcher's leadership. He is an excellent choice to be Surgeon General and Assistant Secretary for Health. The Nation faces significant public health challenges.

We need a Surgeon General who can speak with candor, and advise the nation on smoking, AIDS, teenage pregnancy, the link between diet and disease, and other major health concerns. In the 1940s, Surgeon General Thomas Parran used blunt talk to warn the public about venereal disease. In 1964,

Surgeon General Luther Terry first alerted the public to the dangers of smoking and the link between smoking and lung cancer. Surgeon General C. Everett Koop used his position to raise awareness about AIDS and other major health issues. People listen when the Surgeon General speaks. Dr. Satcher is well-qualified to follow in this distinguished tradition.

Dr. Satcher's nomination has broad bipartisan support. He's been endorsed by a large number of health groups, including the American Medical Association, the American Nurses Association, and a wide range of academic health centers and public health organizations. I look forward to working closely with him in the future, and I urge the Senate to give him the overwhelming vote of support he deserves.

Mr. President, I have about 10 or 15 more minutes. But I see my friend and colleague from Maryland. I would like to be able to conclude my remarks after the Senator from Maryland.

Mr. HATCH. Will the Senator yield?

Mr. KENNEDY. I would be glad to yield.

Mr. HATCH. I was supposed to be here at 2 to give a short speech and introduce a bill. Would it be all right with the distinguished Senator from Maryland if I do that? I have to chair the Judiciary Committee.

Ms. MIKULSKI. I can enter my statement into the RECORD. I am not debating the merits, if my colleague will yield—but just to affirm the competency.

Mr. KENNEDY. I would rather hear from the Senator. If I can't, and if what I have outlined is not satisfactory, I would rather let the Senator speak, and I will take my chances. Could we have the Senator speak for 10 minutes?

Ms. MIKULSKI. I will speak for less than 5 minutes.

Mr. HATCH. If I could go immediately following the Senator from Maryland.

Mr. KENNEDY. Mr. President, I ask unanimous consent that we recognize the Senator from Maryland for whatever time she expects, and following that the Senator from Utah, and then if I could ask that I be recognized.

The PRESIDING OFFICER. Without objection, it is so ordered.

Ms. MIKULSKI. Mr. President, I thank my colleagues for this arrangement.

Mr. President, It is a great honor for me to support the nomination of Dr. Satcher.

I enthusiastically support his nomination to be Surgeon General and Assistant Secretary of Health.

This position, which serves as the nation's spokesperson on public health issues, has been vacant far too long. When I decide whether to support a nominee, I look at the nominee's competence and personal and professional integrity. Dr. Satcher is highly competent. Dr. Satcher has the greatest personal and professional integrity of any nominee who has come before our Committee in recent years. Dr. Satcher has a truly remarkable story. He's overcome substantial odds and hardships. He graduated from that great institution Morehouse College in Atlanta, Georgia, where Dr. Martin Luther King graduated and thousands of African-American men.

At a time when there were few African-American physicians in our country, Dr. Satcher attended Case Western University in Cleveland, Ohio, where he received his medical degree. Dr. Satcher was the first African-American to earn an M.D. and a Ph.D. at Case Western. He was later a professor at Charles R. Drew Medical School in Los Angeles, California and returned to his alma mater, Morehouse, to become the head of the school of Medicine there. He served as president of Meharry Medical School in Nashville, Tennessee from 1982 to 1993 before becoming the director of the Centers for Disease Control.

I have worked closely with Dr. Satcher, when he was the head of the Centers for Disease Control. He was enormously helpful and responsive with my state's psfesteria crisis.

During his tenure at the Centers for Disease Control Dr. Satcher established himself as a very capable leader in the arena of public health. He aggressively took on the responsibilities of promoting health and preventing disease, injury and premature death. Whether it was increasing childhood immunization rates, expanding the breast and cervical cancer screening program, researching effective treatments for AIDS, or stressing preventive measures in pursuing good health, Dr. Satcher has done an excellent job.

I admire his work on the issues of minority health, especially sickle cell anemia, which affects mostly African-Americans. I also admire Dr. Satcher's courage to look at the link between guns and the public health. Too many young African-American men are being killed by gun violence in our cities. I was also pleased with the way Dr. Satcher took on the issue of food safety.

I am very concerned about recent incidents which have forced us to take a good look at the safety of our food supply.

Dr. Satcher was on cue when he laid the groundwork for a new Early Warning System to detect and prevent foodborne illnesses. This initiative will help respond to outbreaks of food-borne illness earlier, and give us the data we need to prevent future outbreaks.

The work Dr. Satcher has accomplished at CDC, along with his experience as a physician and scholar before that, directly prepare him for the role of a good surgeon general.

As Surgeon General, Dr. Satcher will be America's advisor on public health issues and the national leader in developing public health strategies.

I know Dr. Satcher will provide this country with a strong voice for public health. I wholeheartedly endorse this nominee. I urge my colleagues to support Dr. Satcher's nomination.

The PRESIDING OFFICER. The Senator from Utah is recognized.

Mr. HATCH. I thank the Chair.

(The remarks of Mr. HATCH and Mr. CLELAND pertaining to the submission of S.J. Res. 40 are located in today's RECORD under ''Submission of Concurrent and Senate Resolutions.'')

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, some of my colleagues have questioned Dr. Satcher's support for clinical trials of the drug AZT in foreign countries as part of the all-out international public effort to halt the mushrooming epidemic of mother-to-infant transmission of the AIDS virus. Every day more than 1,000 babies in developing countries are born infected with HIV. Clinical trials in the United States in 1994 showed that it is possible to reduce the mother-to-infant transmission of HIV by administering AZT during pregnancy, labor and delivery. However, it is recognized that such treatment would not be feasible in developing countries.

Senator FRIST talked about this briefly in his presentation. It is too expensive, and it requires ongoing therapy which is not possible in remote areas. It also prohibits breast feeding. For these reasons a group of international experts convened by the World Health Organization in June 1994 recommended that research be carried out to develop a simpler, less costly treatment. The idea was to make it affordable in terms of the limited resources for African countries and also that would be culturally suitable in terms of the breast feeding and in terms of the amount of times that individuals would have to come back for treatment. The idea was to tailor the regime to the existing cultural, economic and social regimes which exist in areas of the world where we have high concentrations of HIV but recognizing that one of the very encouraging areas with regard to HIV is trying to intercept the passage of the HIV into newborn children.

Recognizing the possibilities for trying to reduce the communication of HIV to these infants, the challenge was, can we develop an alternative regime that would prevent the babies of those infected with HIV from contracting this disease, and do it in a way which is affordable, culturally acceptable, and effective? So, responding to this urgent need, the Centers for Disease Control and Prevention, the National Institutes of Health, the World Health Organization and other international experts worked closely with scientists from developing countries to develop a treatment that is usable in these countries and can reduce the devastating toll of HIV on their children.

Dr. Satcher has acted entirely ethically and responsibly on this issue. The World Health Organization and the developing countries urgently requested

the CDC and NIH to provide assistance in designing and conducting these trials, in cooperation with the research communities in the host countries.

In a letter to NIH dated May 8, 1997, Edward K. Mbidded, chairman of the AIDS research committee of the Uganda Cancer Institute wrote:

These are Ugandan studies conducted by Ugandan investigators on Ugandans. Due to lack of resources, we have been sponsored by organizations like yours. We are grateful that you have been able to do so. There is a mix-up on issues here, which needs to be clarified. It is not NIH conducting the studies in Uganda, but Uganda's doing the study on their people for the good of their people.

Dr. David Ho, the director of the Aaron Diamond AIDS Research Center in New York City and Time's 1996 Man of the Year, has stated:

These clinical trials were created for Africans by Africans with the good of their people in mind and with their informed consent. The studies were designed to be responsive to local needs through the constraints of each study site. African scientists have argued that it is not in their best interests to include a complicated and costly AZT regime for the sake of comparison, for such a regime is not only unaffordable but logistically indefensible.

Before patients were enrolled in the clinical trials, they were specifically informed of their AIDS status and counseled about the risks and benefits of participation, including the fact they might be in a study group that received a placebo instead of an AZT anti-virus drug.

This is the critical issue or one of the very major issues that obviously distinguish it from the Tuskegee study where there was no informed consent. At the time when the study started with the African Americans, blacks in this country, in the South, primarily in Alabama, those who participated in the venereal disease studies were never told that there was a cure. They were never informed that there was medical information that could make these individuals healthy. They were maintained, effectively, by the U.S. Public Health Service, in their stage of sickness. And some of them even died.

This whole issue of informed consent was a matter of very considerable debate and discussion here in the U.S. Senate in the early 1970's. I had the opportunity of chairing the hearings during that period of time. After those series of incidents, we required informed consent. Every Member of this body and everyone who is listening to this knows that every time they go into a doctor's office and they sign that little sheet, ''informed consent''—they never did that before 1975. That was as a result of Senate hearings. Any tie-in with Tuskegee is a distortion and misrepresentation and a disservice and inaccurate.

In Tuskegee there was no ethical review. In these studies there was an ethical review. There was no oversight of those kinds of studies. In this study there is an oversight. There was no counseling about the transmissibility. In this study there was. No informed consent. In this case—yes. It is entirely different.

Now, as a practical matter, the only AZT treatment—to come back to the proposal again that was approved for the African countries—as a practical matter the only AZT treatment available to any women in these developing countries is the treatment provided to participants in the study. There was no other kind of treatment. The HIV-infected women in these countries do not have access to AZT because, as has been pointed out, it costs too much.

Ethics Committees in both the United States and the developing countries conducted continuous, rigorous ethical reviews of the trials. The committees were made up of medical scientists, ethicists, social scientists, members of the clergy, and people with HIV. The role of these committees guaranteed that the trials would conform to strict ethical guidelines for biomedical research, including the Declaration of Helsinki and the International Guidelines for Biomedical Research Involving Human Subjects.

The AMA president-elect, Dr. Nancy Dickey, has stated that these studies are ''scientifically well founded'' and ''in the long run will provide serious answers and are not the kind of superficial, unethical research that the critics are trying to make them out to be.''

Dr. Neil Halsey, the Professor and Director of the Division of Disease Control of the Department of International Health at Johns Hopkins University; Dr. Andrea Ruff, Associate Professor at Johns Hopkins, wrote to Secretary Shalala on October 24, 1997 stating:

''. . . we strongly believe that these trials are ethical and essential for identifying effective, practical regimes that could be implemented in most developing countries.''

Even those within the scientific community who have raised concerns about these trials, such as Dr. Sidney Wolfe, the director of the Public Citizen Health Research Group, have expressed their support for Dr. Satcher.

So, I ask unanimous consent to have printed in the RECORD a series of articles that indicate the broad ethical support for the conduct of these trials.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From the New England Journal of Medicine, Oct. 2, 1997]

ETHICAL COMPLEXITIES OF CONDUCTING RESEARCH IN DEVELOPING COUNTRIES

(Harold Varmus, M.D. and David Satcher, M.D., Ph.D)

One of the great challenges in medical research is to conduct clinical trials in developing countries that will lead to therapies that benefit the citizens of these countries. Features of many developing countries—poverty, endemic diseases, and a low level of investment in health care systems—affect both the ease of performing trials and the selection of trials that can benefit the populations of the countries. Trials that make use of impoverished populations to test drugs for use solely in developed countries violate our most basic understanding of ethical behavior. Trials that apply scientific knowledge to interventions that can be used to benefit such populations are appropriate but present their own ethical challenges. How do we balance the ethical premises on which our work is based with the calls for public health partnerships from our colleagues in developing countries?

Some commentators have been critical of research performed in developing countries that might not be found ethically acceptable in developed countries. Specifically, questions have been raised about trials of interventions to prevent maternal-infant transmission of the human immunodeficiency virus (HIV) that have been sponsored by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). Although these commentators raise important issues, they have not adequately considered the purpose and complexity of such trials and the needs of the countries involved. They also allude inappropriately to the infamous Tuskegee study, which did not test an intervention. The Tuskegee study ultimately deprived people of a known, effective, affordable intervention. To claim that countries seeking help in stemming the tide of maternal-infant HIV transmission by seeking usable interventions have followed that path trivializes the suffering of the men in the Tuskegee study and shows a serious lack of understanding of today's trials.

After the Tuskegee study was made public, in the 1970s, a national commission was established to develop principles and guidelines for the protection of research subjects. The new system of protection was described in the Belmont report. Although largely compatible with the World Medical Association's Declaration of Helsinki, the Belmont report articulated three principles: respect for persons (the recognition of the right of persons to exercise autonomy), beneficence (the minimization of risk incurred by research subjects and the maximization of benefits to them and to others), and justice (the principle that therapeutic investigations should not unduly involve persons from groups unlikely to benefit from subsequent applications of the research).

There is an inherent tension among these three principles. Over the years, we have seen the focus of debate shift from concern about the burdens of participation in research (beneficence) to equitable access to clinical trials (justice). Furthermore, the right to exercise autonomy was not always fully available to women, who were excluded from participating in clinical trials perceived as jeopardizing their safety; their exclusion clearly limited their ability to benefit from the research. Similarly, persons in developing countries deserve research that addresses their needs.

How should these principles be applied to research conducted in developing countries? How can we—and they—weigh the benefits and risks? Such research must be developed in concert with the developing countries in which it will be conducted. In the case of the NIH and CDC trials, there has been strong and consistent support and involvement of the scientific and public health communities in the host countries, with local as well as United States-based scientific and ethical reviews and the same requirements for informed consent that would exist if the work were performed in the United States. But there is more to this partnership. Interventions that could be expected to be made available in the United States might be well beyond the financial resources of a developing country or exceed the capacity of its health care infrastructure. Might we support a trial in another country that would not be offered in the United States? Yes, because

the burden of disease might make such a study more compelling in that country. Even if there were some risks associated with intervention, such a trial might pass the test of beneficence. Might we elect not to support a trial of an intervention that was beyond the reach of the citizens of the other country? Yes, because that trial would not pass the test of justice.

Trials supported by the NIH and the CDC, which are designed to reduce the transmission of HIV from mothers to infants in developing countries, have been held up by some observers as examples of trials that do not meet ethical standards. We disagree. The debate does not hinge on informed consent, which all the trials have obtained. It hinges instead on whether it is ethical to test interventions against a placebo control when an effective intervention is in use elsewhere in the world. A background paper set forth our views on this matter more fully. The paper is also available on the World Wide Web (at http://www.nih.gov/news/mathiv/mathiv.htm).

One such effective intervention—known as AIDS Clinical Trials Group protocol 076—was a major breakthrough in the search for a way to interrupt the transmission of HIV from mother to infant. The regimen tested in the original study, however, was quite intensive for pregnant women and the health care system. Although this regimen has been proved effective, it requires that women undergo HIV testing and receive counseling about their HIV status early in pregnancy, comply with a lengthy oral regimen and with intravenous administration of the relatively expensive antiretroviral drug zidovudine, and refrain from breast-feeding. In addition, the newborn infants must receive six weeks of oral zidovudine, and both mothers and infants must be carefully monitored for adverse effects of the drug. Unfortunately, the burden of maternal-infant transmission of HIV is greatest in countries where women present late for prenatal care, have limited access to HIV testing and counseling, typically deliver their infants in settings not conducive to intravenous drug administration, and depend on breast-feeding to protect their babies from many diseases, only one of which is HIV infection. Furthermore, zidovudine is a powerful drug, and its safety in the populations of developing countries, where the incidences of other diseases, anemia, and malnutrition are higher than in developed countries, is unknown. Therefore, even though the 076 protocol has been shown to be effective in some countries, it is unlikely that it can be successfully exported to many others.

In addition to these hurdles, the wholesale cost of zidovudine in the 076 protocol is estimated to be in excess of $800 per mother and infant, an amount far greater than most developing countries can afford to pay for standard care. For example, in Malawi, the cost of zidovudine alone for the 076 regimen for one HIV-infected woman and her child is more than 600 times the annual per capita allocation for health care.

Various representatives of the ministries of health, communities, and scientists in developing countries have joined with other scientists to call for less complex and less expensive interventions to counteract the staggering impact of maternal-infant transmission of HIV in the developing world. The World Health Organization moved promptly after the release of the results of the 076 protocol, convening a panel of researchers and public health practitioners from around the world. This panel recommended the use of the 076 regimen throughout the industrialized world, where it is feasible, but also called for studies of alternative regimens that could be used in developing countries, observing that the logistical issues and costs precluded the widespread application of the 076 regimen. To this end, the World Health Organization asked UNAIDS, the Joint United Nations Programme on HIV/AIDS, to coordinate international research efforts to develop simpler, less costly interventions.

The scientific community is responding by carrying out trials of several promising regimens that developing countries recognize as candidates for widespread delivery. However, these trials are being criticized by some people because of the use of placebo controls. Why not test these new interventions against the 076 regimen? Why not test them against other interventions that might offer some benefit? These questions were carefully considered in the development of these research projects and in their scientific and ethical review.

An obvious response to the ethical objection to placebo-controlled trials in countries where there is no current intervention is that the assignment to a placebo group does not carry a risk beyond that associated with standard practice, but this response is too simple. An additional response is that a placebo-controlled study usually provides a faster answer with fewer subjects, but the same result might be achieved with more sites or more aggressive enrollment. The most compelling reason to use a placebo-controlled study is that it provides definitive answers to questions about the safety and value of an intervention in the setting in which the study is performed, and these answers are the point of the research. Without clear and firm answers to whether and, if so, how well an intervention works, it is impossible for a country to make a sound judgment about the appropriateness and financial feasibility of providing the intervention.

For example, testing two or more interventions of unknown benefit (as some people have suggested) will not necessarily reveal whether either is better than nothing. Even if one surpasses the other, it may be difficult to judge the extent of the benefit conferred since the interventions may differ markedly in other ways—for example, cost or toxicity. A placebo-controlled study would supply that answer. Similarly, comparing an intervention of unknown benefit—especially one that is affordable in a developing country—with the only intervention with a known benefit (the 076 regimen) may provide information that is not useful for patients. If the affordable intervention is less effective than the 076 regimen—not an unlikely outcome—this information will be of little use in a country where the more effective regimen is unavailable. Equally important, it will still be unclear whether the affordable intervention is better than nothing and worth the investment of scarce health care dollars. Such studies would fail to meet the goal of determining whether a treatment that could be implemented is worth implementing.

A placebo-controlled trial is not the only way to study a new intervention, but as compared with other approaches, it offers more definitive answers and a clearer view of side effects. This is not a case of treating research subjects as a means to an end, nor does it reflect ''a callous disregard of their welfare.''[2] Instead, a placebo-controlled trial may be the only way to obtain an answer that is ultimately useful to people in similar circumstances. If we enroll subjects in a study that exposes them to unknown risks and is designed in a way that is unlikely to provide results that are useful to the subjects or others in the population, we have failed the test of beneficence.

Finally, the NIH- and DCD-supported trials have undergone a rigorous process of ethical review, including not only the participation of the public health and scientific communities in the developing countries where the trials are being performed but also the application of the U.S. rules for the protection of human research subjects by relevant institutional review boards in the United States and in the developing countries. Support from local governments has been obtained, and each active study has been and will continue to be reviewed by an independent data and safety monitoring board.

To restate our main points: these studies address an urgent need in the countries in which they are being conducted and have been developed with extensive in-country participation. The studies are being conducted according to widely accepted principles and guidelines in bioethics. And our decisions to support these trials rest heavily on local support and approval. In a letter to the NIH dated May 8, 1997, Edward K. Mbidde, chairman of the AIDS Research Committee of the Uganda Cancer Institute, wrote:

These are Ugandan studies conducted by Ugandan investigators on Ugandans. Due to lack of resources we have been sponsored by organizations like yours. We are grateful that you have been able to do so. . . . There is a mix up of issues here which needs to be clarified. It is not NIH conducting the studies in Uganda but Ugandans conducting their study on their people for the good of their people.

The scientific and ethical issues concerning studies in developing countries are complex. It is a healthy sign that we are debating these issues so that we can continue to advance our knowledge and our practice. However, it is essential that the debate take place with a full understanding of the nature of the science, the interventions in question, and the local factors that impede or support research and its benefits.

[From the New York Times Oct. 15, 1997]

AIDS EXPERTS LEAVE JOURNAL AFTER STUDIES ARE CRITICIZED

(By Lawrence K. Altman)

Two internationally recognized AIDS experts are resigning from The New England Journal of Medicine's editorial board over the content and handling of articles criticizing the ethics of Federally financed studies of AIDS treatments in third-world countries.

The countries seek a drug regimen less costly than those used in the United States to thwart transmission of the AIDS virus from mothers to infants. In trials involving more than 12,000 infected pregnant women in Africa, Thailand and the Dominican Republic, some women receive the drug AZT, which has worked in studies in the United States, while others receive dummy pills.

The journal's attack on the studies, which compares them to the infamous Tuskegee experiment, has led to wide discussion, including harsh criticism of the journal itself, and focuses attention on the role of the 25-member editorial aboard and the two who are resigning in protest, Drs. David Ho and Catherine M. Wilfert. The two objected to not being consulted before publication of an attack on research that could save lives, and Dr. Ho worried that the attack itself could jeopardize future research on experimental AIDS vaccines.

Dr. Jerome P. Kassirer, the journal's chief editor, said the board's function is to give advice on broad issues and suggestions of authors for editorials and reviews, but that the board was not routinely consulted.

Dr. Ho, a virologist at the Aaron Diamond AIDS Research Center in Manhattan, and Dr. Wilfert, a pediatrician at Duke University in Durham, N.C., are the journal board's chief advisers on AIDS.

A third board member, Dr. Richard P. Wenzel, chairman of medicine at the Medical

College of Virginia in Richmond, said in an interview that he agreed with much of Dr. Wilfert's criticism but was withholding a decision about resigning until after the issue was discussed at the board's annual meeting in December.

Drs. Ho and Wilfert said in separate interviews that they had resigned independently largely because the journal had not consulted them before publishing an editorial that likened the new experiments to the Tuskegee experiment, in which poor black men suffering from syphilis were left untreated.

Dr. Ho, Dr. Wilfert and others have taken issue with the Tuskegee comparison in part because the subjects in the AZT studies were told that some would get dummy pills. In the Tuskegee study the men were not told that penicillin had became available while the study was under way, and so did not know that effective treatment was being withheld.

A full-time staff of editors produces the weekly journal, but Dr. Ho said that ''the reason you have an editorial board to help with policy is to get some input when you have major issues like this one, and that clearly did not take place.''

In the editorial process, ''it was clear that my role was not crucial,'' he said.

Dr. Ho said he was deeply concerned about how the critical editorial would affect the future of studies to evaluate experimental AIDS vaccines in developing countries.

Dr. Wilfert said she was resigning because the journal published the editorial and another critical article on Sept. 18 without presenting the other side.

''It was like ignoring half of it on purpose,'' Dr. Wilfert said.

Because her name was on the masthead, ''It implied that I agreed with it when I didn't,'' she said.

''It is an error and bad policy'' and ''a grievous misuse of the journal's power,'' Dr. Wilfert said.

''Those are not decisions that a few people in the editorial office ought to feel comfortable with, because no one small group of persons, no matter who they are, can cover the waterfront well enough'' in translating health policy and practice in developed countries to those in developing countries, Dr. Wilfert said.

Dr. Wilfert said she was resigning effective Dec. 31 in order to ''vent my spleen'' at the annual meeting. She said she feared that if she resigned sooner ''the issue might not be discussed at the meeting.''

The journal published a rebuttal two weeks after its attack. It was written by Dr. Harold Varmus, the head of the National Institutes of Health, and Dr. David Satcher, the head of the Centers for Disease Control and Prevention, and would not have been printed so quickly had not Dr. Varmus received a leaked copy of the original editorial before publication, those involved in the dispute said.

Dr. Marcia, Angell, the journal's executive editor, wrote the editorial.

Dr. Wenzel, the board member from Richmond, said that if the authors of the critical articles ''really knew the facts they would have done a better job.''

The journal's chief editor, Dr. Kassirer, said he regretted Dr. Ho's said Dr. Wilfert's decisions to resign and was unaware of any similar resignations at the journal, which was founded in 1812.

The editorial board members, who have no set term, Dr. Kassirer said, are named by the chief editor, who can elect not to renew them as members and has done so.

Dr. Kassirer said that Dr. Wilfert ''wanted to have prior consultation of the material in the journal, which is just not acceptable to me because prior consultation is not what the editorial board is for.''

He said the journal intentionally did not strive to present all sides of an issue ''because if you did you would end up with a kind of Talmudic discussion in ''which readers could end up having no particular view one way or the other and it would be rather boring.''

Dr. Varmus, the National Institutes of Health director, said that ''The New England Journal of Medicine is trying to attract more attention by making political ethical philosophical and economic statements that have traditionally not been in that journal in such an inflammatory way.''

But he also said that ''before you inflame the public and attract so much attention, you might want to ask experts on the editorial board what they thing.''

The Massachusetts Medical Society owns The New England Journal of Medicine. Dr. Ronald A. Arky, a Harvard Medical School professor who heads the society's publications committee to which Dr. Kassirer reports, said he learned of the resignations last Friday.

''The committee will want to hear from the editor about the resignations'' at their next meeting in early November, Dr. Arky said.

[From Time Magazine, Sept. 30, 1997]

IT'S AIDS, NOT TUSKEGEE—INFLAMMATORY COMPARISONS WON'T SAVE LIVES IN AFRICA

(By David D. Ho, M.D.)

In the current issue of the New England Journal of Medicine, Peter Lurie and Dr. Sidney Wolfe of the advocacy group Public Citizen charge that some U.S.-sponsored AIDS-research projects in Africa are unethical. The journal's editor, Dr. Marcia Angell, goes even further, comparing these studies to the infamous Tuskegee experiment in which black men in the South were deliberately deceived and denied effective treatment in order to determine the natural course of syphilis infection. This comparison is inflammatory and unfair and could make a desperate situation even worse.

Doctors in the U.S. have known since 1994 that the drug AZT can substantially reduce the chance of transmission of the AIDS virus from an infected woman to her newborn child. Unfortunately, administering AZT to pregnant women is complicated and quite expensive—about $1,000 per mother. That's far beyond the means of most developing countries, where 1,000 newborns are infected each day.

Hoping to find an AZT regimen they could afford, African researchers sought sponsorship from U.S. health agencies and launched a number of scientific studies in which some mothers were given short treatments with AZT and some, for the purpose of comparison, received a placebo. It is the inclusion of these placebo groups that the critics find objectionable. Giving a sugar pill to an AIDS patient is considered ethically unacceptable in the U.S. To give one to a pregnant African, Dr. Angell writes, shows a ''callous disregard of [a patient's] welfare for the sake of research goals.''

These clinical trials, however, were created for Africans, by Africans, with the good of their people in mind and with their informed consent. The studies were designed to be responsive to local needs and to the constraints of each study site. African scientists have argued that it is not in their best interest to include a complicated and costly AZT regimen for the sake of comparison when such a regimen is not only unaffordable but logistically infeasible. They have, instead, opted for a study design that is achievable in practice and is likely to provide lifesaving answers expeditiously, even though it includes a group of women receiving a placebo. While the inclusion of this placebo group would not be acceptable in the U.S., the sad truth is that giving nothing is the current standard of care in Africa.

The ethical debate here is obviously a complex one, without a clear distinction between right and wrong. Comparisons to Tuskegee don't help; neither does the imposition of Western views, or what Dr. Edward Mbidde of Uganda calls ''ethical imperialism.'' Calm and careful deliberations are in order. Insisting on the infeasible in the name of ethical purity is counterproductive in the struggle to stop this deadly virus.

Mr. KENNEDY. I see my friend and colleague, Senator WELLSTONE. I had some other remarks, but I will either make them later in the afternoon or include them in the RECORD.

I yield the floor.

The PRESIDING OFFICER. The Senator from Minnesota.

Mr. WELLSTONE. I thank the Senator from Massachusetts. I say to Senators who are out here for the debate, I shall not take long.

I rise to support the nomination of Dr. David Satcher to be the next Surgeon General of the United States and Assistant Secretary of Health. Dr. Satcher is a man above reproach, whose life path has brought him here today to serve as the 17th Surgeon General. We should not delay in confirming this nomination.

What is it that makes Dr. Satcher such a wise appointment for Surgeon General of the United States? Look back over this man's life, for the fabric of a person is woven over the course of a lifetime. Dr. Satcher's fabric is tight knit, vibrant, trustworthy and strong.

Where does he come from? Is it from his childhood, growing up in rural America in a poor family with poor access to medical care, nearly dying at the age of 2 from whooping cough? Is that what makes him such an outstanding spokesperson for childhood immunization, for childhood nutrition, for preventive health? Is that what makes him such a powerful role model for children to follow their dreams?

Or is it from the tragic loss of his first wife, the mother of his children, at a very young age from cancer? This man knows the tragedy of disease, not just on an academic level, not just on a professional level, but also on a very personal level.

Or is it from his professional, academic and public service careers that truly do make him very special? This is a man who has used his considerable skills to serve those people in our country who were quite often the poorest of poor and, in particular, I have in mind poor children all across our Nation.

After graduating from Case Western Reserve Medical School, his life has been spent caring for patients, teaching students and promoting public health, and he has done it well. His most recent position has been as Director for the Centers for Disease Control and Prevention.

In his 4 years as Director for the Centers for Disease Control and Prevention, Dr. Satcher had—a little bit of

evidence—spearheaded initiatives that have increased childhood immunization rates from 55 percent in 1992 to 78 percent in 1996; improved the Nation's capability to respond to emerging infectious diseases; laid the groundwork for a new early warning system to detect and prevent foodborne infections; expanded the CDC's comprehensive breast and cervical cancer screening program from 18 States to all 50 States; and under Dr. Satcher's stewardship, the CDC has directed its attention to the causes and consequences and prevention of an epidemic which has long been a concern of my wife Sheila and of concern to me, and that is the epidemic of domestic violence against women in our country.

Mr. President, I frequently come to the floor to talk about fairness, what is the right thing to do, what is the fair thing to do. And today I want to talk about fairness; yes, to Dr. Satcher, but even more so to fairness to the people in our country who are waiting for leadership from this Surgeon General; fairness to the families and children of inner cities I have visited all across America who are waiting for a spokesperson to tell them how to improve some of the unsafe conditions that they live under, how to improve their health care for themselves as parents and for their children; fairness to the residents of rural America who are medically underserved and are waiting for new ideas to make health care accessible; fairness to the youth of America who have been waiting for a clear and credible voice to lead them away from tobacco addiction before they light their first cigarette; and fairness to the victims of domestic violence and cancer and drug and alcohol abuse who are waiting for Dr. Satcher to speak from his bully pulpit about preventing these terrible tragedies.

Mr. President, it is not fair for us to delay any longer Dr. David Satcher's nomination. We have the responsibility to vote. We have the wisdom, or should have the wisdom, to vote for this man who can do so much for our country. Elementary justice demands that the United States Senate vote for confirmation of Dr. David Satcher as Surgeon General and Assistant Secretary of Health. I yield the floor.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, that was an excellent statement by my friend and colleague, the Senator from Minnesota.

Mr. BINGAMAN. Mr. President, I rise in support of Dr. David Satcher for confirmation both as the Surgeon General of the United States and Assistant Secretary for Health. In so doing, I want to speak both to the position of Surgeon General itself and to the qualifications of this nominee.

From 1871 until the present, 16 individuals have had the honor to serve as this nation's chief advisor on public health matters. These individuals served to protect, improve, and advance the health of all people in the United States. While there are those that criticize and may disagree with the position, in many ways the Surgeon General serves as the health conscience for the country.

Many Americans may not know the history of this position and can name few of the 16 individuals who have served as Surgeon General. However, most Americans can point to ground breaking reports or initiatives that were conducted by Surgeon Generals. For instance, they are aware of the role of the Surgeon General in programs to immunize millions against polio. Most can cite the important declaration in 1964, by the Surgeon General that: ''smoking can be hazardous to your health.'' Indeed, past Surgeon Generals have issued benchmark reports on smoking, nutrition, water fluoridation, and HIV and AIDS.

The public deserves to have this position filled; it has been vacant for too long. We have been without a Surgeon General since December of 1994. We need an identifiable, objective leader as we deal with the broad spectrum of health care issues before the country. Dr. David Satcher is that leader.

Dr. Satcher is a distinguished family physician, academician, and leader in the arena of public health. Indeed, he has headed the Centers for Disease Control and Prevention since 1993. He has written that he will utilize the position of the Surgeon General to focus on issues that unite Americans. I am particularly interested in his commitment to, and expertise on, the issues of health promotion and disease prevention. During his confirmation hearing before the Committee on Labor and Human Resources, he emphasized his desire to promote healthy lifestyles and focus on issues of critical importance such as better nutrition and exercise. Dr. Satcher recognized the opportunities for lifestyle modification as a way of improving the health of Americans. His performance in this arena in the past and his stated agenda for the future, place prevention as a focal point.

Mr. President, the accomplishments of Dr. Satcher at the CDC have had a direct impact in my home state of New Mexico. For New Mexico, border health issues are of utmost importance. Dr. Satcher has helped develop an innovative strategy to combat threats from new and reemerging communicable diseases like tuberculosis which cause problems in our border region. Greater outreach to the general public and health professionals has resulted in four straight years for declining TB rates.

Additionally, he has worked to improve the quality and quantity of immunization services. He has promoted better community involvement in the immunization programs. Nationwide, childhood immunization rates rose to a record 78 percent under his leadership at the CDC.

Another initiative, the CDC comprehensive breast and cervical cancer screening program, has flourished under Dr. Satcher's leadership. This program has undeserved and minority women has grown from being offered in the initial eighteen states, to including 50 states, the District of Columbia, 5 U.S. territories, and thirteen Native American organizations. Outreach efforts such as this lead to increased access and are key to reaching low income minority and older women. They afford the opportunity as well to educate at risk women on early detection of cancers.

In closing, Dr. David Satcher is eminently qualified to speak out for the public's health and the nation's health needs. The nation deserves to have this position filled now. His commitment to public health will be a credit to this country. Please join me in supporting Dr. David Satcher for Surgeon General and Assistant Secretary for Health.

Mr. KENNEDY. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. ASHCROFT. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered. The Senator from Missouri is recognized.

Mr. ASHCROFT. Thank you, Mr. President.

There have been a number of charges made and some pretty strong language suggested, as well as a lot of repetition and volume regarding some of the circumstances surrounding the conduct of Dr. Satcher in his role as an individual involved both in domestic health situations and international health situations.

Let me begin by going through a number of these issues and referring to what notable authorities and investigators have indicated.

When I raised the issue of the CDC, under the direction and in cooperation with Dr. Satcher, being involved with blind HIV testing for newborns—and while learning about the level of HIV present in the newborns not providing information to parents and sending newborns home without that kind of information—there was a pretty vociferous response, indicating that there were things in the studies that were worth learning. I don't challenge that. There are things that are worth learning that can be learned from medical research. As a matter of fact, it is sometimes easier to learn a lot of things more quickly if you don't really pay much attention to the ethics that are involved. You can learn the most, probably, with research that might be damaging to individuals.

So the mere fact that there are items to be learned and that there is value in terms of statistical data that can be assembled from the study, doesn't justify the existence of a study. As a matter of fact, when you are running rats

in a study, you can learn a lot of things very quickly. The reason we use animals in a lot of studies is because we accord to human beings a kind of standing that says the learning objective is not the end of all that we do: we also have to respect the dignity of the individuals involved.

So I just wanted to mention a couple of the kinds of things that were said around the country and by authorities regarding these so-called blind HIV tests.

Here is what was said in the New York Daily News on the 27th of June in 1995. They put it this way:

Only politics, radical politics, explains the separate standard for AIDS.

Meaning there is a separate approach:

The Centers for Disease Control and Prevention carried this illogic to an absurd end by requiring testing of newborns, then keeping the results secret. That let officials track the epidemic but denied treatment. Fearful of the push to use the results for actual care, the CDC turned churlish and quit testing.

It is kind of interesting to me that the New York Daily News, which doesn't have an ax to grind here, indicates that there was a set of circumstances that resulted in the CDC pursuing a logic to an absurd end, including testing newborns and keeping the results secret. And then when it was suggested that the CDC provide information to parents, instead of approaching the problem this way, the CDC just decided to quit the program altogether rather than provide information to parents.

My view is that our objective in health, in confirming one who would be a health voice for all the people, should not be that one promotes controversial health measures by just keeping people from knowing about the situation. We should be informative and have a culture of information for people. If people have trouble accepting the information, we should work with them to help them get into a position where they digest the information appropriately and take steps to curtail the risks.

The Washington Post made a pretty clear statement about this at the same time. I think it is important for us to understand that the Washington Post isn't some sort of organization that would be unfair in its assessment of this kind of situation:

For the last 10 years, the Federal Government's Centers for Disease Control has urged doctors and hospitals to advise pregnant women at risk for AIDS to be tested for the disease. Now the CDC has recommended extending this effort to all pregnant women.

The Washington Post goes on to say:

This expansion is due primarily to completion of a study showing that administering the drug AZT to an infected mother during pregnancy and delivery and to her baby for a period after birth reduces incidence of transmission of the disease from 25 to 8 percent. If only those pregnant women known to be at risk are tested, others with the affliction will inevitably be missed and their babies won't receive the drug therapy that has proven to be so effective. Congress is now considering legislation that will make the AIDS testing of newborns mandatory. The congressional effort to include AIDS in this category deserves support.

I think that's important:

A positive test of a child is a sure indication that the mother has the disease. With this information, breastfeeding, which transmits this disease, could be avoided.

I think it is very important to note that if you had provided information about the existence of the HIV virus to the parent, then they would know to avoid breastfeeding in certain situations. And because some of the babies, as Senator KENNEDY has noted, first test positive for HIV and then later remit that indicator spontaneously, those babies shouldn't be breast fed by mothers with risk of additional contamination.

The article makes another interesting point:

And finally it is particularly important that the status of children who are placed in foster care be known. The CDC enumerates all these reasons supporting voluntary testing for all pregnant women. In fact, they are of sufficient weight to require the routine testing of all newborns for AIDS.

The point is this, that testing newborns for AIDS should be attended by being able to take advantage of the appropriate therapies and the appropriate remedial action.

Arthur J. Ammann, who is the professor of pediatrics at the University of California Medical Center in San Francisco and who was the man who discovered both pediatric AIDS and blood transfusion AIDS, really was distressed about a program of this kind testing blood samples from unidentified children and collecting the epidemiological data but not telling parents whether or not kids have AIDS.

Dr. Ammann is a noted authority who, incidentally, was invited by the Labor committee to give a briefing just this week. And he put it this way. He indicated that the policies were a violation of the international Nuremberg code. ''The failure to inform the guardians of known HIV-infected infants, when treatment is available, violates both international and national codes of ethics.'' The quote comes from an August 3, 1995, Wall Street Journal article.

I think it is important for us to note that there are very serious questions about the kind of testing and the information resulting from the tests and the ethics involved therein. And there may be ways in hindsight to come back and say, ''Well, there was value to what was learned and, therefore, it was appropriate for us to do what was done.'' But I do not think this adequately answers the questions. It does not really adequately address the question why, when we could have moved toward identification and notification, we simply acceded to the politics of the situation.

The New York Daily News said that only radical politics explains the separate standard here, in referencing the fact that there are so many other diseases which, if you had that kind of information, would have been made available immediately.

Another item which I raised earlier about Dr. Satcher was the idea of needle exchanges. The U.S. Congress has expressed itself on needle exchanges. And the American people are, I think, loathe to be participants in a program which would promote needle exchanges.

A Member of this body came to the floor to say that Dr. Satcher had never supported the expenditure of any resources to provide clean needles at Government expense. I think that is technically true. Dr. Satcher and the CDC have, I think, not had a program. They have had studies in which clean needles were provided, and those have been funded.

The Berkeley study in California was a study funded by the CDC which provided so-called ''clean needles'' to drug addicts. As a matter of fact, the group known as the Harm Reduction Group, which means trying to reduce the harm of IV drug use through needle exchanges, put on a conference called the Atlanta Harm Reduction Working Group Conference. It was a 2-day meeting designed to advance harm reduction in the Southeastern United States by providing government-sponsored or other privately sponsored needle exchange programs.

The CDC was a sponsor or provided funding for this. So it is technically true, almost in a sort of lawyerspeak sense, that the CDC did not engage in a program of needle exchange. It has just had studies where the needle exchanges are used. And they have not exactly advanced the policy in some respect of needle exchanges, they have just undertaken to do it by sponsoring conferences for private groups, whose prime objective is to sponsor these so-called clean needle programs.

We will have more to say about clean needle programs in the future because one of the things that is very difficult about clean needle programs is that they frequently provide clean needles to so-called drug addicts, and then the needles are not appropriately disposed of. And in a variety of settings those needles then are available in the culture because they are left laying around. It is dangerous to have those needles available.

Let me move to the ethics of some of the studies that have been conducted. It is important to know that challenges have been made to the suggestion that the studies in Africa involved breaches of ethics. The study in Africa is said to involve a serious breach of ethics, as stated by the New England Journal of Medicine, a very important medical journal.

The point was raised by supporters of the studies that two members of the board of directors resigned from the New England Journal of Medicine when the criticism of the studies was made.

Let us look at what that means. According to one article, there are 25

members of the board of directors. There were two who agreed sufficiently with the nature of the studies to resign and 23 who thought that their resignations were inappropriate and apparently did not think they should resign.

If we are to infer that the two who did resign supported the ethics of the way the study was conducted, we might infer that the 23 that did not resign opposed the ethics of the study.

It is pretty clear that in our culture there are separate standards, in a lot of ways, for AIDS as a disease and for the HIV virus as a disease.

I think some of that took place as a result of the early acquaintance of the culture with the HIV virus. Then people who had the disease could not get treatment and individuals would not get close to them, and there were elevated desires to have privacy. So HIV was treated in a different way than other viruses or deadly viruses would be treated.

But the only individuals who resigned were individuals who were accustomed to the special ethical standing, if it is appropriate to say that, or the special rules for HIV. They were AIDS individuals. The people in the conventional medical community did not resign.

Dr. Jerome Kassirer, the editor in chief of the New England Journal of Medicine—which is published by the Massachusetts Medical Society—was asked about his response. He said he was surprised and dismayed at the resignations, but he said it was never policy to have editorial board members review editorials or other opinions before they were published.

And these individuals who were interested in, I suppose, having the opportunity to screen what would be said about these kinds of studies simply had not been accorded that opportunity because the medical journal itself did not want to accord any special status or differential treatment here.

A lot has been said about the ethics of the studies. Others indicated that maybe we should not have followed the ethical requirements because not much money is spent on individuals in Africa for health care on an annual basis.

I think there was a statement made about $5.50 being spent per year in some of the countries. It varies in different countries in Africa. I believe the study that is most sharply in focus would have occurred in the Ivory Coast. The key is, some experts said we could not have used as a part of the study the 076 AZT regime which has been proven to be effective in reducing the number of HIV and AIDS cases among newborn children of HIV infected mothers.

They said we could not use 076 because that treatment is a substantial regime and has substantial costs. They were trying to find a way for a lower-cost regime. And they were going to compare low doses of AZT to a placebo to find out whether low doses could be effective. However, that can be accomplished by comparing low doses to the standard, proven regime.

As a matter of fact, the latter comparison is what ethics requires. According to the New England Journal of Medicine, published by the Massachusetts Medical Society, ''Only when there is no known effective treatment is it ethical to compare a potential new treatment with a placebo.'' Again, the use of a placebo is ethical ''Only when there is no known effective treatment.''

We have had effective treatments substantiated and approved in the United States and internationally with the 076 AZT regime. Now, it would be possible to compare a lower level of AZT with this effective known treatment to find out whether the low levels were as efficacious as the 076 regime. But we chose instead—and I use the word advisedly, saying we ''chose'' instead—to use the unknown, low dosage with a placebo, with a sugar pill, which has a known consequence.

We are not comparing two unknowns here. We are comparing a known consequence of no treatment, that is the placebo, with the unknown consequence of a treatment. But this is not the proven treatment. And the real approach we have to understand here is that the ethics of modern medicine in America, in a country that cares about individual patients as well as about scientific data can be generated, would not allow such research. Even though one can generate a lot of data in studies that are very dangerous to the people, our standards of ethics would not allow it. When there is a known treatment, we compare new treatments to the known treatment rather than comparing new potential treatments to something that we know will have no beneficial effect.

And here is the way the editorial in the New England Journal of Medicine went forward. It said:

> Those requirements are made clear in the Declaration of Helsinki, of the World Health Organization, WHO, which is widely regarded as providing the fundamental guidelines of research involving human subjects. It states in research ''The interests of science and society should never take precedence over considerations relating to the well-being of the subject.'' And in any medical study every patient, including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method.

Now, there was a proven diagnostic and therapeutic method. It was the 076 regiment which has been proven in the United States and internationally. Instead of comparing low dosages of AZT to the best proven therapy and diagnosis, they chose to compare low doses of AZT to a known placebo. And to say to individuals, ''Well, those of you that get the placebo are destined to have no therapy''—and we know what that means when it comes to the HIV virus.

The New England Journal of Medicine noted, ''Further, the Declaration of Helsinki requires control groups to receive the best treatment, not the local one.'' Individuals have raised in the study the idea that ''Well, people wouldn't be getting good treatment over here anyhow, so we are eligible to disregard the treatment standards for them.'' They observe that these are poor people. These are African individuals. We can adopt a different standard there. We certainly could not do this in the United States, but we can do this over there because things are not what they ought to be over there.

And here is what the New England Journal says: ''Acceptance of this ethical relativism''—this is important—''Acceptance of this ethical relativism could result in widespread exploitation of vulnerable Third World populations for research programs that could not be carried out in the sponsoring country.''

Now, additionally, it has been suggested that the reason researchers could not use the 076 regime, which is an expensive regime as in comparison to the low dose of AZT, is that there is not enough money in these African countries ever to give people the high-dose program. Therefore, we cannot experiment with any high-dose programs and find out, using them, whether or not the low-dose program would also work.

The truth of the matter is, you can learn a great deal by comparing the low-dose program to the high-dose program. I submit that you have the opportunity to learn about as much, if not more, than you have by comparing the low-dose program to the placebo. But more importantly is that this is consistent with the ethical standards.

It was suggested that the reason you could use the no-treatment program as part of the study—the placebo—is because there was a low, low amount of money to be spent per capita on health care in these countries. And it said you could not use an $800 program in the test because the people could not afford it. They only spend $5 a year on medicine. Why is it, then, that you could use the low-dose program, which is a $50 program? If one can't afford but $5, one is ineligible for $50 just like he would be for an $800 regime. I do understand that we are not talking about a regime for trying to give everybody the $800 program. Theirs was an effort to try and prove that a $50 program might work. So all they needed to do was to be able to compare the $50 program to subjects who were getting the full program. If the less expensive program it worked just as well, they would at least have the cost down to the $50 level.

But the point being made by the proponents of the research as it was conducted was that it is ethical, because of the costs involved. My own view is that if you only have $5, you can't really buy a $50 treatment any more than an $800 treatment. To say $50 is close enough and $800 isn't misses the point. If you are trying to develop the availability of the $50 treatment, the tests themselves could be measured against a therapy which is more costly.

The last point I make is that if none of the treatments would be used in the countries where the tests are being made, it is unethical to conduct tests there. It's clear from international standards, whether one is talking about the Nuremberg Code or other standards, you only conduct tests in countries where there is a chance that the therapy would be used. If the testimony of those who argue against the New England Journal of Medicine and these individuals is that you might have used the low dose, that is fine, we can conduct them there. However, you don't make laboratory rats out of people in the conduct of those tests merely because there is not a sufficient level of medical resources there to justify the more expensive program being used in the United States.

The New England Journal of Medicine directly indicates that ''The test directly contradicted Department of Health and Human Services' own regulations governing U.S.-sponsored research in foreign countries, as well as joint guidelines for research in the Third World issued by the WHO and the Council for International Organizations of Medical Science, which require that human subjects receive protection at least equivalent to that in the sponsoring country.''

Now, here you have another standard. It is not that this fell short of the ethics of one part or another part, or one little fraction, or another little fraction. In the first instance, you never use a placebo when an effective treatment is known. Secondly, control groups are required to receive the best current treatment, not the local one. Thirdly, you don't do, in a Third World country, what you could not do in your own country.

Now, it is pretty clear that there are a number of settings in which that idea of using other countries might be productive. But one might have trouble getting agreement to this, especially in the light of some of the controversy that has existed in the United States. Dr. Satcher testified at one time, ''What may not be readily apparent to all is how the CDC and the U.S. learned and benefited from international public health activities, including those related to HIV protection. It is clear that, in some instances, research relevant to both developing countries and the U.S. can be conducted more efficiently and expeditiously in developing countries because of the magnitude of the problem in those settings and, therefore, we have utilized that approach.'' Yes, it's more efficient and expeditious, if it is only because there is a bigger population. I think that justifies the potential if we follow the ethical guidelines. But if we say that we can do it more efficiently and effectively there because we don't have to provide real medicine, we say to the people of those countries that we don't care as much about your lives as we care about lives in our own country. If we say these things, we have then also embarked on a course of action that has very serious ethical complications.

I would like to quote from Dr. Arthur Kaplan, the Director of the Center for Bioethics at the University of Pennsylvania:

> If you tried to do this study in the U.S., you would have to do it through a throng of demonstrators and a sea of reporters,'' he states. ''I would not do this study without a design that would let me run it without a placebo. I think you owe that to your subjects, even if they are not educated enough or savvy enough to demand it from you.

Now, that is strong language. I have no doubt that Dr. Satcher is an individual of tremendous achievement and great scientific capacity. I have not sought to question that, and I certainly don't want to question his achievement, his capacity, his intellect, or the fact that he does represent the American dream. But I will question the ethics of the studies in which individuals were given placebos when it's clear that placebos are only ethical in comparisons when there is no known effective treatment. I will question the ethics of the studies when we owe treatment to our subjects and we fail to give it to them because they are in a culture where it's not normally expected. I think Dr. Arthur Kaplan is right. I wouldn't do this study without a design that would let me run it without a placebo. I think you owe that to the subjects. ''Subjects'' is a kind of interesting term there; it is really talking about the people who are in the medical study. ''. . .Even if they are not educated enough, savvy enough to demand it from you.''

Here is another article titled ''An Apology is Not Enough.'' This was printed in the Boston Globe on the 18th day of May, 1997:

> No research in developing countries is ethically justified, unless the treatment developed or proven effective will actually be made available to the population.

We have had testimony here that the treatments could not be available, they would be too expensive. The low dosage treatment researchers were seeking to develop was estimated to cost $50. It might be possible to create a less costly regimen. But the components of the study should be performed ethically, regardless of what the ultimate objective is. Even though the objective was a $50 treatment, that doesn't mean that there could be no components greater than $50 in the study. Because ethics requires it you should be measuring the $50 treatment that is being experimented with and comparing it to the best known treatment. You don't compare it to a placebo.

A lot of comment has been made about informed consent. I would just like to take a few minutes to talk about informed consent, because I think it is important for us to try dealing with this problem in the cold light of what the international ethical requirements are. All guidelines stress the importance of obtaining informed consent from individuals asked to participate in the studies. Informed consent isn't just signing a paper. I would indicate in a setting where you are giving individuals sugar pills and it is known that the individuals who get sugar pills are going to have no treatment, that the level of information in the consent should be more than a ''sign here,'' or a rush to consent. It should be an informed, considered, deliberate consent.

Let's see what the international standards are on informed consent. The Declaration of Helsinki, which the New England Journal of Medicine cited, makes informed consent a sort of touchstone of ethics requirements. The Declaration says:

> In any research on human beings, the potential subject must be adequately informed of the aims, the methods, anticipated benefits, and potential hazards of the study and the discomfort it may entail.
>
> Guideline 10: When obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress.

Certainly, in the African studies where these individuals are in a situation where the health care availability is not substantial, these people are in a dependent relationship to the physicians. In that case, the informed consent should be obtained by a physician who is not engaged in the investigation or is completely independent of this official relationship.

Another guideline is from the Council of International Organizations of Medical Sciences—international ethical guidelines for biomedical research involving human subjects. We are not talking about running rats through a maze, or animal trials, taking the heart out of a pig and seeing if it will work in a variety of circumstances, but rather the international ethical guidelines for biomedical research involving human subjects. The Council of International Organizations of Medical Sciences, CIOMS, in collaboration with the World Health Organization make these statements regarding informed consent.

> Guideline 1: For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject.
>
> Guideline 2: Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information, in language that he or she is capable of understanding: Each individual is invited to participate as a subject in research and the aims and methods of the research.

So they have to be told that they are invited to participate as a subject and what the aims and methods are.

> The benefits reasonably to be expected to result to the subject, or to others, as outcome of the research, and any foreseeable risks for discomfort to the subject associated with participation in the research; any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being tested.
>
> Guideline 3: Obligations of investigators regarding informed consent. The investigator has a duty to communicate to the prospective subject all the information necessary for adequately informed consent.

All the information necessary. This is a technical area. All the information in a technical area like this might include being informed that there is a known therapy and that it is unethical to conduct a trial without providing the known therapy, according to the Helsinki Declaration and a variety of other ethics guidelines.

Guideline 4: Subjects may be paid for inconvenience and time spent and should be reimbursed for expenses incurred in connection with their participation in the study, and may also receive free medical services. However, the payment should not be so large on the medical services, so extensive as to induce prospective subjects to consent to participate in the research against their better judgment.

The idea here is, if you are going to offer a bunch of medical care free to a person, they might make a judgment about getting involved in your program and might look aside and not be aware of, or be sensitive to, the risks that would otherwise inure to them as an individual participant.

There is a specific science guideline, No. 8, for research involving subjects in underdeveloped countries.

Before undertaking research involving subjects in underdeveloping communities, whether in developed or developing countries, the investigator must be sure that every effort is made to ensure that the ethical imperative of consent of the individual subjects be followed.

The first guideline of the Nuremberg code relates to informed consent.

Here we are with another code. We have been through the Helsinki, through the CIOMS, which was the Council of International Organization of Medical Sciences, and now we go to the Nuremberg code.

The voluntary consent of human subjects is absolutely essential.

This means that the person involved should have the legal capacity to give consent.

. . . should be so situated as to be able to exercise free power of choice without the intervention of any element of fraud, force, deceit, duress, overreaching, or other ulterior force, constraint, or coercion, and should have knowledge and comprehension of the elements of the subject matter involved to enable him to make understanding and enlightened decisions.

I could go further.

The truth of the matter is that Dr. Satcher claims that there was informed consent here. And there has been a lot of statements on the floor about the nature of informed consent. The facts of the matter, as I have come to understand them—it could be that I need to be corrected—is that the informed consent has not been as thorough as those who have joined in this debate would want to lead people to believe.

Dr. Satcher, in an article that he wrote with Dr. Varmus states that there was informed consent in their studies.

In the case of the NIH and CDC trial, there has been the same requirements for informed consent that would exist if the work were performed in the United States.

Well, was there informed consent?

It is kind of interesting. The New York Times sent a reporter to the area, and decided that there wasn't the level of informed consent that should exist in these cases. The New York Times article says:

According to the CDC, before deciding about entering the studies, women who were potential study participants were provided information about HIV and AIDS and about the intended study, and the possible risks and benefits for their children. It was clearly intended that women involved, their children, and others receive a placebo, a capsule without active medication. There would be no way for them to tell which group they were in. Women must give informed consent before participation commences.

That is what the CDC says. That is in a CDC study, to prevent HIV transmission in developing countries, and their report of April 30, 1997.

So the CDC, in the case of everybody being given all of the information, and that there is an informed consent.

Here is what happened when the New York Times sent a reporter, and the New York Times article brings into question whether many of these women truly gave ''informed consent.''

I indicate to you that I have blotted out the names of the actual individuals involved here respecting their privacy. Here is an excerpt of the article, along with the accompanying photograph of one of the women who participated in the study. According to the article—we will call this woman ''AB,''—a 23-year-old, illiterate, HIV-infected mother and patient in the study ''still does not grasp, even after repeated questioning, exactly what a placebo is, or why she might have been given that instead of real medicine.''

They gave me a bunch of pills to take and told me how to take them. Some were for malaria, some were for fever, and some were supposed to be for the virus. I knew there were different kinds. But I figured if one didn't work against AIDS then one of other ones would.

This is a picture of AB.

The reason to enroll in the study last year was clear. It offered her and her infant free health care and a hope to shield her baby from deadly infection. Unmarried and unemployed, this new mother, like many others, said the prospect of health as she brought her baby into the world made taking part in the experiment all but irresistible. Still the question of whether she and other pregnant women knew of the implications of consenting to a placebo test hangs over the subject.

Let me give you what the New York Times said about this individual's circumstance, AB. This is CD? I have the initials on the individuals—

Minutes after she was informed for the first time that she carried the virus, one pregnant woman—

This is her picture, CD.

still visibly shaken by the news, was quickly walked through the details of the test, as well as general advice about maintaining her health and protecting others from acquiring the disease, in less than 5 minutes.

This is the eyewitness testimony of how this so-called ''informed consent'' was obtained ''in less than 5 minutes in which the previously unknown concept of a placebo was briefly mentioned.''

The session was over and DC.—

Unemployed, and illiterate—

had agreed to take part in the test. One of the most highly educated of the women who spoke to a reporter, a 31-year old single mother with a degree in law who gave her name only as X, said she had never been made to understand that the medicine being tested, ATZ, was already known to stop the transmission of the virus DURING pregnancy.

So what we have here is a feint toward ''informed consent.'' We have people with formal training with a law degree not knowing about effective therapies, not knowing what the real options are, not knowing what the real facts are, and we have a situation where we are using a placebo knowing that the utilization of placebo in that setting is going to result in the absence of any treatment for a disease which is, understandably and acknowledged, to be fatal in virtually every situation.

I think this New York Times article suggests to us that some of the so-called highly touted ''informed consent'' wasn't as informed as it should have been, and by just reading what the international conventions and the international declarations require you know that it is virtually impossible for a person even of great and substantial medical awareness to understand about ''informed consent'' in a 5-minute interval.

This is obviously a difficult situation.

I said when I started that America deserves better. I think Africa deserves better than this kind of treatment. I think people in Africa deserve to be treated with the same kind of dignity that the people America ought to be treated. I don't think we should say local conditions over there are different and that changes our ethics. I don't think our character is determined by the people we are dealing with. It is not OK to do things that are not ethical because you are dealing with people who are less well endowed than you are. I don't think it is OK to do things that are unethical or wouldn't meet the ethical standards here at home because the people are poorer than you are, or because they don't have the education. I think as Americans we understand that character is not a condition of circumstance. Circumstances may reveal character. But character is something on the inside that is determined by character itself—not by the circumstances outside.

I really think these are very serious questions about the conduct of medical experimentation. No question in my mind that there is a lot to be gained from these studies. But the truth of the matter is time and time again people, because they have had a a lot to gain from studies who haven't been as sensitive to ethics as we have been, have

done things that are inappropriate or ashamed of. There was something to be gained from the study. I am not saying this was Tuskegee. There was something to be gained by it. And the people who excused it said, ''Well, these are just poor individuals, and they are not very intelligent individuals. So we can treat them differently than we treat other individuals.'' And I think the Nation has a real tug in its heart. We realized we were wrong. It was inappropriate, and it was appropriate that there be an apology. And an apology obviously doesn't solve that situation.

I think we have to ask ourselves whether or not we can excuse away the absence of the right ethical standards based on local conditions, based on local education, based on the individual's intelligence, based on any circumstances. I believe that we have a responsibility to adhere to the guidelines. And in the absence of our commitment to those guidelines there is a serious deficiency. I believe if we do not have a strong commitment to ethics in the office of Surgeon General that we will not have a strong commitment to serving the people of this country in the way that they should be served.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER (Ms. COLLINS). The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, I know that there are others that choose to speak. So I will not take long.

Just in a brief response, we have on the one hand the life of Dr. Satcher when we talk about ethics. And if there is any real kind of a question about his judgment and his failing a duty in terms of ethics, I think we ought to take a look at what the facts are and also take a look at what kind of life he has led in terms of the service of the underserved in his professional life, and the work that he has done. And you will see, this extraordinary light that shines brightly in terms of working for the disadvantaged and those that are left out and left behind, those that do not have good health and medical services, and those that are the sickest and neediest in our society.

To try to take a situation here about informed consent when we have those that have been involved in the programs themselves who describe the various ways that they went about informing potential subjects to be involved in these trials—particularly with the statements of the in-country personnel and to try to use anecdotal information based upon the conversations with one or two of those people that are involved in the trials—as being somehow a reflection of the failure of Dr. Satcher to reach a high ethical standard is a pretty far stretch.

Madam President, I listened with great interest to my friend from Missouri talk about the Helsinki accords, and about the importance of making available the known, effective treatment, that we shouldn't have various kinds of research being conducted if we are denying known effective treatment to these individuals. Well, understand the regimen are talking about when we are talking about known effective treatment because it was the judgment of the medical professions that if we took the known effective treatment that is used here in the United States that there was serious doubt as to whether it would be effective. That is why the lower dose regimen is being tested in developing countries.

What do I mean? By using the known effective treatment that is used here in the United States that is referred to by the Senator from Missouri, you have to stop breast feeding. You can't use that regimen and continue to breast feed. It was the judgment of the Centers for Disease Control that if you used the 076 regimen you might also be exposing these subjects to other health risks, such as high levels of drug toxicity due to their entirely different diet. It must be recognized that the 076 regimen is not known to be an effective regimen for populations in developing countries. It was known at the Centers for Disease Control if you are going to use the 076 treatment the standard in the United States, you have to have 100 milligrams of AZT five times. You have to have treatment for 12 weeks of pregnancy and you need to receive intravenous AZT during labor and pregnancy. In order to do this, you have to have a sufficient health infrastructure, one which is going to bring these various infected individuals and bring them back to the center frequently. This infrastructure just is not available.

Senator, get real; the regimen that is effective in the United States, the majority of the scientists at the Centers for Disease Control do not believe it could be effective over there. So when you say, they have no effective treatment, we have this treatment here in the United States of America and we are denying those people that effective treatment and it is violating all those ethical considerations, I have to disagree. Understand what is happening in these situations. Understand the these regimens. These developing countries just do not have the infrastructure. You cannot get them to stop breast feeding so they have to follow a different regime, one that permits them to breast feed, one that doesn't require them to come to a clinic on a frequent basis, one that says they do not have to have the elaborate infrastructure that is necessary under the 076 regimen.

The idea to put out on the floor that Dr. Satcher is not qualified, not qualified to be Surgeon General because of this kind of a situation is the most extraordinary stretch in terms of misrepresentation and failure to understand what these trials are really about. I am just amazed as we get further and further into it how weak that case is.

The Senators who are opposed to Dr. Satcher better do a lot better tonight and tomorrow in their opposition than they have done today. I have listened to these arguments, and I can't believe any one of our colleagues who has been following them can believe that there is very much to it. Take this man whose total life has been committed to his fellow human beings, and try and do the acrobatics and gymnastics and trapeze work in terms of misinterpreting these kinds of studies to show that he is basically flawed in terms of his ethical standards, my goodness, Madam President, give us a break. Give us a break.

So, Madam President, I will have more to say on some of these other questions, on the other misrepresentations. There were a series of others. I will just mention in addition one further area that has been raised during the consideration here earlier in the afternoon. Critics have also charged that Dr. Satcher at CDC supported HIV studies on newborns that allowed them to be sent home without telling their parents of their HIV status.

This survey was part of an effort to obtain a better idea of how HIV was spreading in different populations.

It was implemented by State and local health departments across the country with support from CDC. The survey began at a time when little was known about the impact of HIV on women and their children.

The studies were designed to check for the presence of antibodies to HIV infection in newborns. The presence of such antibodies would indicate that the mother is infected with HIV and that her child has been exposed to the virus. Approximately 25 percent of children exposed to HIV develop HIV infection, too.

That is the point I made in the debate earlier in the afternoon. That is why this whole area of study is so important and so exciting, and the consequences so important, because this is an area in medical research that offers some really important potential breakthroughs for babies whose mothers are infected.

The studies were carried out using blood samples that were left over from other routine purposes and that otherwise would have been discarded. The samples were not identified as coming from specific individuals. At the time, AIDS was not well understood. CDC was surveying newborns as a group to learn more about the incidence of the disease in particular communities. No treatment was available for newborns at that time—none. This was in 1988.

This study was part of a responsible scientific effort to learn more about the prevalence of HIV, so that resources could be targeted quickly and effectively. The survey followed strict ethical principles and was approved by the Office for Protection from Research Risks at NIH. A task force of ethicists, lawyers, civil liberties advocates, gay rights proponents, and public health officials met at the Hastings

Center, a bioethics think tank, to consider the issue. No objection was raised to these studies.

The Hastings Center is one of the important resources in this country in terms of bioethical issues. They have a number of very thoughtful teachers and scholars who have testified before our committees over the years. And they have been included in this review of this particular project. A 1988 review of the issue by a Canadian work group also gave its approval to the studies. So did the World Health Organization's Global Program on AIDS.

The Institute of Medicine of the National Academy of Sciences reviewed the survey and approved it as a well-established approach to public health surveys.

Here you have it. You have the NIH Office for Protection from Research, you have the Hastings Center, which is one of the leading bioethic think tanks in this country, approving it. No objection was raised. The Canadian group also reviewed the work and so did the World Health Organization's Global Program on AIDS. The Institute of Medicine of the National Academy of Sciences reviewed the survey and approved it as a well-established approach to public health surveys. All of these bodies have approved these surveys.

The information in the surveys was used by communities for education, screening, and treatment.

The surveys ended in 1995, when new treatments for infants exposed to HIV and other ways to monitor HIV population trends in women of childbearing age became available.

In September of 1997, Dr. Satcher recommended the study be formally terminated, and HHS agreed. So Dr. Satcher terminated it. It was going on when he became the head of the Centers for Disease Control, but he terminated the survey. CDC continues to work with States to identify ways to monitor trends of HIV in women of childbearing age.

Now, Madam President, I was in the Senate during this period of time. It was in 1988 that we had the first initiatives on pediatric AIDS. My good friend from Ohio, Senator Howard Metzenbaum, on the Health and Human Resources Committee—and I will include the exact references tomorrow in the RECORD—was the one who offered the first amendment. It was $10 million to try to help and assist in the area of pediatric AIDS. It was a brand-new challenge in public health. And these studies have been referred to as something we would not subscribe to today, but at a time when we were attempting to find out the nature of the threat in terms of mothers and the extent of the challenge for communities and States in our Nation, these surveys were considered and reviewed and approved.

To try to use today's standard for an earlier period of time when we virtually knew nothing about how to deal with pediatric AIDS—and there was enormous resistance in this body to doing anything about it then, enormous resistance to get into it at all. People forget all of that. Why get involved in this kind of disease research? We went through all of that. We eventually had the work with the Ryan White bill and several other breakthroughs that were important that moved us into a direction which respected the science rather than the ideology of the time. But during this period of time, and I remember very clearly, it was extremely difficult. We were trying to find out more as a nation and as a people about the prevalence of this disease within the population, and so this kind of survey took place. It is easy to flyspeck it now in terms of how surprising it is that any such study could possibly take place today. And it is always useful and valuable to be a Monday morning quarterback. The studies that were done then had been reviewed in terms of their ethical considerations. Maybe some agree, some differ. We could all certainly find criticisms of it knowing what we know today, but that isn't the question.

The fact is this issue was actually started under a Republican administration and ended by Dr. Satcher.

Now, it is nice to come out here and say, well, he should have ended it earlier and therefore he is not qualified. If that is your argument, so be it. But it is not, nor should it be, an argument that is elevated to a serious reason for having any second thoughts about this outstanding nominee.

Finally, I just say, Madam President, as I started out today, we have an extraordinary doctor who has been willing to take on the responsibilities of Surgeon General and tend to our nation's public health concerns. These are tough issues. They deal with the most difficult kinds of problems that we can possibly imagine. We understand that. And Dr. Satcher deserves great credit for being willing to stand up and say I want to continue to serve, as he has his whole life.

We are very fortunate to have such a person willing to stand up, and we are fortunate to have the President nominate him. I am going to be proud to vote in support of him, and I am confident we will have an overwhelming majority of the Senate to do so.

As I said, I have been proud to respond to the questions that have come up today and look forward to further debate and discussion on this outstanding nominee. Hopefully, we will get the opportunity of having a chance to approve him.

I yield the floor.

Mr. CRAIG addressed the Chair.

The PRESIDING OFFICER (Mr. FAIRCLOTH). The Senator from Idaho is recognized.

Mr. CRAIG. Mr. President, sometimes my colleague from Massachusetts and I disagree openly, sometimes loudly, on different issues, but he and I will not disagree today on the integrity or the excellence of the individual before us, David Satcher. But we will disagree. Nobody deserves a break on the truth or the facts as it relates to the performance of an individual.

So let the Senator from Massachusetts and I agree that David Satcher is an outstanding individual of high quality. We agree. But because of differences in philosophy that sometimes produce politics we will disagree. I think my colleague from Missouri was doing that today. And so no breaks are given to anyone, nor should they be given. We are talking about building a record that is tremendously important as we reach out to decide whether this gentleman should become America's family doctor as the Surgeon General of the United States and therefore the record and the facts as they relate to this individual's performance and what he has done in the past are relevant and very important.

There is no question that David Satcher will probably be confirmed as the Surgeon General, and as he is confirmed and as the American public gets to know him it is important that they know a little bit about his background so they can be ready and aware of what he might do along with what he will be required to do as our Surgeon General.

I would like to talk about two areas that I think are very important to our country as a whole. As I have said, his philosophy is generally very different from my own, and that means that I will and do fundamentally disagree with the views of many of his efforts and my view, my politics, my philosophy is different from our President's. And so it is not unusual that he might nominate somebody that I would not agree with nor would I want to vote to confirm. But I also recognize the reality and the importance of our President being able to nominate those whom he feels would serve best under his Presidency based on his philosophy and his vision of how the country ought to be. So, while I believe the President's choice deserves some deference, I do not believe the Senate should automatically rubberstamp any decision that our President makes. This is one that he has made. It deserves reasonable debate on the floor. I believe I can offer some of that this afternoon.

David Satcher comes to us with a background that includes service as a Federal officer. In his capacity as Director of the Centers for Disease Control, he was made aware of serious concerns that I and other Members of both the House and the Senate had talked about and had visited with him about. I was privileged to have that conversation in my office some time ago with Dr. Satcher. I was pleased that he would come, sit down and engage in a thoughtful and earnest way about something that was of concern to me and a very large constituency in this country; that I felt he and the tax dollars engaged at the National Centers for Disease Control were being misused.

The House and the Senate had concerns about a crusade mounted by the National Center for Injury Prevention and Control about certain kinds of things, and our director, the Director of the Centers for Disease Control, Dr. Satcher, went in a different direction. He launched a study against private firearms ownership in this country.

Now, you have to scratch your head a bit and say, ''What? Firearms? Guns? Centers for Disease Control?'' I did. I scratched my head and said, ''Dr. Satcher, where are you coming from?'' Well, he was quoted to say this, that his efforts and the studies he was putting forth were ''to convince Americans that guns are first and foremost a public health menace'' and to that end they had ignored years of study by criminologists, people much more directed in the area of guns and crime than the Centers for Disease Control. But Dr. Satcher being politically correct for his President moved on. And therefore went on to say that they had labeled violence as an ''epidemic,'' and concluded that gun control was the way to cure it.

What they failed to recognize, and they should have recognized if they are good clinicians, is that the state and the condition in which the individual is raised produces a violent person, and that a violent person will reach out in his or her act of violence and use any tool available to them. But, no, because it was politically correct, they chose firearms.

Dr. Satcher, firearms are not an epidemic in this country, they are a constitutional right and you ought to understand that. And, while you were being politically correct for this President and your philosophy, you were being unconstitutional. You were directing the energies and the taxpayers' dollars of this country against something that in my opinion was, frankly, none of your business. But you chose to move ahead, for all the reasons I think I have just stated.

In short, the so-called research done by that agency was, in my opinion, both politically motivated and from a scientific point of view—and we have heard about his tremendous scientific credentials this afternoon—seriously flawed. Although Dr. Satcher did not personally conduct the research, he used his position to defend it. Even worse, his leadership at CDC caused it to continue even after it came under criticism. So you have to question. My job is to question. I think my argument today is legitimate. Dr. Satcher, you were acting beyond your professional credentials and, therefore, your science in my opinion was flawed. Now he wants to be America's family doctor.

Mr. President, law abiding gun owners are not a public health menace. Violent people are, and have demonstrated by their actions that they can become a menace to people's health. It is outrageous that the head of any Federal agency would endorse using taxpayers' dollars in a political campaign against a constitutionally protected right of the taxpayer who paid for the campaign. But the gentleman this Senate is about to vote on did just that. He very openly talked to me about it in my office and I respect him for coming to visit about it. His only argument was he just thought it was important to do.

I noted that he was very much in sync with the President, and therefore he was obviously doing the right thing politically. But I think it is time we question him on that issue.

This is not the only area where Dr. Satcher's extreme views, I think, generate some concern. He also supports the legality of partial birth abortions. His position on this controversial procedure is at odds with what most polling data suggest today is 80 percent of the American people, and with the professional and ethical judgment of the American Medical Association. In taking this position, Dr. Satcher clearly chooses the President's political agenda over the views of his medical colleagues. So I think it is important, when there are some who get a bit exercised here that somehow we are questioning this gentleman's sincerity, or most important his professional integrity, that this man is quite often very willing to politicize beyond science something that happens to fit the agenda of the President that he serves.

His views on this particular procedure are so far in the minority, and I think it is important that we recognize that. Many Members of Congress who advocate abortion voted in favor of banning partial birth abortion. Dr. Satcher and President Clinton say the decision to have an abortion should be between a woman, her conscience, and her doctor; and that abortion should be safe and legal. The partial-birth abortion procedure is indefensible on any of those grounds. The procedure we are talking about is one of causing and then stopping delivery of a child. I could go into the details of that. That isn't necessary to do. It has been talked about for a long time on the floor of the U.S. Senate. I think Senators, in a large majority now, fit the understanding of the American people on this issue.

So, let me conclude by saying that my intent this afternoon is not to impugn the talent or the integrity of Dr. Satcher. It is, though, to clearly demonstrate that he is a political nominee who can operate in political ways and has chosen to do so to stay in step with the President who nominated him and to be out of step, not only with the Constitution of this country, but in many instances the vast majority of the American people.

I am not going to attempt to predict the outcome of the vote on the floor but my guess is that when the vote settles, Dr. David Satcher will be the next Surgeon General of the United States. I and others will watch him very closely, hoping he will serve with integrity and responsibility, and that he will not choose to use his bully pulpit as a leverage against fundamental constitutional rights in our country, or what a vast majority of the American people think would be a wrong procedure, a wrong process, or an unnecessary law.

I yield the floor.

Mr. WARNER addressed the Chair.

The PRESIDING OFFICER. The Chair recognizes the distinguished Senator from Virginia.

Mr. WARNER. Mr. President, I rise in support of the nomination. If my colleagues will permit me to tell a short personal story, my father was a medical doctor and he practiced the last half of his career in the greater metropolitan area of the Nation's Capital, largely in Virginia. He was a marvelous man. His whole life was his family and medicine. He was sort of in that vintage of the old timers who, when you called, he got in his car or he walked or whatever the case may be, and he went to the homes and the hospitals and tended to the sick and the needy.

I can remember in the Depression days, people would come to our front door and he never hesitated to give his God-given brains and expertise to the assistance of others. I have to tell you, Mr. President, I have said this before, if I had half the brains of my father I would have gone to medical school but I came up short and had to sort of accept the lot that was cast me.

The nominee came to visit me, as I am sure he did with many others, and I talked to him at great length. He impressed me as a man of considerable skills in the medical profession, not in one narrow area but a very broad area. His education, his demeanor—I was very impressed with him. And I then sought, as all of us do, the consultation of our constituents, people who might have known him or had a judgment. I found in the State of Virginia he is highly regarded professionally. As a matter of fact, one of the most eminent physicians in Richmond VA, Frank S. Royal, Sr., whom I have known now for more than 30 years personally as a friend, and who has been a friend and a counsel to a number of Governors—indeed, Republican Governors. He was the late Governor Dalton's physician and closest friend. Anyway, he knew the nominee very well, all the way beginning back in his education. And he wrote me this letter which I ask unanimous consent to have printed in the RECORD following my remarks, giving an unequivocal endorsement of the nominee.

The PRESIDING OFFICER. Without objection, it is so ordered.

(See exhibit 1.)

Mr. WARNER. That letter, together with the endorsement of other recognized medical organizations and physicians in my State, corroborated my own findings. For that reason I am privileged and pleased to cast my vote for the nominee.

I regret, however, that he does not hold all the views that I hold. Particularly, I am opposed to partial-birth abortion and have consistently and will consistently vote to try to end that tragic practice. But we cannot expect this nominee or the nominee for Secretary of State or Defense to hold views which are consistent in their entirety with the views of individual Senators. I have been here, this is my 19th year now. I have cast many votes for nominees, and often you do so based on the totality of the credentials.

Mr. President, I will ask unanimous consent to have printed in the RECORD other documentation which I feel is important to this nomination and those reviewing it, and indicate in my own personal judgment we are fortunate to have a man of this depth of experience and dedication, who could obviously earn many times over a Government salary in private practice, to step forward and volunteer to help the ever-increasing problems associated with America's health system.

Mr. President, I yield the floor.

EXHIBIT 1

EAST END MEDICAL CENTER,
Richmond, VA, September 30, 1997.

The Hon. JOHN W. WARNER,
The U.S. Senate,
Washington, DC.

DEAR SENATOR WARNER: I am very pleased to lend my support to the nomination of Dr. David Satcher to the position of Assistant Secretary for Health & Human Services and Surgeon General. I am confident that all will benefit from his continued advocacy in his new role.

I am very familiar with Dr. Satcher's creative and innovative approaches to increasing access to health care services for all people through public-private partnerships. His unique proposal to consolidate the acute hospital services offered by Nashville's Metropolitan General Hospital and Meharry Hubbard Hospital into one modern facility on the Meharry campus is scheduled to come to fruition in January 1998.

Dr. Satcher is uniquely qualified for this position because of his dedication to two causes-improving the diversity and quality of the educational experience of health professionals and enhancing the capacity of our public health infrastructure to address the needs of the nation's communities.

I pledge my support for this nomination and request that Dr. Satcher be confirmed for this position.

Sincerely,

FRANK S. ROYAL, Sr., M.D.

Mr. JEFFORDS. Mr. President, I thank the Senator for his very excellent words about the nominee, Dr. Satcher, as we work in order to, hopefully, bring about his confirmation.

I would like to make a few comments while we wait and see if someone else is ready to talk.

I think it is important to briefly go through, and I am going to do it again another time with perhaps a little visual presentation of what we are talking about when we talk about the AZT trials and the responsibility of Dr. Satcher and Dr. Varmus, who is the head of NIH.

We are talking about trials which were designed in Africa, by Africans, for Africans, after the review of many boards and groups that were working toward a solution to this problem. We are not talking about trials in the United States. Those of you who have visited Africa know the incredible AIDS epidemic that is going on in those nations. We think we have a problem here. The problems in the African nations where there is some evidence that the AIDS epidemic started—there are millions of pregnant women who are in danger of transmitting HIV to their children—are unimaginable.

The question was, how do you handle that situation? It was decided by doctors and health officials in the host countries that they had to design some sort of a treatment protocol where they would know what would happen when they administered certain doses of drugs. So what they did—out of the huge pool of HIV infected pregnant women—was invite a group of them to participate in this trial.

They invited these women—who were not going to receive any treatment for their HIV infection—and they said to them that, ''We would like you, if you are willing, to participate in our trial; some of you will get medicine which might help your baby, some of you will receive a sugar pill. You may stop participating in this trial anytime you want. The only way we can determine whether the medicine is safe for you and your baby, however, is to do it in this way.''

So it is not a question of whether these HIV infected pregnant women had an alternative to go out and get help someplace else. They did not. Participation in this trial was the best hope for getting any treatment that might prevent them from giving HIV to their babies. Not only that, most of these women were not in a situation, for instance, where they could have used the 076 regimen even if it had been made available as part of the drug trial. They could not buy infant formula; thus, they ended up having to nurse anyway. The 076 regimen requires that women give up nursing.

There are a lot of differences—differences in culture and differences in circumstances—between here and in Africa. The host countries and the international organizations involved discussed all of these issues and finally agreed on this regimen for testing. They did so because they believed it provided the greatest hope for their own people.

Now they get criticized because these pregnant women who would never have gotten any help were invited to participate in a trial where they might get some help. They are criticized for doing this, because the participants didn't know whether they would receive the medicine or the sugar pill. It is a difficult situation, but it can be misleading if you don't understand the dynamics of the situation which the various countries were facing.

I hope as we go forward to make an additional point to my colleagues—and I am going to try to explain this a little more articulately and specifically later. The heads of CDC and NIH were separated a long, long ways from what was going on, and they had all sorts of review boards and organizations approving this regimen. It is not like Dr. Satcher and Dr. Varmus were over there in Africa conducting these trials. It was something that Dr. Satcher and Dr. Varmus have responsibility for as leaders of CDC and NIH, but certainly the design was something which came about by virtue of the many U.S. and international organizations trying to figure out how to take care of this terrible epidemic and how to, hopefully, save as many of the young babies as they can from being infected.

Mr. President, I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. KENNEDY. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. KENNEDY. Mr. President, I will just take a few moments to wind up today's comments on truly an extraordinary nominee of the President and an incredibly gifted and talented medical professional doctor, Dr. Satcher.

I want to just mention at this time and I will read part of an excellent letter that was made available to us. It was written to our friend and colleague, Senator ASHCROFT, from the Morehouse School of Medicine. It is from Dr. Louis Sullivan, who was the Secretary of HHS under President Bush and had a very distinguished career there and has had over the course of his lifetime a very distinguished career.

I will read this part, and I will submit the letter in its entirety for the RECORD:

DEAR SENATOR ASHCROFT: I understand that in a dear colleague letter you recently questioned the ethics and leadership of Dr. Satcher because of his support of AZT trials to reduce perinatal HIV transmissions in developing countries. You also questioned his role in the HIV-blinded ''Surveys of Childbearing Women'' which started in 1988 and was suspended in 1995. As a biomedical scientist, former Secretary of the Department of Health and Human Services under President Bush, and one who has known and worked with Dr. Satcher for twenty-five years, I write to respectfully take exception to your assessment of the studies and especially Dr. Satcher. I share the view of the World Health Organization, UNAIDS, the National Institutes of Health and the Centers for Disease Control and Prevention that these studies were ethical, appropriate and critical for the health of babies in developing countries. I also agree with public health leaders at every level of government that the HIV-blinded survey which was started five years before Dr. Satcher entered government were ethical, appropriate and critical during the early phase of the AIDS epidemic. More importantly, I agree with those such as Dr. Sidney Wolfe, of Public Citizen, who, while questioning the AZT trials in Africa, strongly attest to the ethics and leadership of Dr.

Satcher and strongly support his nomination for Surgeon General.

Then it goes on in a very, very important way in this letter. I ask unanimous consent that the letter be printed in the RECORD. It gives both the history and the background on these AZT tests and responds to all the various issues that I think have been raised on that particular program.

There being no objection, the letter was ordered to be printed in the RECORD, as follows:

MOREHOUSE SCHOOL OF MEDICINE,
Atlanta, GA, January 30, 1998.

The Hon. JOHN ASHCROFT,
U.S. Senator, U.S. Senate, Washington, DC.

DEAR SENATOR ASHCROFT: I understand that in a dear colleague letter you recently questioned the ethics and leadership of Dr. Satcher because of his support of AZT trials to reduce perinatal HIV transmission in developing countries. You also questioned his role in the HIV-blinded *Surveys of Childbearing Women* which started in 1988 and was suspended in 1995. As a biomedical scientist, former Secretary of the Department of Health and Human Services (DHHS) under President Bush, and one who has known and worked with Dr. Satcher for twenty-five years, I write to respectfully take exception to your assessment of the studies and especially of Dr. Satcher. I share the view of the World Health Organization (WHO), UNAIDS, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) that these studies were ethical, appropriate and critical for the health of babies in developing countries. I also agree with public health leaders at every level of government that the HIV-blinded survey which was started five years before Dr. Satcher entered government were ethical, appropriate and critical during the early phase of the AIDS epidemic. More importantly, I agree with those such as Dr. Sidney Wolfe, of Public Citizen, who, while questioning the AZT trials in Africa, strongly attest to the ethics and leadership of Dr. Satcher and strongly support his nomination for Surgeon General.

In 1994 scientists in the United States found a regimen using the drug AZT that dramatically reduces the transmission of the HIV virus from mothers to newborns. As a result of this breakthrough, perinatal AIDS transmission in the United States has dropped by almost half since 1992. Naturally, such an advance raises hopes of making dramatic reductions not only in the developed world, but in developing nations, where 1,000 babies are born each day infected with HIV.

Unfortunately, it is generally agreed that the regimen that has worked so well in the United States is not suitable for these developing nations. Part of the problem is that the cost of the drugs involved is beyond the resources of developing nations. In Malawi, for example, the regimen for one woman and her child is more than 600 times the annual per capita allocation for health care.

Just as important, developing nations lack the medical infrastructure or facilities required to administer the regimen, which requires (1) that women undergo HIV testing and counseling early in their pregnancy, (2) that they comply with a lengthy therapeutic oral regimen, and (3) that the anti-HIV drugs be administered intravenously at the time of birth. In addition, mothers must refrain from breast feeding; the newborns must receive six weeks of oral drugs; and both mothers and newborns must be closely monitored for adverse effects of drugs.

Given the general recognition that this therapy could not be widely carried out in developing nations, the WHO in 1994 convened top scientists and health professionals from around the world to explore a shorter, less costly, and less complicated drug regimen that could be used in developing countries. The meeting concluded that the best way to determine efficacy and safety would be to conduct research studies that compare a shorter drug regimen with a placebo—that is, no medicine at all.

After the New England Journal of Medicine (NEJM) published its editorial criticizing the AZT trials in developing countries, two of the three AIDS experts on this editorial board resigned in protest because they disagreed. Many other outstanding biomedical scientists and ethicists have since taken issue with the NEJM editorial.

As one who feels strongly about what happened in Tuskegee, let me say that it is utterly inappropriate to compare these trials with Tuskegee where established treatment was withheld so that the course of the disease could be observed while these men died. The AZT trials being carried out in developing countries are for the purpose of developing treatment that is appropriate, effective and safe to prevent the spread of HIV from mother to child. Unlike Tuskegee, these programs have a very strong informed consent component.

Likewise, I do not believe that your criticism of the blinded-surveys of childbearing women is inappropriate. These surveys, which started in 1988, five years before Dr. Satcher came to government, were supported by public health leaders at every level. They were considered to be the best way to monitor the evolving epidemic during that very difficult period when we knew so little of the nature of the problem and virtually no treatment was available. These surveys use discarded blood from which all indentifying information had been removed, to measure the extent of the HIV problem in various communities and groups. The information was invaluable to state and local communities in planning education and screening programs. Using these surveys we were able to document that the percentage of women infected with HIV grew from 7% in 1985, to almost 20% in 1995. At no time was any baby, known to be positive for HIV, sent home without the parent being informed.

Again, I acknowledge your right to criticize Dr. Satcher, the nominee for Surgeon General. But, I believe that Dr. Satcher's long and distinguished career speaks for itself relative to his commitment to ethical behavior, service to the disadvantaged, to excellence in health care and research and to human dignity.

Should you wish, I would be happy to review any of the areas where there is any remaining confusion or questions.

With best wishes and regards, I am

Sincerely,

LOUIS W. SULLIVAN, M.D.
President.

Mr. KENNEDY. Mr. President, in another letter from Dr. Sullivan to Senator LOTT that was made available to all the membership, he said:

I enthusiastically support the nomination of David Satcher, M.D., for the positions of Surgeon General and Assistant Secretary for Health of the Department of Health and Human Services.

In light of the recent debate about issues regarding his nomination, I wish to communicate with you my experience with, and opinion of, David Satcher. I have known David for over twenty-five years, and I can state unequivocally that he is a physician. . .of [extraordinary] integrity, conviction, and commitment. As Surgeon General and Assistant Secretary of Health, I know that David has no intention of using those positions to promote issues related to abortion or any other political agenda. He has worked throughout his career to focus on health issues that unite Americans—not divide them.

And the letter goes on.

Both of these letters are from a very, very distinguished leader of the Department under President Bush and someone who has made, in his own way, an extraordinary contribution to public health and to health policy generally. Someone who has known Dr. Satcher for a long period of time should have a very important influence, I would think, and weight with our colleagues.

I just mention, finally, Mr. President—and I am sorry my friend from Missouri is not here, Senator ASHCROFT. He talked about the State surveys that were taken, and he was highly critical of the State surveys.

It has been brought to my attention that the surveys went into effect in 1988, and then were concluded in 1995. Dr. Satcher came to the Centers for Disease Control—started under a Republican administration. But it is interesting that Senator ASHCROFT was Governor of Missouri during this period of time, and he signed on for these various State surveys, and supported them.

It just has to have somewhat of a ring here today as we are considering these surveys and as the point is being raised about how effective or how wise these surveys will be, that the person who is raising this and the most critical is someone who was a Governor of a State that actually endorsed and signed the applications. I do not think it is necessary, but we will have those available for the RECORD tomorrow.

I think this is just, again, interesting. If these are the best cases that can be made against someone who has such a distinguished record, such a powerful life record in terms of the public interest and service, then we should be about the business of moving ahead and supporting this nomination.

We look forward to the further debate. I am puzzled about where those are that have the serious reservations. We have been out here ready to debate this record. We look forward to debating it.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. THURMOND. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. DURBIN addressed the Chair.

The PRESIDING OFFICER. The Senator from Illinois.

Mr. DURBIN. Mr. President, I rise today to speak in favor of the nomination of Dr. David Satcher to the position of Surgeon General. As many colleagues have noted, he is exceptionally

well qualified for this position. He has been involved, throughout his professional career, in a very broad range of health issues and has championed improvements in all the areas that he has been involved with.

I find it somewhat unusual that this appointment to an important position, though not a Cabinet-level position, seems to always attract such debate and such controversy. Certainly, we want someone with real leadership skill to serve as the Surgeon General; but why, time after time, do we find ourselves embroiled in a debate over who that person might be? Some critics will say it is the fault of President Clinton for bringing names before the Senate that are so controversial. Yet, I think if history serves me correctly, I believe Dr. Koop, an appointee of President Reagan's, was a controversial nominee. Dr. Koop caused a lot of people some concern. He had some rather strongly held personal views on a controversial issue, the issue of abortion. The Democratic-controlled Congress wrestled with his nomination and came to the conclusion that Dr. Koop's medical credentials and in the area of public health were so compelling that he should be given a chance to serve, even though a majority of the Democrats might disagree with his position on the issue of choice or abortion. It is a good thing we did because, despite our differences with Dr. Koop on that issue, he proved to be an exceptional leader on public health issues for America. In fact, some of the initiatives that Dr. Koop really spearheaded, I think, were so timely and so important that history will treat him very kindly. For example, alerting America at that moment in time to the dangers of HIV/AIDS was a controversial thing to do. Yet, he did it with the approval of the Reagan administration, at a time when it was appropriate. I think lives were saved as a result of that. So I have always drawn from the experience of Dr. Koop, who has become a friend of mine on the tobacco issues, that you should not judge a person on one life experience or one issue, but you should look at the totality of the circumstances, look at their values and principles and try to determine whether or not that person, man or woman, can do the job.

That is why it is easy today to rise in support of Dr. David Satcher to fill the spot as our Surgeon General of the United States. Some of the areas he has worked in have been extraordinary. From increasing childhood immunization rates, to improving breast and cervical cancer screening, Dr. Satcher has been a leader.

I want to focus on one aspect of his work at the CDC, in improving the Nation's food safety programs. Make no mistake—and I want to underline this, if I can—America is blessed with the safest and most abundant food supply in the world. You need only travel to any other country and take a look at the alternative to appreciate what I have just said. But we can do better.

The General Accounting Office estimates that as many as 33 million Americans will suffer food poisoning this year, and more than 9,000 will die from it, primarily infants and elderly people. The annual cost of foodborne illnesses in this country may rise to as high as $22 billion a year.

Since 1993, the CDC, under Dr. Satcher's direction, has played a critical role in modernizing our food safety programs and responding to challenges created by the large amount and variety of food now available in the United States.

As part of this effort, the CDC has led rapid response to outbreaks of foodborne illnesses, conducted research into the cause and transmission of foodborne illness, and expanded outreach to health officials and the public on treatment and prevention of foodborne illness.

The Department of Health and Human Services predicts that foodborne illnesses and deaths are likely to increase 10 to 15 percent over the next decade. Such estimates make increased vigilance even more important. Both early detection and rapid response are critical to minimizing health hazards from unsafe food.

Building on these efforts, President Clinton announced in January 1997 that the CDC will join forces with the Federal, State, and local agencies on new efforts to improve the safety of our Nation's food supply.

CDC and Dr. Satcher have played a key role in the new early warning system to help try to catch and respond to outbreaks of foodborne illness earlier and to give us the data we need to prevent future outbreaks.

In 1995, the CDC, with the FDA, Department of Agriculture, and State health departments, established this network of ''sentinel'' surveillance sites in five States that conducted in-depth surveillance for foodborne illness and related epidemiological studies.

Since becoming operational in 1996, the network already has identified an outbreak of salmonella caused by contaminated alfalfa sprouts and an outbreak of E. coli from lettuce.

I hope we can do more. We need a Surgeon General in place who is sensitive to that need. I think that we can start to consolidate under one Federal agency the many disparate Federal agencies that now try to keep our food supply safe. Isn't it a curious thing that when you take something as common as an egg, and if that egg is broken and served as a product, it is the jurisdiction of the Food and Drug Administration. If that egg remains in the shell and is sold as a product, it is the jurisdiction of the Department of Agriculture. Consumers have to shake their heads in wonderment that we would make such arbitrary distinctions between products which families view as the same thing, as far as they are concerned. It calls for leadership not only in the Department of Agriculture, the FDA, the Environmental Protection Agency, the Department of Commerce, and many other agencies, but it calls for the leadership of a Surgeon General, and that vacancy should be filled by Dr. Satcher, sooner rather than later.

Dr. Satcher, as head of the Centers for Disease Control and Prevention, has dramatically expanded the CDC's landmark ''National Breast and Cervical Cancer Early Detection Program,'' which offers comprehensive breast and cervical cancer screening services to medically underserved women nationwide.

Prior to Dr. Satcher's tenure and leadership at CDC, 18 States had the program. Today, all 50 States do, as well as 5 U.S. territories, and 13 American Indian/Alaskan Native organizations have programs. This expansion was based on strong scientific evidence showing that breast and cervical cancer screening can save women's lives.

As of 1996, more than 1.2 million cancer screening tests were provided by the program. There are some critics of Dr. Satcher who might dwell or focus on one or two controversial things. I hope they will judge the man in his totality, and that they will judge his contribution fairly, because if you look at his work in public health, it is truly extraordinary.

There is one area I would like to speak to that has been brought up on the floor, and I would like to close with this. Some have been critical of the efforts by the Centers for Disease Control to address the whole issue of firearm injuries in the United States. Many believe that this is entirely too political for an agency that is supposed to be dedicated to public health. I disagree. Over 38,500 Americans are killed each year with firearms in America; 17,800 homicides; 18,700 suicides; 1,300 unintentional deaths; 5,800 children and teenagers die in America each year from firearm injuries; they are the leading cause of death among African American teenagers and the second leading cause of death among white teenagers.

In the city of Chicago, IL, there is a hospital that we all admire so much, Mount Sinai. Next to it is a facility known as the Schwab Rehab Institute. Mount Sinai Hospital is in a tough neighborhood. In fact, a visit there on any weekend evening would be a sobering experience for all of us, because the people who come in there, the victims of dramatic injury and gunshot wounds, unfortunately, are in great number. Those physicians, nurses, and medical personnel scramble to do their best to try to keep these people alive. They manage, in many cases, to do that, and it takes the miracle of medicine to do it. Those folks might find themselves, a few weeks or months later, across the street at the rehab institute, Schwab Rehab, where I visited a few times to speak to victims of gunshots, and to talk to men in wheelchairs, paraplegics and quadriplegics, who will never have a chance to enjoy

full physical mobility, because they were so victimized. It is not a surprise to me that many of the Nation's largest medical organizations and physician groups are now starting to focus on firearm injuries as a national epidemic —not only because of their number, but because of the severity of injury that is suffered. What day goes by in a major city in America where we don't hear or read about some innocent victim, many times a child waiting for a school bus, or a child who is out front playing on a bicycle, who is sprayed by random bullets and becomes a victim and is perhaps even killed? In that situation, we should step back and say, what can we do not just to treat the injury, but to reduce the likelihood that that injury will occur.

I think the CDC, which really tries to improve public health across America, should include firearm injuries on the agenda. I am happy that Dr. Satcher feels the same way, and I hope CDC does not relax its efforts in this area in any way whatsoever.

Finally, let me say, over the years, I have worked with the CDC on the issue of tobacco and tobacco-related diseases. They have really been leaders. They have brought out sound, credible evidence of the devastation caused by tobacco in America. They have talked about what we need to do to reduce what is the No. 1 preventable cause of death in America from occurring. I think the CDC has that responsibility.

Our Surgeon General, in the past, has exhibited the same kind of leadership. We have seen those men and women come forward to the post and try to identify those issues that are important to Americans. Some friends of mine are managers of television stations. Since most of us spend a lot of our waking moments watching television, I sometimes say to them, ''When you are scheduling your programming for television, what do you look for? What are people interested in? What are American families anxious to watch and hear about?'' An interesting thing has occurred over the last 10, 12 years. You will notice it if you watch the news tonight, or any other night for that matter, or any morning. Americans are interested in public health issues. They are primarily interested in breakthroughs in medical discoveries. You see it every day. Since talking with this one station manager in Decatur, IL, 10 years ago, I have been focusing on it. Most news programs include a story about medicine. America's families want to hear what we know and what we can share with them that might improve the quality of their lives. I think that is a indication of why this debate over the appointment of the Surgeon General is so important, and why we should not delay it or in any way sidetrack this debate over some tangential political issue. What is important is that we put a person of quality in this position, who can address the important public health challenges facing America. I think that is our responsibility here.

Let me tell you, after reviewing his background, I think there is nobody better qualified for that position than Dr. David Satcher. I am happy to support his nomination.

I yield the floor.

The PRESIDING OFFICER (Mr. ABRAHAM). The Senator from Arkansas.

Mr. BUMPERS. Mr. President, I rise this afternoon not just in support of but in strong support of the nomination of Dr. David Satcher to be Surgeon General of the United States.

I also want to state that I have a personal prejudice because I have worked closely with Dr. Satcher over the last 5 years since he became head of the Centers for Disease Control.

There is a current cute saying making the rounds in Washington, and unhappily it is true. This is the only nation on Earth where a person is presumed innocent until they receive a Presidential nomination.

We have had a lot of contentious debate on this floor about various nominations. I have not participated in many of those debates. But I am participating and I will continue to participate in the nomination of Dr. Satcher because I think he is one of the finest medical people in the United States. I also happen to think that he is one of the finest men, one of the finest people in the United States. I believe that the President could not have chosen better for this position.

Mr. President, it is a real travesty to me that people who want to serve their Government in a position such as this are subjected to such a contentious process. Admittedly, the position of surgeon general doesn't have a lot of clout, but it does have a lot of public relations value. There are a lot of public appearances made by the Surgeon General. They take a lot of different positions on medical techniques and medical practices in this country. In some respects, I can sympathize with the Senator from Missouri who is opposed to this nomination, apparently based on Dr. Satcher's presumed feelings about the issue of partial-birth abortion. I happen to agree with Dr. Satcher on partial-birth abortions, but I recognize it is a very, very difficult moral question for everyone. I also have to confess to the Senate that I voted against Dr. Koop's confirmation to be Surgeon General because of his position on that issue, and have lived until this day to regret my vote because he turned out to be one of the greatest surgeon generals this country has ever had. I didn't know Dr. Koop. If I had known him maybe I would have voted differently.

I do know Dr. Satcher in a very personal, intimate way because I have worked closely with him for 4 years. But aside from that, I ask my colleagues to look at his credentials. Look at the life of this African American who has risen from a poor rural community to become prominent, to become a role model. He went to Morehouse College, the same school Dr. Martin Luther King graduated from. Do you know what he did there? He was Phi Beta Kappa, which means that intellectually he was superior; a good student. From there he went on to get his MD and Ph.D. from Case Western Reserve in Cleveland. He did that in 1970, and then went into a career of academic and public health medicine.

So far that is pretty impressive, is it not? A man who has spent his entire life since 1970 in public health and was a Phi Beta Kappa with the highest degrees you can get in medicine. After he graduated he served on the faculty at the UCLA Medical School, and as Dean of Family Medicine at King-Drew Medical Center in Los Angeles. He was then appointed president of Meharry Medical College in 1982. He was President of Meharry Medical College until 1993 until President Clinton chose him to head up the Centers for Disease Control, an agency to which we turn time and time again every year. Whether there is an EColi breakout, or a virus breakout in Africa, or whether it is mad cow disease in England, or whether it is an avian flu virus in the chickens of Hong Kong, it is the Centers for Disease Control who the world calls on, and they respond. They respond always in a very professional and effective way.

I don't know what else may be involved in this, other than partial-birth abortions. I have heard that some people take exception to the role of the Centers for Disease Control in conducting research in developing countries aimed at reducing transmission of HIV from pregnant mothers to newborns through AZT therapy. Let me say, first of all, that tests to measure the effectiveness of long-term AZT therapy on pregnant women were started long before Dr. Satcher came to the Centers for Disease Control. Let me also say those tests were expanded upon to measure the effectiveness of short-term drug therapy, because the public health infrastructure in Africa could not support the longer-term regimen. Getting AZT to pregnant African women during their entire pregnancy was almost impossible because of logistics. It was just not practical. The short-term regimen provides massive doses to pregnant women just before they deliver. And it is this short-term approach that holds out hope for the thousands of HIV-infected children who are born in Africa each week. In every experiment, the health ministers of each African country in which the trials were conducted approved the study design.

But whether you like that or whether you do not like that, or whether you don't think the tests should have been conducted, or if they were not conducted correctly, the entire process started long before Dr. Satcher came to CDC. And the process was a joint effort of NIH, CDC and the World Health Organization. And what difference should

it make when we consider the nomination of this outstanding candidate for the post of surgeon general?

Mr. President, there is also controversy on the question of preventing AIDS transmission through needle exchange and on the issue of making condoms available in public schools. Regarding the former, Dr. Satcher has said that science rather than politics should determine our policy. On the issue of condoms, Dr. Satcher has stated that such decisions should be made in local communities by parents, teachers and community leaders. Who here can disagree with those positions?

Mr. President, on the issue of partial-birth abortion, the American Medical Association came out and said they are opposed to it but here is what they say about Dr. Satcher.

The American Medical Association continues to enthusiastically support Dr. David Satcher . . .'' [The surgon general's office] ''has been vacant far too long,'' [and] ''the American public needs a credible voice they can turn to in times of a public health crisis. . . . We urge Congress to look at the totality of Dr. Satcher's expertise and experience. He is a physician, administrator, educator, and outstanding public health leader.

Why is it we turn to the agencies like the AMA when we agree with them and want to ignore them when we don't agree with them?

Mr. President, I want to go back to say that Betty Bumpers, my wife, and I have devoted a large part of our public life, which now spans 27 years, to improving the immunization of children. It was Betty's idea. It was not mine. And until this day she is extremely active. She and Roslyn Carter have their own program, and have had it for 7 years, called ''Every Child by Two.'' They go around the country and work with governors and community groups to educate parents and providers on the importance of immunizing our young children by age two. I have paid close attention to CDC's immunization program ever since I came to the Senate, and over the past five years under Dr. Satcher's leadership, our nation has achieved the highest immunization levels and the lowest rates of childhood disease in our country's recorded history. What parent in the United States wouldn't take great pride in that achievement? What Senator would not applaud Dr. Satcher for the role he has played in eradicating polio from the Western Hemisphere? Who would not applaud Dr. Satcher's efforts to eliminate polio in Africa? The elimination of polio in the United States alone saves the taxpayers of this country $250 million a year. He had whooping cough when he was a child. It made an indelible impression on him, and it was the reason he went into medicine.

So when I think of the many conversations and meetings I have had with Dr. Satcher in my office, he is always at the highest professional level. I have never heard him utter a statement that didn't reflect credit on him personally and didn't reflect credit on his total commitment to the health of the people of the United States. What in the name of God else do you want—would we reject a man who came up from nothing to become one of the preeminent medical people in this country simply because we disagree with him on one or two things?

I notice people who do not want Washington telling them what to do often want Washington to tell the rest of the country what to do. If an atheist invented a cure for cancer, would you refuse to take it because he was an atheist? Of course you wouldn't.

That is the kind of logic we are confronted with here because you may disagree on a policy that really is not a policy. You want to deprive this man of the post that the President nominated him for. And what did he say in answer to a letter from Senator FRIST from Tennessee? What did he say to Senator FRIST about the issue of partial-birth abortion? I see Senator FRIST on the floor. He knows exactly what he said and it is this:

Let me say unequivocally that I have no intention of using the position of Assistant Secretary for Health and Surgeon General to promote issues related to abortion. I share no one's political agenda, and I want to use the power of these positions to focus on issues that unite Americans—not divide them. If confirmed by the Senate, I will strongly promote a message of abstinence and responsibility to our youth, which I believe can help reduce the number of abortions in our country.

Where can you find a more noble or professional statement than that?

I say to my colleagues: Let us not divide ourselves over an appointment of this importance and destroy a man who has devoted his entire life to the well-being of the children of this country as well as its adults.

I yield the floor, Mr. President.

Mr. ALLARD addressed the Chair.

The PRESIDING OFFICER. The Senator from Colorado.

Mr. LEAHY. Mr. President, there are many reasons to support the nomination of Dr. David Satcher for Surgeon General. An experienced physician, Dr. Satcher has distinguished himself as the Chairman of the Morehouse School of Medicine, the President of the Meharry Medical College, and most recently as the Director of the Centers for Disease Control and Prevention (CDC). In recognition of his achievements, Dr. Satcher recently received the Surgeon General's Medallion for significant and noteworthy contributions to the health of the nation.

Heading an agency with eleven major branches and responsibility for promoting health and preventing disease, injury and premature death is no easy task. Since 1993, Dr. Satcher has met the challenge with initiative, poise and professionalism. Under his direction, the CDC has been instrumental in increasing childhood immunization rates, reducing vaccine-preventable childhood diseases, and improving national and international defenses against food-borne illnesses and infectious diseases.

Under Dr. Satcher's leadership, the CDC has done its best to respond to the threat that infectious diseases like tuberculosis, influenza, AIDS and malaria pose to Americans and people everywhere. In 1994, the CDC introduced a strategy to improve early disease detection, surveillance and outbreak containment worldwide. The CDC is also developing and implementing new diagnostic tests and prevention guidelines, and providing training, equipment, and supplies for public health personnel and national and international institutions.

The U.S. has a central role to play in the international fight against infectious diseases. By providing $50 million to strengthen global surveillance and control of infectious diseases in the FY98 Foreign Operations Appropriations Bill, Congress clearly indicated the urgent need for U.S. leadership in this area. As Surgeon General, Dr. Satcher would be able to bring together U.S. agencies such as the CDC, the Agency for International Development, the Department of Defense and the National Institutes of Health in a united effort against emerging, re-emerging and endemic diseases. He would also provide an important link to the World Health Organization and the health ministries of foreign governments.

Mr. President, I am confident that Dr. Satcher would bring the same degree of dedication, commitment, and vision to the position of Surgeon General that he has to the CDC. If Dr. Satcher is confirmed, and I hope he is, I look forward to working with him in the fight against infectious diseases.

Mr. ALLARD. Mr. President, I ask unanimous consent to go into morning business for a period of 45 minutes, that my comments be placed at the appropriate place in the RECORD, and that Senator ENZI's comments follow my comments.

The PRESIDING OFFICER. Without objection, it is so ordered.

The Senator from Colorado is recognized.

Mr. ALLARD. I thank the Chair.

(The remarks of Mr. ALLARD and Mr. ENZI pertaining to the introduction of S. 1608 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

Mr. DODD. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. DODD. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. DODD. Mr. President, I rise today in strong support of the nomination of Dr. David Satcher to the positions of Surgeon General and Assistant Secretary for Health.

I commend the president for selecting him to serve as a voice for the Nation's public health needs and goals.

Dr. Satcher is a renowned physician, scholar and public health leader. During his tenure at the Centers for Disease Control and Prevention, the nation saw a dramatic increase in childhood immunization rates as well as an increased capacity to respond to and detect emerging infectious diseases. In addition, while under Dr. Satcher's leadership, the CDC placed a significant emphasis on prevention programs, including efforts to screen low-income women for breast and cervical cancer. I also applaud his quest to protect the health of our nation's children by supporting research into prevention of deaths and injuries from gun injuries.

Dr. Satcher, as has been noted on numerous occasions, is a remarkable individual of distinguished accomplishment. This Nation will be richer and better off were he to fill the job of Surgeon General and Assistant Secretary of Health.

I am distressed that there are some who want to make another issue of Dr. Satcher's nomination. There are those who would argue that there is no need for a position of Surgeon General. That has been raised in the past. I think that is a legitimate debate, although I happen to believe that having an Office of Surgeon General has been tremendously valuable to this country, having someone who can speak on behalf of the Nation in a clear voice about issues of national concern. No one better epitomized that role than Dr. C. Everett Koop, who led the Nation on numerous health care issues over the years, speaking very clearly. To this day he plays a very important role as a former Surgeon General of the United States.

The position of Surgeon General has been vacant since December of 1994. We are now going to the fourth year not having filled this position. That is inexcusable. This Nation deserves to have a Surgeon General.

As I said a while ago, if there are those who want to eliminate the position altogether, then offer legislation that will do that. But we have a position that needs to be filled, a position that can play an important role, as shown by various Surgeons General over the years, leading this Nation in the debate on health care issues. So I hope within the coming days here we can complete this nomination process and send it to the President and allow Dr. Satcher to assume the job of Surgeon General and Assistant Secretary for health.

Mr. President, parliamentary inquiry. I have a bill I want to introduce. I inquire as to whether or not it would be permissible for me to do so in this debate?

The PRESIDING OFFICER. The Senator will be permitted to do so should the Senate, by unanimous consent, consent to that act.

Mr. DODD. Mr. President, I ask unanimous consent to speak as in morning business.

The PRESIDING OFFICER (Ms. COLLINS). Without objection, it is so ordered.

The Senator from Connecticut is recognized.

Mr. DODD. I thank the Chair.

(The remarks of Mr. DODD, Mr. KERREY, and Mr. BINGAMAN pertaining to the introduction of S. 1610 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

Mr. ASHCROFT addressed the Chair.

The PRESIDING OFFICER. The Senator from Missouri is recognized.

Mr. ASHCROFT. Madam President, may I inquire as to the state of the proceedings? What is the position of the Chamber?

The PRESIDING OFFICER. The Senate is in executive session and is considering the nomination of David Satcher to be Surgeon General and Assistant Secretary of Health and Human Services.

Mr. ASHCROFT. Thank you, Madam President.

I rise to continue my debate with respect to the nomination of Dr. David Satcher, a nomination for two positions, that of U.S. Surgeon General and Assistant Secretary for Health.

The PRESIDING OFFICER. The Senator is recognized.

Mr. ASHCROFT. Thank you, very much.

Madam President, there has been some considerable discussion today surrounding the ethics of the Centers for Disease Control and the studies that they have conducted regarding the transmission of AIDS from mothers to newborns—those studies having been conducted not here in the United States, but having been conducted in the underdeveloped countries of the world.

These studies were conducted and have continued to be undertaken under the auspices of the Centers for Disease Control, under their authority and during the time which Dr. Satcher has had responsibility for the Centers for Disease Control.

It is troublesome to me that a number of these studies have not really provided the same kind of guarantee in terms of the care which would be accorded to individuals if those individuals participating in the study were in the United States. Basically what I am saying is that the studies were conducted in such a way that they would probably be unacceptable in the United States of America.

A disregard for individuals who participate in clinical trials or medical studies is, unfortunately, something that we have had problems with before. Not long ago, the United States apologized to a number of individuals who are part of what was called the Tuskegee experiment because the participants in the study had simply been left without treatment as doctors watched the progression of the disease.

I think the Nation's conscience was shocked as a result of the fact those conducting the experiment were interested in scientific data that could be developed by watching people suffer and die. It was troublesome that we would somehow decide we could allow people to have been involved in that kind of experiment. When we discovered the nature of the Tuskegee experiment, the country was shocked and saddened by what had occurred.

What was even perhaps more shocking is that after we had been through all the problems in assessing the difficulties of Tuskegee, there were revelations about these studies in Africa. The Boston Globe, on the 18th day of May of 1997, published an article entitled ''An apology is not enough.'' The article stated that ''Even as the President laments the Tuskegee experiment, the United States is conducting questionable research in Africa.'' This particular article—while it does not purport to say that the African research is similar in every respect to the Tuskegee situation, did point out that there are some real problems with what is being done in Africa. One of the problems is that in Africa individuals who are a part of the study are not given the best known medical help. They are not being accorded medical treatment which would be required by ethical standards. They were given, however, sugar pills or placebos in the face of a virtually always fatal virus. They were given capsules which had no real medicinal value.

This was so shocking to the medical community and individuals who cared about medical ethics that it found its way into the editorial pages of the Massachusetts Medical Society's journal, the New England Journal of Medicine. The New England Journal of Medicine is the most widely respected medical journal in the world. Virtually no major announcements of medical import are made in the United States without appearing in the New England Journal of Medicine. The New England Journal of Medicine is prudent with regard to what it publishes. The Journal does not publish medical findings just because they have scientific value. It is alert to the dangers of science which would cause people to set aside ethics.

For instance, in an editorial of the Journal's, the publication states clearly that reports of unethical research will not be published, regardless of their scientific merit. You could have reports that would be very valuable scientifically, but they could be unethical. You could probably learn some things by watching people die without treatment, and that data would be valuable scientifically. As a matter of fact, that is what happened in the Tuskegee setting. But it was clear that kind of experiment was wrong and improper. This medical journal takes a stand against that. It says it refuses to publish reports, even if they are scientifically meritorious, if those reports are the result of unethical research.

Now, the research which was conducted in Africa was controversial for a couple of reasons. The first point of contention was the use of the placebo, or the sugar pill that doesn't have medicine, as part of the study. The New

England Journal of Medicine indicates clearly, ''Only when there is no known effective treatment is it ethical to compare a potential new treatment with a placebo.'' In other words, if you know that you can do absolutely nothing, there is no known way to cure something, no known way to impair or stop the progress of a disease, then you are allowed to try something and measure it against nothing—which is basically the placebo. But when you know, in fact, that there is something that works, it is unethical, according to the New England Journal of Medicine, to use a placebo against some other proposed remedy.

I think that is the reason the New England Journal of Medicine took exception with the CDC studies, particularly as it related to the Ivory Coast. Prior to the time of these studies it was pretty clear that a regimen had been developed which had been effective in substantial measure in curtailing the transmission of the HIV virus from women to their children. As a matter of fact, the AZT treatment is called the AZT 076 regimen. That regimen has had pretty good results. Normally in newborns, 25 percent of those that are born to mothers with HIV carry the HIV virus themselves. But the studies indicated that if you followed the AZT regimen, the AZT 076 regimen, instead of having 25 percent, or 1 out of every 4 children emerge with the HIV virus, that you could cut it down to 8 percent. So from one-quarter of all the babies, 1 out of every 4 babies, to 1 out of every 12 babies. Now that is a substantial improvement. It is a clear demonstration, accepted by medical authorities, that it is a regimen of treatment that has promise, it is effective, and it is worth doing.

So when you go to Africa to conduct a study, to do it ethically, according to the New England Journal of Medicine, it would require that individuals in the study compare proposed new treatments not with a placebo, but since there is a known effective treatment, new treatments would have to be compared against the known effective treatment.

I quote from the New England Journal of Medicine: ''Only when there is no known effective treatment is it ethical to compare a potential new treatment with a placebo.'' Now, what we have in the studies in Africa is the comparison of a known effective treatment with a placebo. This is not appropriate. Only when there is no known effective treatment is it ethical to compare a potential new treatment with a placebo.

In reaching this conclusion—this isn't just the opinion of the editorialists at the New England Journal of Medicine. They cite the Declaration of Helsinki of the World Health Organization as providing what is widely regarded as the fundamental guiding principles of research involving human subjects. In research on man, they say, ''The interests of science and society should never take precedence over considerations related to the well-being of the subject,'' and ''In any medical study, every patient, including those of the control group, if any, should be assured of the best proven diagnostic and therapeutic method.''

It is pretty clear that the best, proven diagnostic and therapeutic method is not the placebo, not the sugar pill. The best, proven therapeutic and diagnostic method is the 076 regimen, which cut the transmission rates from 1 out of every 4 to 1 out of every 12 infants infected with HIV. That is a substantial cut. I think it is always important for us to understand that we are talking about a nearly always fatal virus. We are not talking about a situation where maybe a few more people are threatened. The HIV virus, as it ultimately develops into a condition known as AIDS, is a final and fatal condition. So I don't think it behooves us to take it lightly. As a matter of fact, medical authorities have not taken it lightly.

I will just point out that even those individuals who were involved in the very discovery of AIDS and the transmission of AIDS in the birth process do not take it lightly. As a matter of fact, studies of intensive treatment of AZT ended in 1994, just as soon as it was shown that the drug sharply reduced HIV transmission to infants. Four years ago, we made it clear that the use of the placebo was over. You would not be doing placebo-based tests any longer, because it had been demonstrated that the drug sharply reduced transmission of the virus from mothers to their babies. That is from the New York Times article, ''AIDS Research in Africa; Juggling Risks and Hopes.''

The Third World studies, however, were in progress in 1995. They continue to be in progress. Apparently, they were ongoing as of late January. Now, the CDC provided funding for the studies on the Ivory Coast. The study was simply designed to determine whether a new course of AZT—a short course, as opposed to the 076 regimen—whether that new short course would have an impact of curtailing the virus in the children born to HIV-infected mothers. As we indicated before, the 076 course cuts transmission of HIV from 25 percent of all infants down to 8 percent of all infants, or approximately a two-thirds reduction. The studies were designed to determine if a smaller dose of AZT would have any impact.

CDC decided to use a technique known as the placebo controlled study, and it was their methodology of choice. Now it seems to me that we have a clear problem here, and that is that we have an ethical standard for a medical test and trial that says you don't use placebos when there are effective known treatments. You have had a clearly established treatment since 1994, recognized in the United States as a treatment that is effective in reducing the incidence of HIV in new-born infants by two-thirds.

One of the reasons that the CDC chose to move forward with the placebo-based trials is that the trials are well understood to be very informative scientifically. Those who have come to the floor of the Senate on repeated occasions during the day have talked about how wonderful this was to get this information. I really don't want to get into a big argument about whether or not you can get good scientific data in trials where you let people die because you give them sugar water or sugar pills instead of real medicine. I think it is very likely that you can get good scientific data. I think it is very likely that the outcomes of your tests will be scientifically valid. You can prove that certain kinds of therapies are better than sugar and water. But we are not here just to find out what could be scientifically advantageous. I think it is important that we remind ourselves of that.

There were scientists who thought they learned a lot from the Tuskegee studies. The mere existence of advantageous or helpful data at the end of a test or the mere facility with which scientific data can be collected doesn't really determine what the standard should be for us. The standard should be that we have our tests conducted in a way that is consistent with the ethical standards and with the requirements that have not only been developed for the United States, but are recognized in the international community.

Among the guidelines in the international community for tests that are clinical and designed to inform our health care procedures is a guideline that says you should never test in a culture what the culture is totally unlikely to be able to implement. In other words, one culture is not allowed to go to another culture that isn't ever going to be able to use the therapy and say, ''We are going to use you as guinea pigs, we don't want to endure this on our own.''

There is another standard that is relevant, whether we are talking about Helsinki or a number of the other codes. We have the Helsinki Declaration; the Nuremberg Protocols; the WHO Guidelines developed in Geneva—a variety of guidelines. Another one of these ethical standards is that you should not test for a therapy in a country that can probably never use it. And you should not test where the cost of using a therapy will make it virtually inaccessible.

That is one of the reasons that I think individuals want to support what was done by the Centers for Disease Control in this situation. They want to say, well, the 076 regimen is very expensive, therefore, it could not be part of a test to discover a less expensive regimen. It's important to understand that it is the expense of the outcome, the therapy that you are seeking to develop that should define whether or not a country or a society would be able to use it. It's not the expense of conducting the test that is the key issue, but

the expense of using the therapy after the test is over. Unless the proponents of these tests want to argue that they were really hoping that sugar pills, which are very cheap, would be the ultimate therapy, they have to say that the ultimate therapy they were proposing is approximately the $50 therapy that CDC was experimenting with, which was the short course, or more confined schedule of administering AZT. That is a $50 dose. The 076 regimen, already proven effective, is an $800 dose. There is a big difference.

The point I make is that what you are seeking to test in the country is not the $800 dose. That has already been established. That was established in the United States, and it was established in France. What you are seeking to test is not the placebo. We all know that is useless and worthless. You don't even have to be a medical practitioner. That is understood. What you are testing is the $50 dose. And so you have to ask yourself the question, is the $50 dose something that might someday be available and utilized there? If it is, that is the test. It doesn't change the need to treat people humanely in seeking to provide a basis for using that $50 test.

So what we really have here is a question of whether or not the United States Centers for Disease Control treated individuals in Africa with the same kind of respect that they would have treated individuals in the United States. The real question is whether or not they followed the guidelines which require us to treat individuals as distinct and different from the way we would treat, say, laboratory animals where we might disregard their health and safety.

Of course, the New England Journal of Medicine says when effective treatment exists a placebo may not be used, and it cites the Declaration of Helsinki saying that any medical study of patients, including those of a control group, should be assured of the best proven diagnostic and therapeutic method.

I don't think there is any other way of saying it. No matter how thin you slice this, it is still baloney. It is clear that the placebo is not the best therapeutic method. It simply cannot be categorized as the best therapeutic method, which is the method, according to the New England Journal of Medicine, that participants in the study are required to have.

This afternoon I took the time to go through the assurance of protection document entered into by the Ivory Coast and the CDC that lays out the guidelines, principles, and procedures that the parties agree to follow in the research. I believe that in the assurance of protection document mention was made of the Declaration of Helsinki.

In biomedical research, involving human subjects and international ethical guidelines for them, the protection document states that research must be conducted in accordance with established international standards for protection of human subjects—for example, the Declaration of Helsinki, or CIOMS. Those are examples. But it says we must live in accordance with those established international standards.

The signature page for the relevant officials says that the research will be conducted in accordance with the established international standards for the protection of human subjects.

It is kind of interesting that the assurance of protection was not obtained until July of 1997, according to Dr. Satcher's written responses to questions from the Senate Labor and Human Resources Committee. We were dealing with these individuals in the Ivory Coast in a way which did not even provide them with a guarantee of the protections included in the Declaration of Helsinki and other relevant international guidelines. We did not see the guarantees until we had articles appearing in major newspapers in the United States that criticized the African studies—articles which compared them to the Tuskegee experiment.

Dr. Satcher has claimed that the studies complied with all the rules. In the New England Journal of Medicine article with Dr. Harold Varmus of the National Institutes of Health, Dr. Satcher asserts that the NIH and CDC support trials have undergone a rigorous process of ethical review, including not only the participation of the public health and scientific communities in developing countries where the trials are being performed but also the application of the U.S. rules for the protection of human research subjects by relevant institutional review boards.

Dr. Satcher also relies on World Health Organization guidelines developed in Geneva in 1994 as authority for the studies. He said that the CDC chose to use a placebo controlled study because such an approach has been recommended by a WHO conference of international experts, including those from many developing countries.

This World Health Organization conference to which Dr. Satcher refers took place in Geneva in June of 1994. Marcia Angell and Michael Grodin of Boston University criticized the conference recommendation, saying that the CDC and the researchers involved developed the recommendations simply to justify their desire to conduct the AZT trials in Third World countries.

I would like to review some of the international guidelines. It is pretty clear that people around the country and around the world understand that you shouldn't use placebos when there is an effective treatment, particularly if you are conducting a trial that includes victims of deadly viruses.

Again, I mentioned that Dr. Marcia Angell said in the New England Journal of Medicine that only when there is no known effect or treatment is it applicable to compare a potential new treatment with a placebo.

The director of Harvard's Human Subjects Committee has stated that use of placebos would be unethical in such cases. The New England Journal of Medicine reports that in 1994 a researcher at the Harvard School of Public Health applied for NIH funding for an equivalency study in Thailand in which three shorter AZT regimens were to be compared with the regimen similar to the 076 regimen. The journal indicates that the NIH study section pressured the researcher and his institution to conduct a placebo trial, which prompted the director of Harvard's Human Subjects Committee to reply in a letter. The conduct of a placebo controlled trial for AZT in pregnant women in Thailand would be unethical and unacceptable since an active controlled trial is feasible.

So here we have medical authorities resisting efforts by our Government to accept and conduct a trial which is ethically substandard. You have them saying it is unethical; it is unacceptable because there are actively controlled trials that are feasible. Basically this is a reflection for which we can be grateful in the medical community. We don't use sugar pills when we have known capacity for treatment.

I could go through the guidelines as I did this afternoon. I do not want to do this. The point is the simple ethics of the matter come down to this: If there is a known treatment which is a therapeutic treatment it can make a difference. It is unethical instead of giving patients that treatment to provide them with sugar pills, or with placebos. The known treatment is well established. It is well documented in the medical literature. Its availability makes impossible the use of placebo studies in the United States in this kind of setting, and to echo the statements of many experts, I think it should make it impossible in Africa as well.

Some of those who have commended the unethical studies overseen by Dr. Satcher in the Centers for Disease Control have indicated that these are poor people and they will never be able to afford the 076 high-dosage, long-schedule regimen of AZT.

The truth of the matter is this was a study to experiment with lower doses, shorter schedules, and could have been conducted in a manner consistent with medical ethics by using as a control group the 076 regimen. There are medical authorities that will provide testimony to that extent.

The truth of the matter is that we would not do in the United States what we did in Africa. And I think that is an important point.

Dr. George Annas, a bioethicist and professor of health law at Boston University, and health law professor Michael Grodin have criticized the AIDS work in Africa not only on the basis of the placebo but they said that these studies with lower ethical standards were imposed on a population that will never receive the fruits of the research.

It seems to me that there are so many ethical questions surrounding this particular AZT trial that demand answers that we should look carefully at this study.

One of the answers of individuals who have commended these tests is that ''The individuals knew what was happening''—that participants had given their informed consent.

I will concede that there is virtually always an ironclad, high standard of informed consent that is required for medical trials and experimentation to take place, and virtually every one of the protocols—whether it is the Helsinki Declaration, the Council of International Organizations of Medical Sciences, the Nuremberg Code, or any number of other CDC or Federal regulatory items—they almost all require that participants give their informed consent. Those who would defend these AZT trials seem to want to emphasize that since there was informed consent, we can overlook breaches in the ethics that might have taken place in the design of the studies and in the implementation of the trials.

First of all, the presence of informed consent does not authorize unethical activity. The mere fact that people would agree to engage in unethical activities and unethical trials with our Government or with agencies of our Government does not mean that our Government can or should do that. We have standards that require a certain respect for human beings and that do not allow our health organizations to treat them as experimental subjects. Whether or not there is consent does not obviate or does not alleviate or does not mitigate the demand of our ethical codes for treating people like human beings and not experimental subjects.

But there still is a real question about the level of the so-called consent that was given. This afternoon I had the opportunity to refer to an article in the New York Times which talked about a woman who, 5 minutes after she was informed for the first time that she carried the HIV virus, still shaken by the news, was walked through the details of the so-called trials and tests, as well as given general advice about what she should do to help herself and her baby. In less than 5 minutes she was given a quick explanation of what a placebo was. The session was over and this unemployed, illiterate individual had agreed to take the test. Asked what had persuaded her to do so, she said, ''The medical care they're promising me.''

Here is a situation where this is a mockery of informed consent. People who don't even know what a placebo is agreeing to participate in a medical study where they have a 50–50 chance of getting the placebo, a sugar pill.

The New York Times article talked about another individual. One of the most highly educated women in the test spoke to a reporter. She was a 31-year-old single mother with a degree in law who gave her name only as ''X.'' She said she had never been made to understand that the medicine being tested, AZT, was already known to stop transmission of the virus during pregnancies. One of the fundamentals of informed consent is helping people understand what kind of therapeutic, known cures or known treatments exist, and she wasn't even told about that. ''I am not sure that I understand all this so well,'' she said, ''but there were some medicines that they said might protect the child, and they wanted to follow the evolution of my pregnancy and the effectiveness of the treatment.''

People have talked about the situation of following the evolution of the pregnancy and the effectiveness of treatment. We have seen situations where we have followed the evolution of disease and the effectiveness of nontreatment and for half the people in this study we are talking about the effectiveness of nontreatment. There is no evidence in terms of this woman's testimony that she would have gotten real treatment rather than a sugar pill.

''Pressed further, X, like other mothers, said that she had not been told the results of the tests on her 1-year-old. Asked how she would feel if she learned tomorrow she received a placebo when proven treatment existed, X's tone changed abruptly,'' according to the New York times. ''I would say quite simply that that was an injustice,'' she said.

Well, it appears to me she has a good understanding of ethics if she does not have a good understanding of medicine. She understands that to provide individuals with a placebo, with a fake pill, and not to tell them that there is a real treatment that is available, would be an injustice. I could not agree more.

One of the important concepts about medical ethics is that you should only use treatments that host countries could reasonably be expected to use. As I mentioned earlier, those who support the studies say that we could not use the 076 regimen because it was too expensive. We could use the $50 treatments. However, that doesn't comport with their statistics which also state that the average expenditure for health care is $5. If the per capita spending in these countries is often less than $10 per person, as the CDC says, how can these countries afford even the $50 treatment.

Dr. George Annas, whom I mentioned, from Boston University, was publicly critical of the AIDS studies on the grounds that ''they were being carried out with lower standards in a population who will never receive the fruits of the research.''

These same authors talk about the research being largely unrelated to the potential for treatment in these countries. ''No research in developing countries''—and I am quoting again from these same two authors, Dr. George Annas and Michael Grodin of Boston University—''No research in developing countries is ethically justified unless the treatment developed or proven effective will actually be made available to the population. And the best CDC can say about its new AZT regimens, if they work, is that they would be a far more feasible option for the developing world.''

More feasible, yes, but would they be attainable? No evidence of the fact they would be attainable. I resume quoting. ''This is a far cry from assuring that they will actually be made available.'' And then they say, ''In the absence of such assurance, the African women and their children are being used purely as guinea pigs. They will be subjected to the intrusions and risks of research without any hope, much less any expectation, that they or their communities can ever benefit from the studies.''

The problem of treating individuals as experimental subjects is a serious problem. It is an ethical problem. And it is one which was so problematic that it caused the New England Journal of Medicine and a variety of other scholars to say that this is unacceptable.

As we are debating whether or not we have a nomination for a Surgeon General that should be the doctor for America's families, the leader in terms of what America should be and can be, I think the ethics of the research conducted at his specific direction and under his control are important and legitimate concerns.

I am saddened that Dr. Satcher chose to get involved in experimentation in Africa which would have been unacceptable here, which medical ethicists have indicated could not have been done here, which would have occasioned an outcry from the public and from authorities here, but which he thought could be done in Africa because these individuals have a different standard of living and that local conditions are different than ours. The situation of ethics is not something that relates to the economic standing of people, and it should not be related to a capacity on the part of a nation to transfer experimentation which it would not allow in its own country to be undertaken in another country.

I believe America deserves the highest and best when it comes to ethics. I believe we deserve a Surgeon General who would criticize rather than implement this kind of anemia in the ethical world. I believe we deserve a Surgeon General who understands that human beings, regardless of their wealth, social station, national origin or citizenship, deserve to be treated as human beings and not as laboratory experiments. I regret that too often in Washington we have come to the place of thinking that if we can get a big value, or if there is a lot of scientific knowledge to be gained, we can disregard ethics—that if the payoff is big enough, and particularly if the price to be paid is not in our own families, that we can look away from the ethics.

I really don't think that ethics and integrity are divisible. Just like we

should be one Nation, indivisible, I think we should have one ethical standard that is indivisible, and I think it should be a high one. I think America deserves better than a Surgeon General who is willing to adjust on a relative scale of values the ethics that relate to those in another setting as compared to individuals who would be here in the United States. It is time for us to demand a Surgeon General who will appeal to the better angels of our nature, not bow to our basest desires.

As I conclude my remarks, I would indicate the African AZT trials and the ethical problems surrounding them are just one aspect of the serious difficulties I have with this nomination, difficulties that lead me to oppose this nomination. This nominee endorses the practice of partial-birth abortion. This nominee has indicated a willingness to fund studies for the distribution of clean needles to drug addicts. He has indicated a willingness to fund conferences to promote the distribution of clean needles to drug addicts, to put the Government in the business of facilitating the administration of illegal drugs.

He has reserved, in a technical statement, that he had never provided funding for a Government program to provide clean needles to addicts. But he has provided funding for Government studies and he has provided funding for other programs to promote the distribution of such needles. He has indicated that if he could get the right result from the studies he would be willing to have a program that distributed clean needles. It may be true that clean needles might help some people avoid illness, but frankly I don't know that we should be in the business of assisting individuals in the administration of IV drugs merely because there would be some ''health benefit'' in a discrete situation where the Government provided a sterile instrument for the administration of illicit substances.

Individuals have come to this floor also indicating that they don't believe firearms are a disease. As you know, and I think as Senator CRAIG of Idaho indicated pretty clearly, the Centers for Disease Control has sought to limit or otherwise conduct studies which might be used in seeking to limit the availability or eligibility of people to own firearms in this country because they say that firearms are dangerous to a person's health. Frankly, the provision that guarantees the right of individuals to bear arms in America is the second amendment to the Constitution of the United States and I don't believe that the Bill of Rights is a disease. I think if we have resources that need to be devoted in our culture to the abatement and mitigation of diseases, we ought to deploy those resources to fight diseases and not to try and build a case for depriving Americans of a right guaranteed them by the Bill of Rights.

In all of these settings the cumulative effect of this candidate, this nominee of the President, shows us that we are not being offered the kind of Surgeon General to lead the American people in ways that I think are appropriate and consistent with the ambitions and aspirations of Americans. For these reasons—in addition to my focus today on the ethical deficiencies of the African AIDS studies—I think this nominee should be defeated.

Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. Madam President, I make a point of order a quorum is not present.

The PRESIDING OFFICER (Mr. GORTON). The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. GORTON. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. BROWNBACK). Without objection, it is so ordered.

Mr. GORTON. Mr. President, I ask unanimous consent to speak as in morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

JENNY LYNN STILES HUDSON

Mr. GORTON. Mr. President, it is with great sadness that I speak here in the U.S. Senate this evening. I share a story of a wonderful and talented young woman, Miss Jenny Lynn Stiles Hudson, whose life was lost tragically in an automobile accident a week ago today, on January 28.

Jenny was only 21 years old at the time of her death and had just begun a career as my deputy director for eastern Washington. While Jenny was with the Gorton organization only for a few short weeks, she had already demonstrated the talents to be a valuable member of my organization.

But Jenny Hudson will not be remembered for being a Gorton staffer. Rather, she will be remembered as an amazing and dynamic young woman who accomplished so much in her 21 years and who touched the lives of all around her.

Jenny grew up in Lyman and Hamilton, in rural Skagit County, north of Seattle. She was a joy and a delight to her family and a participant in almost all of the school and community activities offered to her in that rural setting.

Jenny graduated from Washington State University only in December of last year. At the university she was active in the Block and Bridle Club, the Livestock Judging Team, the Washington Cattlemen's Association, all while raising and showing Limousin beef cattle throughout the State of Washington.

Jenny enjoyed swimming and singing. At the same time, she maintained a strong belief in God, working as the youth director of her local church.

Jenny Hudson will be missed by all who knew her. In her short 21 years, Jenny inspired those around her with her vibrant outlook on life, her ambition and her many accomplishments. An early death reminds us of the sanctity and the fragility of life. Let the lesson of Jenny Hudson's remarkable life be no less deep.

My thoughts and prayers go out to Jenny's parents, to her husband of just 6 months, Tipton, and to her countless friends and relatives as they deal with this difficult time.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. ASHCROFT. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

MORNING BUSINESS

Mr. ASHCROFT. Mr. President, I ask unanimous consent there now be a period of morning business with Senators permitted to speak for up to 5 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

INTERMODAL SURFACE TRANSPORTATION EFFICIENCY ACT

Mr. WARNER. Mr. President, I have listened very carefully to the senior Senator from West Virginia, Mr. BYRD, as he has every day taken the floor regarding the need for the U.S. Senate to address S. 1173, a bill that I named the ISTEA 2 authorization bill, since it came through my subcommittee on the Environment and Public Works Committee.

I joined with Senator BYRD, the senior Senator from Texas, Mr. GRAMM, and the senior Senator from Montana, Mr. BAUCUS, who is the ranking member on my subcommittee and the full committee, in an amendment which will ensure that a greater amount of funds will go to the Nation's infrastructure of highways.

Under the leadership of Senator BYRD, the four of us on this particular amendment have been talking to a number of Senators. We are very pleased to announce that we are up to 52 cosponsors. I met earlier today with a group of Governors who have an organization termed ''trust,'' and they have visited the Nation's Capitol to speak particularly with Senators on the urgency of addressing this bill and passing the needed legislation so funds can flow to the new construction programs for this calendar year.

The most fervent appeals for prompt consideration of this bill understandably come from the States in the northern tier of the United States of America, because they have a very short season within which to do the needed construction because of the severity of the weather. The distinguished Presiding Officer has some specific knowledge about the needs based