

THE DRUG ADDICTION TREATMENT ACT OF 1999

HEARING
BEFORE THE
SUBCOMMITTEE ON
HEALTH AND ENVIRONMENT
OF THE
COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

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**THE DRUG ADDICTION TREATMENT ACT OF
1999**

FRIDAY, JULY 30, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:05 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Greenwood, Deal, Whitfield, Bryant, Bliley (ex officio), Brown, Waxman, Stupak, Green, Barrett, Capps and Dingell (ex officio).

Staff present: Marc Wheat, majority counsel; and John Ford, minority counsel.

Mr. BILIRAKIS. This hearing will come to order. The Chair apologizes to the Senators and to the audience for the late start, but I have been waiting for someone from the other side to get here. I am not really sure what is happening on the House floor, but I understand that the Senate has a vote taking place right now. So we are going to defer even my opening statement and ask you gentlemen to testify. I apologize for not having an audience up here, but hopefully we will get to read it all. And Patty will advise us anyhow.

Mr. BILIRAKIS. Senator Levin, please proceed.

Senator LEVIN. Senator Hatch and I have introduced a bill which Senator Hatch would describe, I hope, and then he will leave and protect our turf back in the Senate. Let them know that I will be a little later than you, but I will be there.

**STATEMENT OF HON. ORRIN HATCH, A UNITED STATES
SENATOR FROM THE STATE OF UTAH**

Senator HATCH. Yes, I will take good care of you. I promise.

Mr. Chairman, I want to thank you for allowing both of us to testify before your subcommittee today. And I always, always appreciate the opportunity to work with you and other Members of the House. I am sorry that we have only a brief moment, but we are, like you say, starting a series of stack votes over there on the tax bill. So I ask your permission to insert the entire text of my prepared remarks in the record.

Mr. BILIRAKIS. Without objection that is the case for both of you.

Senator HATCH. Earlier this year Senators Levin, Moynihan and I introduced S. 324, the Drug Addiction Treatment Act of 1999. This is called the DATA Act. Last week Senator Biden joined us

as cosponsor. Now, the goal of this bill is simple, but it is important. S. 324 attempts to make drug treatment more available and more effective to those who need it. One of the most troublesome problems that our Nation faces today is, of course, drug abuse.

The spectrum of deleterious by-products of drug abuse include rampant and often violent crime, breakdown in family life and other fundamental structures, and inability of addicted individuals to reach their full potential as contributing members of their communities. Our legislation focuses on increasing the availability and effectiveness of drug treatment.

The purpose of the Drug Addiction Treatment Act of 1999 is to allow qualified physicians as determined by the Department of Health and Human Services to prescribe schedules IV and V antiaddiction medications in their offices without an additional drug enforcement registration if certain conditions are met. This program will continue after 3 years only if the Secretary and Attorney General determine that this new type of decentralized treatment should not continue.

This bill would also allow the Secretary and Attorney General to discontinue the program earlier than 3 years if, upon consideration of the specified factors, they determine that early termination is advisable.

In drafting the waiver provisions of the bill, the Drug Enforcement Agency, the Food and Drug Administration, and the National Institute on Drug Abuse were all consulted. In 1995, the Institute of Medicine of the National Academy of Sciences issued a report: "Development of Medications for Opiate and Cocaine Addictions: Issues for the Government and Private Sector." This study called for, "developing flexible alternative means of controlling the dispensing of antiaddiction narcotic medications that would avoid the methadone model of individually approved treatment centers."

The Drug Addiction Treatment Act, DATA, is exactly the kind of policy initiative that experts have called for in America's multifaceted response to the drug abuse epidemic. Now, I recognize that the DATA legislation is just one mechanism to attack this problem, and I plan to work with my colleagues in the Congress to devise additional strategies to reduce both the supply and the demand for drugs.

And, Mr. Chairman, once again I appreciate the opportunity to testify before your subcommittee today. This legislation promotes a policy that dramatically improves these lives because it helps those who abuse drugs to change their lives and become productive members of society.

In addition, if you would permit me to make one quick and somewhat sensitive remark about some of the perceived atmospherics surrounding S. 324, and the SAMHSA reauthorization bill. In short, I favor moving both bills this session. I would ask Chairman Bilirakis if he would let my two good friends Chairman Bliley and Ranking Member Dingell, two of the finest men serving in the House, in my view—it is my understanding that it may be the case of my friend from Michigan is upset at attempts at the end of the last Congress to include S. 324-like language into the omnibus bill. Let me state in public that I favored such an endeavor and wrote to the appropriators of my wishes at that time. Now, this has been

a bipartisan effort in the Senate from day 1. Senators Levin and Moynihan have been with me every step of the way, and we are pleased to have recently been joined in this legislation by Senator Biden. And we have had extensive discussions.

I would ask that the balance of my remarks be placed in the record at this particular point.

Mr. BILIRAKIS. Without objection, sir.

[The prepared statement of Hon. Orrin Hatch follows:]

PREPARED STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

Mr. Chairman, I want to thank you for the opportunity to testify before your Subcommittee today.

Earlier this year, Senators Levin, Moynihan, and I introduced S. 324, the "Drug Addiction Treatment Act of 1999"—the DATA bill. Last week, Senator Biden joined us in cosponsorship.

The goal of this bill is simple, but it is important: S. 324 attempts to make drug treatment *more* available and *more* effective to those who need it.

One of the most troublesome problems that our nation faces today is drug abuse.

The spectrum of deleterious by-products of drug abuse include rampant and often violent crime, breakdown in family life and other fundamental social structures, and the inability of addicted individuals to reach their full potential as contributing members of their communities.

Unfortunately, no state or city in our great Nation is immune from the dangers of illicit drugs.

I want children across the country to grow up drug free so that they may realize their enormous potential.

And I want to help people across the country who are addicted to break the grip of this deadly dependence. Our legislation focuses on increasing the availability and effectiveness of drug treatment. The purpose of the Drug Addiction Treatment Act of 1999 is to allow qualified physicians, as determined by the Department of Health and Human Services, to prescribe schedule IV and V anti-addiction medications in physicians' offices without an additional Drug Enforcement Administration (DEA) registration if certain conditions are met.

These conditions include certification by participating physicians that 1) they are licensed under state law and have the training and experience to treat persons addicted to opiates; 2) they have the capacity to refer patients to counseling and other ancillary services; and, 3) they will not treat more than 20 in an office setting unless the Secretary of Health and Human Services adjusts this number.

The DATA bill provisions allow the Secretary, as appropriate, to add to these conditions and allow the Attorney General to terminate a physician's DEA registration if these conditions are violated. This program will continue after three years only if the Secretary and Attorney General determine that this new type of decentralized treatment should not continue.

This bill would also allow the Secretary and Attorney General to discontinue the program earlier than three years if, upon consideration of the specified factors, they determine that early termination is advisable.

Nothing in the waiver policy undertaken in my bill is intended to change the rules pertaining to methadone clinics or other facilities or practitioners that conduct drug treatment services under the dual registration system imposed by current law.

In drafting the waiver provisions of the bill, the Drug Enforcement Agency, the Food and Drug Administration, and the National Institute on Drug Abuse were all consulted. As well, this initiative is consistent with the announcement of the Director of the Office of National Drug Control Policy, General Barry McCaffrey, of the Administration's intent to work to decentralize methadone treatment.

In 1995, the Institute of Medicine of the National Academy of Sciences issued a report, "Development of Medications for Opiate and Cocaine Addictions: Issues for the Government and Private Sector." The study called for "(d)eveloping flexible, alternative means of controlling the dispensing of anti-addiction narcotic medications that would avoid the 'methadone model' of individually approved treatment centers."

The Drug Addiction Treatment Act—DATA—is exactly the kind of policy initiative that experts have called for in America's multifaceted response to the drug abuse epidemic. I recognize that the DATA legislation is just one mechanism to attack his problem, and I plan to work with my colleagues in the Congress to devise strategies to reduce both the supply and demand for drugs.

Mr. Chairman, once again, I appreciate the opportunity to testify before your Subcommittee today.

All of us either know, or have heard about, someone who is struggling with drug addiction.

And drug addiction not only impacts the lives of those who are abusing drugs, it also impacts the lives of the drug users' families and friends.

Our legislation promotes a policy that dramatically improve these lives because it helps those who abuse drugs to change their lives and become productive member of society.

Let me conclude these remarks by making one quick comment relating to the somewhat sensitive relationship of the SAMHSA and the Drug Addiction Treatment Act, S.324. In short, I strongly favor moving both bills this session. I would ask my good friend from Florida, Chairman Bilirakis and my long time colleagues and partners, Chairman Bliley and Ranking Member Dingell—two of the finest men serving in this House—for a chance to amplify my views on this topic.

It is my understanding that it may be the case that my friend from Michigan is upset at attempts at the end of the last Congress to include S.324-like language into the omnibus bill.

Let my state in public that I favored such an endeavor and wrote to the appropriators of my wishes at that time.

The DATA Bill, as Senator Levin will vouch for in a moment, has been a bi-partisan effort in the Senate from day one. Senators Levin and Moynihan have been with me every step of the way and we are pleased to have been recently joined in this legislation by Senator Biden.

Our staffs' had extensive discussions with DEA and HHS, including FDA and NIDA, last fall and were on the verge of arriving at language that would have been acceptable to the Administration. This bill goes exactly in the direction that General McCaffrey should be heading.

We worked closely with Mr. Bliley's office last fall as well.

To the extent that our efforts contributed to something of wholly unintended ruckus over here in the House, I apologize.

And having said that, let me go one step further—at the risk of infringing on the turf of my former and still beloved Labor Committee.

On Wednesday the Labor Committee reported out the SAMHSA reauthorization bill by a 17 to 1 vote. While I have not had the opportunity to study the reported bill in all its details, I can tell you that as both the former Chairman of the Labor Committee and the current Chairman of the Judiciary Committee, I have a strong interest in the SAMHSA bill. We should all work together to pass a SAMHSA bill this year.

I know that this is a priority of Senators Jeffords, Frist, Kennedy, Wellstone and many other Senators, including this Senator. It is a priority of the Administration and, I understand, the Ranking Member of the full Committee as well.

I can only ask my friends from Florida and Virginia to give the SAMHSA reauthorization bill the timely consideration that it deserves.

I could be wrong but my sense is that if the SAMHSA bill picked up some steam the chances are that it might improve the climate for other measures like S.324.

If we all work together I believe that both of these bills can pass this year.

With regard to S.324, I think that Secretary Shalala's July 14th letter to Representative Dingell is very instructive in many respects. As Secretary Shalala's response states:

"In our view, to consign new treatment medications, with enhanced safety and less diversion potential solely into the existing methadone clinic system would be a serious public health mistake. S. 324 would permit incremental treatment expansion to proceed in a manner which is not overburdened by Federal, state, and local requirements as is the case with methadone clinic regulation. This treatment expansion cannot occur if new anti-addiction drug products are only permitted to be dispensed through the existing methadone clinic system, because it is a limited and closed capacity system."

If we all work together I believe that both of these bills can pass this year. I hope that you did not find these comments presumptions and that you take them the way they were intended—in a spirit of mutual cooperation and respect.

With that, Chairman Bilirakis, I leave these matters in your trusty hands.

I look forward to working with you on moving this bill through the legislative process.

Senator HATCH. And note that with regard with SAMHSA, it is a priority of Senators Jeffords, Frist, Kennedy and many other Senators, including this Senator; it is as priority in the administration

and I understand the ranking member of the full committee as well. So I can only ask my friend from Florida, my friend from Virginia to give the SAMHSA reauthorization bill the consideration that it deserves.

I could be wrong, but my sense is that if the SAMHSA bill picked up some steam, chances are it might include the climate for other measures such as S. 324. And if we work together, I believe that both of these bills can pass and do a lot of good.

Mr. Chairman, I want to let you know my personal esteem for you and the leadership you provide here in the House. A lot of good things could not happen but for your leadership and the things that you have done in the past and are doing now. So I just want to express my friendship and regard for you.

Mr. BILIRAKIS. Thank you so much, sir. You are going to leave now, are you?

Senator HATCH. Yes.

Mr. BILIRAKIS. You are supportive then of the companion measure here in the House, which is essentially similar, as I understand?

Senator HATCH. I am.

Mr. BILIRAKIS. We have deferred opening statements until after the Senators testify, Mr. Chairman. I wonder if you have anything quick you want to ask. They have a vote taking place over in the Senate now.

Senator HATCH. Good to see you.

Chairman BLILEY. Good you to see you.

Mr. BILIRAKIS. Mr. Green, anything real quickly here?

Mr. GREEN. No, Mr. Chairman.

Mr. BILIRAKIS. Thank you, Senator.

Thank you very much for being here.

Mr. BILIRAKIS. Senator Levin.

**STATEMENT OF HON. CARL LEVIN, A UNITED STATES
SENATOR FROM THE STATE OF MICHIGAN**

Senator LEVIN. Thank you, Mr. Chairman, members of the subcommittee. First let me tell you that we are delighted that you are holding this hearing. We are grateful that you allow us to go on first and quickly, even ahead of your own opening statements. You know the kind of problem we face; you face it every day here as well. And we are very much appreciative of the collegiality.

Our bill and your bill will accomplish something that is very important for this Nation. We have struggled for a long time to find ways that we can block the craving for drugs in a manner which will make it possible for more people to have access to those drug blockers, as I call them, the substances which will block the craving, the antiaddiction substances.

We spend a lot of money in our country, and properly so, on intervention, on treatment. We have spent a lot of money trying to see if we can't educate our young children not to ever become open to the possibility of taking drugs. We have recently spent some of our resources at NIH and NIDA and other places to try to come up with substances which will block the craving, the antiaddiction substances, and there are now a number of those substances on the market.

One of them now is buprenorphine, and that substance is a schedule V drug, which means it is the least subject to abuse. It is the least addictive. And the question that we must face and you must face is whether or not we will permit that substance to be prescribed under very careful circumstances in private physicians' offices, or will we follow the model that we currently use with methadone, which requires that it be dispensed only in a clinical setting, in a very closed-tight clinical setting where everybody has to go to the same clinic in order to get the prescription. Methadone is a schedule II drug. It is highly addictive. Buprenorphine is schedule V, the least addictive. And it is being recommended by I think just about all of our experts that I can find that we permit this to happen.

And so our bill, like your bill, prescribes very careful conditions, very careful circumstances under which private physicians in their office would be able to prescribe buprenorphine or other schedule IV or V drugs for treatment of drug addiction. This could be a major breakthrough. I can't tell you how important this is from my perspective living in two big cities, both Detroit and Washington, where we have seen too much of the scourge of drugs. Seeing the statistics on our young people where there is a three- or fourfold increase in heroin addiction among our young people.

We have an opportunity here, if we do to carefully and do it right, to strike a blow against heroin addiction. Frankly, I can't think of anything much more important that we can do. We are all involved in trying to get our economy both even better than it is and keep it that way, and we debate these things endlessly, and obviously they are worthy of debate. We are involved in securing the Nation against any kind of peril. I am on the Armed Services Committee in the Senate, and you folks here in the House do the same thing. But I can't think of anything much more important than trying to find a way to block the craving for heroin, not just for the personal good it will do, but for the societal and communal good it will do. The price we pay for crime—and crime is so often drug-related—is simply horrendous. We have an opportunity here to strike a blow against heroin addiction.

I would simply now submit for the record a letter which Secretary Shalala wrote to Congressman Dingell about our bill. And I want to read just very quickly three lines from that letter. It is a long letter, and I obviously won't read it all, but after describing the goal that to try to reduce illicit drug use by 50 percent by the year 2007 and to close the treatment gap, Secretary Shalala says that one of the ways to help address this goal is by developing new drug therapies for the treatment of heroin addiction and she says, "I am especially encouraged by the results in published clinical studies of buprenorphine."

She also says on page 14 of her letter that the NIDA study, which is the pivotal efficacy and safety trial for the buprenorphine, was performed in a nonmethadone clinic setting, i.e., without patients, and she said the efficacy of buprenorphine was demonstrated in this study. So the efficacy has been demonstrated in NIDA studies.

And finally on the last page, and this to me are her most important words, that to "consign new treatment medications with en-

hanced safety and less diversion potential solely into the existing methadone clinic system would be a serious public health mistake.” S. 324, which is our numbered bill, would permit incremental treatment expansion to proceed in a manner which is not overburdened by Federal, State and local requirements as is the case with methadone clinic regulation. This treatment expansion cannot occur if new antiaddiction drug products are only permitted to be dispensed through the existing methadone clinic system because it is a limited and closed-capacity system.

Mr. Chairman, I would ask that in addition to her letter, that a letter from Professor Woods of the Department of Pharmacology at the University of Michigan Medical School and that a letter from the Michigan Public Health Association supporting our bill be inserted in the record at this time.

Mr. BILIRAKIS. Without objection.

Senator LEVIN. And again, I want to thank you and your colleagues for your courtesy, for your bill. I believe that we can make a real difference in an area which has been very much in need of this kind of an effort, and you have got experts in front of you this morning that can go into the detail of why this is a safe, efficacious and very smart, common-sense thing to do. And again, my thanks to you.

[The prepared statement of Hon. Carl Levin, with attachments, follows:]

PREPARED STATEMENT OF HON. CARL LEVIN, A U.S. SENATOR FROM THE STATE OF MICHIGAN

To the distinguished Chairman, Representative Bilirakis, my special friend from Michigan, Representative John Dingell, Ranking Member of the Commerce Committee, Representative Sherrod Brown, Ranking Member of the Subcommittee, and other distinguished members of the Subcommittee, I welcome this opportunity to present my views on an issue that has been a long-term crusade of mine, speeding the development and delivery of anti-addiction medications that block the craving illicit addictive substances.

Mr. Chairman, I am very pleased to note the presence of witnesses who have played, and continue to play, a very active and pivotal role in promising new discoveries that suppress the craving for illicit drugs. Our focus today is on a new anti-addiction medication, Buprenorphine and Buprenorphine combined with naloxone, and how to make this soon-to-be FDA approved medication more widely available and more effective in treating drug abuse.

The National Institute on Drug Abuse (NIDA), in collaboration with a private pharmaceutical company developed Buprenorphine for the treatment of heroin addiction. I know that the experts that you have assembled here this morning, including Dr. Charles Schuster, Director of Wayne State's Research Division on Substance Abuse, NIDA Director Dr. Alan Leshner, and Dr. Westley Clark, Director of the Center for Substance Abuse will address the potential of Buprenorphine as a tool in closing the treatment gap.

Mr. Chairman, I have joined Senator Hatch, Chairman of the Judiciary Committee, Senator Moynihan, Ranking Member of the Finance Committee and Senator Biden, Ranking Member of the Foreign Relations Committee and the Judiciary Subcommittee on Youth Violence, in sponsoring legislation [S. 324, The Drug Addiction Treatment Act] to enable qualified physicians to prescribe schedule IV and V anti-addiction medications in their offices, under certain strict conditions. The goal of this legislation is to allow for Buprenorphine, a schedule V substance under the Controlled Substances Act, to be used in the treatment of heroin addiction in physician offices. It is my understanding that a similar, bipartisan, bill has now been introduced in House and I applaud this effort.

Mr. Chairman, let me take a moment to quote from a letter I recently received from HHS Secretary Donna Shalala, and I quote: “I am especially encouraged by the results of published clinical studies of Buprenorphine. Buprenorphine is a partial mu opiate receptor agonist, in Schedule V of the Controlled Substances Act,

with unique properties which differentiate it from full agonists such as methadone or LAAM. The pharmacology of the combination tablet consisting of Buprenorphine and naloxone results in... low value and low desirability for diversion on the street. Published clinical studies suggest that it has very limited euphorogenic affects, and has the ability to precipitate withdrawal in individuals who are highly dependent upon other opioids. Thus, Buprenorphine and Buprenorphine/naloxone products are expected to have low diversion potential. Buprenorphine and Bullrenorphine naloxone products are expected to reach new groups of opiate addicts—for example, those who do not have access to methadone programs, those who are reluctant to enter methadone treatment programs, and those who are unsuited to them (this would include for example, those in their first year of opiates addiction or those addicted to lower doses of opiates). Buprenorphine and Buprenorphine/naloxone products should increase the amount of treatment capacity available and expand the range of treatment options that can be used by physicians. Secretary Shalala went on to say, “Buprenorphine and Buprenorphine/Naloxone would not replace methadone. Methadone and LAAM clinics would remain an important part of the treatment continuum.”

Mr. Chairman, because of the reluctance of the pharmaceutical industry to become involved in developing anti-addiction medications, NIDA has played an active supporting research at every step of the drug development process. NIDA's Medications Development Division has been working to accelerate the identification, evaluation, development, and approval of new medications to treat drug addiction, what I call anti-addiction drugs/medications. Through this process, NIDA has been able to bring a number of effective medications into drug treatment. In the case of Buprenorphine products, NIDA has supported research for many years which indicates that the medication is a useful in blocking the craving of heroin addiction.

Dr. James H. Wood, Professor of Pharmacology at the University of Michigan Medical School recently wrote: “One of the most important aspects of your bill is the use of Buprenorphine by well-trained physicians to treat narcotic addiction from their offices, which has the potential to attract and treat effectively, sizable populations of currently untreated addicts... a major byproduct of this increased treatment, of course, will be reduction in the demand for illicit narcotics in the U.S. ”

Mr. Chairman, while Buprenorphine and other developments are exciting and offer much promise for treatment, the crisis of illegal drug use continues to cost society both in human toll and in the loss of billions of dollars each year. Consider the startling and compelling findings of the January 1995 Institute of Medicine Report, which estimated the cost to society for drug abuse and dependence treatment at \$66.9 billion in 1990 alone, and estimated the cost of drug-related crime at \$46 billion that same year. A 1995 report of the Office of National Drug Control Policy tells us that users of illegal drugs spent \$48.7 billion on the purchase of illicit substances to feed their addiction.

Recent findings of the Monitoring the Future Program, headed by Dr. Lloyd Johnson of the University of Michigan, indicates that heroin use among American teens doubled between 1991 and 1998, and represents a clear and present danger for a significant number of American young people. Dr. Johnson attributes this “sharp increase in use to the administering of non-injectable modes of heroin—smoking and snorting, in particular. Dr. Johnson goes on to say that, the very high purity of heroin on the street has made these new developments possible and that unfortunately, a number of those users will become dependent on heroin and will switch over to injection, which is a more efficient way to derive the equivalent high”

The President of the Michigan Public Health Association, Dr. Stephanie Meyers Schim, has spoken out eloquently about the “great problems” of substance abuse. In her recent letter in support of S. 324, she says: Substance abuse affects health care costs, mortality, workers' compensation claims, reduced productivity, crime, suicide, domestic violence, child abuse, and increases costs associated with extra law enforcement, motor vehicle crashes, crime, and lost productivity. Dr. Schim goes on to say, “Buprenorphine will allow drug addicted individuals to maximize everyday life activities, and participate more fully in work day and family activities while seeking the needed treatment and counseling to become drug free”.

There are yet many other compelling reasons why we must expedite the delivery of anti-addiction medications, not the least of which are the youth of America and the innocent victims of drug-related crime. Of the juveniles who land behind bars in state institutions, more than 60 percent of them reported using drugs once a week or more, and over 40 percent reported being under the influence of drugs while committing crimes, according to a report from the Bureau of Justice Statistics.

Drug-related incarcerations are up and we are building more jails and prisons to accommodate them—more than 1000 have been built over the past 20 years. According to the July 14, 1999 Office of National Drug Control Policy Update, and I quote:

“Drug-related arrests are up from 1.1 million arrests in 1988 to 1.6 million arrests in 1997—steady increases every year since 1991.”

These sentiments were also expressed during a May 9, 1997 Drug Forum on Anti-addiction Research, which I convened along with Senator Moynihan, Senator Bob Kerrey and other members of the Senate. Forum participants, including distinguished experts such as Dr. Herbert Kleber and Dr. Donald Landry of Columbia University, Dr. Charles Schuster of Wayne State University (who is with us today) and Dr. James Woods of the University of Michigan, made it crystal clear that time is of the essence—we must act expeditiously on new treatment discoveries.

The Drug Addiction Treatment Act of 1999, S. 324, focuses on increasing the availability and effectiveness of drug treatment. The purpose of the legislation is to allow qualified physicians to prescribe schedule IV and V anti-addiction medications in physicians’ offices if certain strict conditions are met. These conditions include: Certification by participating physicians that they are licensed under state law and have the training and experience to treat heroin users; that they have the capacity to refer patients to counseling and other appropriate ancillary services, and that they will not treat more than 20 patients in an office-setting unless the (HHS) Secretary adjusts this number. S. 324 also permits the Secretary, as appropriate, to add to these conditions and allows the Attorney General to terminate a physician’s registration if the conditions are violated. The program may be discontinued at anytime that the Secretary and the Attorney General determine that this new type of decentralized treatment should not continue based on a number of determinations, including: Whether the availability of drug treatment has significantly increased without adverse consequences to the public health and the extent to which covered drugs may have been diverted or dispensed in violation of the law such as exceeding the initial 20 patient per doctor limitation. Also, states may opt out of the provision by passing legislation.

Nothing in the waiver policy undertaken in the new bill is intended to change the rules pertaining to methadone clinics or other facilities or practitioners that conduct drug treatment services under the dual registration system imposed by current law. In crafting the waiver provisions of this legislation, we consulted with the U.S. Department of Health and Human Services, including the Federal Drug Administration, and the Drug Enforcement Administration.

Mr. Chairman, there are a number of reasons why this legislation is necessary. The Narcotic Addict Treatment Act of 1974, requires separate DEA registrations for physicians who want to use approved narcotics in drug abuse treatment and separate approvals of registrants by U.S. Department of Health and Human Services (HHS) and by state agencies. The result has been a treatment system consisting primarily of large clinics, and preventing physicians from treating patients in an office setting or in rural areas or small towns, thereby delaying treatment to thousands in need of it. Additionally, experts say that many heroin addicts who want treatment are often deterred because of the stigma that is associated with such clinics.

The intent of our legislation is to make possible for medications like Buprenorphine, where no likelihood of diversion or abuse or addiction or abuse of such drug to be used effectively to block the craving for heroin. To do this, you must need to make it available in a physician office, and to make sure that such availability is not abused. These protections include the following: Physicians may not treat more than 20 patients in an office setting unless the HHS Secretary adjusts this number; the HHS Secretary, as appropriate, may add to these conditions and allow the Attorney General to terminate a physician’s DEA registration if these conditions are violated; and the program will continue after three years only if the HHS Secretary and Attorney General determine that this new type of decentralized treatment should continue based on a number of determinations. And again, States can opt out of the provision.

In closing, the American Society of Addiction Medicine (ASAM) and the College on Problems of Drug Dependence, the nation’s longest standing organization of scientists addressing drug dependence and drug abuse, states that the availability of Buprenorphine in physicians’ offices adds a needed expansion of current treatment for heroin addiction. ASAM also cautioned that Buprenorphine will have limited utility if it is tied to the regulatory structure for current treatments of heroin addiction.

Mr. Chairman, thank you for inviting me here today.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
July 14, 1999

The Honorable JOHN D. DINGELL
Ranking Member
Committee on Commerce
House of Representatives
Washington D. C. 20515

DEAR MR. DINGELL: Thank you for your recent letter requesting information about increasing the availability and effectiveness of drug addiction treatment. We are particularly pleased with your interest in the development of buprenorphine and buprenorphine combined with naloxone (buprenorphine/nx) products as treatments for heroin (and other opiate) addiction.

Increasing access to treatment and reducing the morbidity, mortality, and cost to society associated with addiction is part of the Administration's overall demand reduction strategy articulated in the National Drug Control Strategy 1999. The Department of Health and Human Services has a major role to play in the strategy's plan to reduce illicit drug use by 50 percent by the year 2007 and to close the "treatment gap." One of the ways to help address this goal is by developing new drug therapies for the treatment of heroin addiction. I am especially encouraged by the results of published clinical studies of buprenorphine.

I would note that as of the date of this response, neither buprenorphine nor the combination drug has been approved by the FDA. Also, while Senator Hatch has introduced S. 324, the bill referenced in this letter, no comparable bill has been introduced in the House.

I would like to provide a quick overview of buprenorphine and buprenorphine/nx to frame the answers to the questions you have posed.

- Buprenorphine is a partial mu opiate receptor agonist (currently in Schedule V of the Controlled Substances Act) with unique properties which differentiate it from full agonists such as methadone or levomethadyl acetate (LAAM).
- The pharmacology of the combination tablet consisting of buprenorphine and naloxone results in subjective effects which are believed to provide low value and low desirability for diversion on the street. Published clinical studies suggest that it has very limited euphorogenic effects, and has the ability to precipitate withdrawal in individuals who are highly dependent upon other opioids. Thus, buprenorphine and buprenorphine/nx products are expected to have low diversion potential.
- Buprenorphine and buprenorphine/nx products are expected to reach new groups of opiate addicts—for example, those who do not have access to methadone programs, those who are reluctant to enter methadone treatment programs, and those who are unsuited to them (this would include for example, those in their first year of opiate addiction or those addicted to lower doses of opiates).
- Buprenorphine and buprenorphine/nx products should increase the amount of treatment capacity available and expand the range of treatment options that can be used by physicians.
- Buprenorphine and buprenorphine/nx would not replace methadone. Methadone and LAAM clinics would remain an important part of the treatment continuum. In fact, clinics are likely to receive referrals for patients who do not do well on buprenorphine and buprenorphine/nx or who need specialized services provided in clinics, and clinics may wish to move some of their patients to buprenorphine and buprenorphine/nx, either for maintenance or detoxification. This could mean that methadone clinics could admit additional patients, currently on waiting lists, for whom methadone or LAAM is the most appropriate treatment choice.

I am pleased to provide you with the enclosure that answers your specific questions. Thank you again for your interest in broadening access to treatment.

Sincerely,

DONNA E. SHALALA
Secretary

1. Would the implementation and administration of S. 324 require the expenditure of resources by any agency of the federal government? If so, which ones? Can you estimate the amount of resources needed to implement S. 324 and whether the bill provides adequate authorization of appropriations for these purposes? What existing programs and activities would be affected if this legislation was enacted without a specific provision of resources for its implementation?

To implement S. 324, additional resources would be required by the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT). Resources would be required to process provider applications and assess provider qualifications, make a determination of adverse use, provide information to the Attorney General, make determinations regarding waivers, and collect data and evaluate the impact of the program.

It is difficult to estimate the resources necessary to carry out the program. We make the assumption that as many as 6,000 physicians (about one percent of the physicians in the U.S.) may seek a waiver under this provision. The bill currently specifies that practitioners must be physicians. If other practitioners such as nurse practitioners, who are licensed in many states and have made great contributions to drug abuse treatment, were to be included, then additional costs would have to be taken into account. In addition, the costs of administering the program will increase as new drugs are approved by FDA for the treatment of opioid addiction and would be subject to the provisions of this bill.

At this time we estimate that CSAT would require approximately \$4 million in the program management costs to implement the program in the first year. As written, S. 324 does not provide the appropriations authority for these requirements.

If resources were not made available to SAMHSA to establish and provide oversight of this new office-based practice system, the agency would have to shift programmatic funds from other intended uses. It would not be possible at this time to identify specific programs or activities that would be adversely affected.

2. Please describe the problem of heroin addiction in terms of factors considered by you to be relevant to the development of public health policy for its treatment. We know that many heroin addicts do not receive treatment for a variety of reasons. Please comment on the extent to which S. 324 is responsive to addressing the needs of those heroin addicts who do not currently receive treatment. More detailed questions follow on issues affecting the utility of this bill to heroin addicts in terms of economic status, severity of addiction, use of other substances, and age. Please do not limit your response to these areas. I would like to know of all limitations on access to buprenorphine in non-clinical settings that may exist and that are not addressed in this legislation. Does the bill, for example, provide financial resources for those who cannot afford access to addiction treatment services in non-clinical settings described in the legislation?

The Problem

The heroin abusing population has grown larger and younger during the 1990's. Data from the 1997 National Household Survey on Drug Abuse (NHSDA) indicates that heroin abuse in the household population age 12 and older, rose dramatically from 71,000 in 1991 to 325,000 in 1996. These estimates may be conservative in that the NHSDA relies on self-reported drug use. The NHSDA also showed an increase in heroin use among youth ages 12 to 17 and 18 to 25.

Many individuals who want effective treatment for their addiction do not have access to it. National estimates of the number of patients in methadone or LAAM treatment increased from over 81,000 in 1987 to 95,000 in 1991, and with a current estimate of 180,000 in 1998. However, the Office of National Drug Control Policy (ONDCP) estimates that there are about 810,000 heroin addicts in the United States. Eight states do not have any methadone maintenance treatment services. In many other states access to this treatment is severely limited by restrictive community zoning practices, inadequate public funding, inadequate commercial health plan benefits and coverage, and other restrictive policies and practices. Current federal and state regulations prevent ease of entry into methadone/LAAM maintenance treatment during the first year of heroin/opiate use. Although short term detoxification treatment using methadone is available under federal regulations (without a one year history of dependence), it is during this first year that new injectors are most likely to be exposed to infectious diseases such as HIV, hepatitis and sexually transmitted diseases. Thus, by the time most younger addicts would have access to maintenance treatment, they already may have contracted infectious diseases which might have been prevented. The use of oral medications (such as methadone) has been shown to reduce the incidence of infectious diseases among opiate addicts.

Existing Anti-addiction Medications Are Stigmatized

S. 324 would increase access to treatment by making available office-based treatment to heroin addicts who are appropriate candidates for new pharmacotherapy treatment. Many heroin addicts who do have access to methadone or LAAM treatment continue to avoid treatment because of either the stigma of being in methadone treatment or their concerns about the medical effects of these medications. The

stigma and prejudice against patients in methadone treatment comes not only from the fear that they may be denied access to certain jobs, child custody or even medical care, but also from the prejudice within the greater community, where they are likely to be labeled as weak and as “trading one addiction for another.”

Withdrawal

Newer treatment drugs that have less protracted withdrawal characteristics may address with an important physical disincentive that keeps patients away from methadone treatment. Patients have a fear of severe and/or protracted symptoms during withdrawal from methadone. While withdrawal from methadone generally causes milder symptomatology than heroin withdrawal, the syndrome does last a considerably longer period. Withdrawal from medications currently under study, e.g. buprenorphine and buprenorphine/nx, are both milder than from heroin and shorter than from methadone. In research situations it has been shown to be significantly easier, both for the patient and for the health professional, to manage withdrawal.

Increasing Treatment Access

S. 324 promotes the office-based use of Schedule IV and V medications to treat opioid addiction. National estimates suggest only 22 percent of opioid addicts are now receiving effective pharmacotherapy (methadone or LAAM) for their addiction. There are only a handful of physicians currently approved by the FDA to use methadone or LAAM to treat heroin addicted patients in their private practice. One expected result of S. 324 is that the number of physicians in private practice who are likely to treat this population with new anti-addiction medications, e.g. buprenorphine/nx, if approved by the FDA, is likely to increase considerably. The bill does not provide appropriations authorization to pay for treatment for those who are uninsured and cannot afford the cost of the treatment. These economic access issues are not addressed.

3. Have buprenorphine or buprenorphine/naloxone been approved by the FDA for any purpose other than the treatment of heroin addiction? Have these products been approved by FDA for the treatment of heroin addiction? Please comment on whether it is prudent or precedented for HHS to support legislation such as S. 324 in the absence of FDA approval for these products. Who is the product sponsor? Would S. 324 apply to any products other than buprenorphine or buprenorphine/nx?

Neither buprenorphine nor buprenorphine/naloxone is an approved drug in the U.S. for treating heroin addiction. An injectable formulation of buprenorphine hydrochloride is approved by the FDA for use as an analgesic. The new drug application holder is Reckitt and Colman. The trade name for the Reckitt and Colman product is Buprenex. There also is a generic version of the injectable product made by Abbott. The injectable formulation is not approved for use in addiction treatment, and thus is not covered under the bill. Naloxone is marketed by DuPont Pharma and various generic companies.

S. 324 would not apply at this time to any approved product. It would apply to buprenorphine and buprenorphine/nx, if approved, and to any other narcotic drugs or combination of drugs in schedule IV or V which are approved for use in maintenance or detoxification treatment, if certain other conditions are met.

4. According to information provided to my staff by SAMHSA, a majority of heroin addicts use or abuse as many as eight other drugs. Does buprenorphine, for example, interact with other substances commonly used by heroin addicts? Please comment on the extent to which these factors may limit the utility of buprenorphine for treating heroin addiction. Are these issues addressed in any clinical trials that have been or will be conducted for buprenorphine? Can these questions be properly answered other than in the context of final FDA approval of these products for heroin addiction treatment? The National Institute on Drug Abuse opined in writing last year that buprenorphine was safe and effective for the treatment of heroin addiction. Please comment. What is the basis for NIDA giving such an opinion? What effect, if any will NIDA's opinion on safety and efficacy have on FDA's process for evaluating the safety and efficacy of buprenorphine and buprenorphine/nx for heroin addiction?

It is true that many addicts may abuse more than one substance at a time. Treatment personnel must try to identify the substances being abused and work with the patient to recommend the treatment modalities that best meet the needs of that individual. Because addiction to several substances is so common in this population, the interaction of buprenorphine with other substances commonly used by heroin addicts has been studied both in clinical trials (where research subjects provide urine samples which are analyzed for metabolites of drugs of abuse and where clini-

cal staff observe and take case histories) and by preclinical interaction studies undertaken in animals. It is a well-known pharmacological fact that all opiate drugs, including buprenorphine, may have serious reactions (respiratory depression) if co-injected with benzodiazepines, so all research subjects are warned of this fact, and it will be included in the product labeling. This interaction has been known for years and is in the Buprenex (injectable) product labeling. No other serious adverse reactions have been noted by investigators to date in the clinical studies with other drugs of abuse or concurrent medications taken by individuals. This information will be reviewed by FDA in approving/disapproving buprenorphine for its intended indication. As with any medication reviewed by the FDA, the FDA must approve specific labeling and package insert material which will adequately describe for physicians potential drug interactions, precautions, and dosing recommendations.

The National Institute on Drug Abuse has relied on published data from multiple studies evaluating buprenorphine given as a sublingual solution or tablets, in the treatment of heroin addiction to conclude that buprenorphine was safe and effective. In addition, FDA had issued an "approvable" letter (NDA 20-732, June 30, 1998) concerning the noncombination version of buprenorphine tablets based on the data submitted and evaluated to date. Specific issues related to the proposed formulation need to be resolved before the product can be approved for marketing.

Additionally, in a clinical study (NIDAIVA #1008, a Multi-center Efficacy/Safety Trial of Buprenorphine/Naloxone for the Treatment of Opiate Dependence), the Data Safety Monitoring Board performed an interim data analysis and found that buprenorphine/nx was so clearly superior to placebo that it recommended that the placebo arm of the study be terminated and that buprenorphine be made available to all research subjects in the trial. NIDA provided this information to Senator Carl Levin, at his specific request, and recognizes that it does not affect the FDA's final deliberations or jurisdiction in this matter. Rather, it was meant to provide Congress, states, and the treatment community advance knowledge about the existence of a new potential treatment which could significantly expand the numbers of persons in treatment.

The possibility of expanding treatment for this population is critically important. Currently, eight states do not have any programs or clinics providing methadone, and many of the approximately 630,000 persons in need of treatment (the Office of National Drug Control Policy currently estimates the number of weekly heroin users at 810,000) would benefit from expansion beyond the current methadone clinic system, which currently serves only about 180,000 clients. As a public health matter, each person who continues to inject heroin is at high risk of contracting and spreading infectious diseases such as HIV, hepatitis, and tuberculosis. We believe, as does the Institute of Medicine (see *Federal Regulation of Methadone Treatment*; National Academy Press, Washington, D.C. 1995, which is provided under a separate cover) that the multiple layers of Federal, state, and local regulation of the current methadone clinic system have hampered treatment expansion. Because buprenorphine and buprenorphine/nx have unique pharmacologic qualities, we are hopeful that these will offer states an opportunity to expand treatment in a manner currently not available under the methadone clinic system.

FDA's process for evaluating the safety and efficacy of buprenorphine and buprenorphine/nx for heroin addiction is based on a careful analysis of the results of controlled clinical trials which is independent of NIDA's opinion on this issue. Any information or data provided by NIDA, on this or any other application, will be evaluated with the same scientific review accorded data from any other source and contained within the submissions to the FDA.

5. Methadone is the predominant drug used in programs for treatment of heroin addiction and requires daily dosing combined with counseling and other treatment services. Recently Barry McCaffrey, the White House Office of Drug Policy Director, indicated that methadone should be considered for non-clinical settings. Should methadone be administered in non-clinical settings? If not, what is the basis for distinguishing methadone and buprenorphine in this manner?

HHS's position is that methadone can be administered in non-clinic settings as a long-term maintenance therapy to patients who have been medically and clinically determined to be in stable recovery. This treatment has been provided successfully on a small experimental basis for some years and is also being implemented in a community in Connecticut with CSAT support and technical assistance. CSAT is now developing practice guidelines to help physicians, patients, and treatment programs better understand how to deliver this service to this select group of patients.

Because some of the pharmacologic characteristics of methadone, buprenorphine and buprenorphine/nx are different, the treatment standards for their use will likely reflect those differences. For example, buprenorphine and buprenorphine/nx appear

to be considerably easier to withdraw from than methadone and appears to engender a much lower level of physical dependence. Therefore, induction onto buprenorphine products will not necessarily be seen as having the long-term implications associated with methadone. SAMHSA is currently working with the FDA to revise the treatment standards for methadone and to propose treatment standards for buprenorphine and buprenorphine/nx, if approved by FDA for this purpose.

6. Is buprenorphine expected to be effective for all heroin addicts? Can you estimate the number of persons for whom buprenorphine is not expected to be effective due to the nature and severity of their addiction?

Buprenorphine and buprenorphine/nx, if approved, may not be effective for all heroin addicts. No medication for any brain disorder claims a 100% response rate. As with any medication, some persons will respond better than others. Clinical experience to date indicates that those persons with the highest tolerance levels for opiates may find that a full opiate agonist medication (such as methadone or LAAM) may be preferable. NIDA estimates that approximately 20-25% of the approximately 630,000 heroin addicts in need of treatment may be treated with buprenorphine and buprenorphine/nx. This is due to many factors, among which are the nature and severity of their addiction. Additionally, there may be no reason for those patients whose opiate dependence is well managed by taking methadone or LAAM to be switched to any other medication. This is an individual physician/patient decision. As in all forms of medicine, it is critically important to allow physicians and patients to have access to as many forms of treatment as may be available, and to choose the best match for each individual.

7. FDA predominantly requires double blind placebo trials to test new drugs. Have clinical trials been conducted that directly compare the safety and efficacy of buprenorphine and methadone?

FDA requires adequate and well-controlled trials, but placebo is not the only acceptable type of control. Active controls and dose controls are frequently used. Several published studies of a different formulation of buprenorphine used methadone as an active control. However, these were not designed to compare the efficacy of the two therapies. We know of no studies that would support a comparative efficacy claim for buprenorphine sublingual tablet or buprenorphine/nx sublingual tablet versus methadone. Of note, FDA does not necessarily require that a new therapy demonstrate superiority to existing therapies in order to gain approval for marketing.

8. Heroin use has doubled among teenagers in the 1990's. Under many methadone treatment programs, a heroin addict under the age of 18 years must have parental consent in order to receive treatment. Will access to buprenorphine be limited to persons in the same manner as methadone? If access to buprenorphine will not be limited on the basis of age, what is the rationale for an age limitation for access to methadone in a clinical setting, but not for buprenorphine in a non-clinical setting? Could you also address the issue of youth heroin addiction in terms of income and severity of addiction as these affect teen access to buprenorphine in non-clinical settings?

You have correctly identified a major public health problem. The fact that heroin use has increased dramatically (almost five-fold) among teenagers in the 1990's is of grave concern to the Department. We plan to address this problem at many levels, including increasing our prevention efforts, as well as increasing the range of treatment options available to adolescents. We speculate that the anticipated availability of partial agonist medications such as buprenorphine and buprenorphine/nx could significantly help toward this end. The general scientific assessment, based on clinical pharmacology studies, is that the partial agonist quality of buprenorphine and buprenorphine/nx is associated with two important pharmacological properties: a ceiling effect on respiration imparting a lessened risk of fatal overdoses, and milder withdrawal than full agonist medications. Thus, buprenorphine and buprenorphine/nx may be appropriate for short-term treatment in adolescents, utilizing the anticipated effect of milder withdrawal to ease individuals off these products with what NIDA believes will be relative ease.

In fact, NIDA is about to commence a study of buprenorphine/nx in "office-based" settings. One of the stated objectives of this study is to evaluate buprenorphine/nx in the treatment of the adolescent opiate dependent population aged 15 or older. The protocol provides for assessments for both short-term and longer-term (up to one year) use of buprenorphine/nx in the treatment of opiate addiction. Data from this study could be used to inform the development of practice guidelines for the use of buprenorphine/nx in adolescent addicts, or to augment regulations promulgated by the Department.

Access to methadone treatment by adolescents is currently restricted by FDA regulations. These regulations (21 CFR part 291.505(d)(1)(iv)) specify that adolescents under 18 must have had two documented attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment. We cannot comment at this time whether similar restrictions would be placed on buprenorphine and buprenorphine/nx treatment. However, it is unlikely that the treatment setting would matter if an age limitation were imposed on buprenorphine products for the treatment of narcotic addiction.

Access by teenagers to buprenorphine and buprenorphine/nx treatment in “office-based” practices will most likely depend on the patient’s ability to pay for treatment services, either through coverage under a parent’s private health insurance, through Medicaid, or out of pocket. Across all states, only about 35 percent of persons below age 19 are covered as dependents under any type of employer coverage. Medicaid coverage across all states for youth below age 19 is about 38 percent. This means over a quarter of all youths who may need substance abuse treatment have no ability to get it. In addition, many commercial insurance plans and State Medicaid plans specifically exclude or limit benefits for substance abuse treatment under managed care arrangements. Most often, benefits for substance abuse treatment are restricted to detoxification and very limited outpatient counseling services.

9. Please provide an estimate of the expected per dose costs of buprenorphine and methadone. Please include a comparison of the costs of methadone and buprenorphine in terms of the number of doses and duration of treatment in similar cases. Will federal health care or substance abuse treatment funds be available to heroin addicts who want to receive buprenorphine in non-clinical settings? If so, please identify their source and state whether these resources are expected to be adequate in view of the number of and economic status of persons who may wish to have access to buprenorphine in non-clinical settings.

The drug sponsor has not provided the agency with data on cost per dose and we have no way of estimating them or making comparisons with the cost of methadone at this time. The cost per dose of methadone is approximately \$1.50 per day and \$10 per day for treatment. Methadone is one of the cheapest of all pharmaceutical products for opiate addiction due to its ease of synthesis and its availability since the 1960s. The Department has not requested funds targeted to pay for administration of buprenorphine and buprenorphine/nx in non-clinic settings in the FY 2000 budget.

Substance abuse and prevention and treatment block grant funding are limited to public and nonprofit private entities. The states generally allocate these funds to community-based treatment providers, not to individual health care practitioners.

Other Federal health care or substance abuse funds, e.g., the Department of Veterans Affairs or the Medicaid program, may be available for this population based on eligibility criteria and other factors. Currently, under Medicaid, substance abuse treatment is a state option, not a required service. About half of all states do not include benefits for methadone treatment in their Medicaid program. Based on this we can anticipate that coverage for buprenorphine and buprenorphine/nx would be minimal. There are also few benefits for substance abuse treatment under the State Children’s Health Insurance Programs (CHIPs). Additionally, treatment funds may be available to treat heroin addicts with buprenorphine and buprenorphine/nx through other HHS agencies, e.g., Indian Health Service and the Health Resources and Services Administration’s Bureau of Primary Health Care.

10. Buprenorphine has been given orphan drug status. Because the number of heroin addicts is estimated to exceed 200,000 persons, was the determination of orphan status dependent upon the product sponsor’s cost of developing this product? Can you please provide us with the factual basis upon which the decision to grant orphan status was made? What are the total expected number of years of patent and market exclusivity the product sponsor can expect for buprenorphine and buprenorphine/nx? Does this status preclude competition from bioequivalent products during that time?

The determination and grant of orphan drug status for buprenorphine and buprenorphine/nx was based upon economic data projected by the sponsor on the costs of research and development for the designated indication. Information from NIDA on its CRADA (Cooperative Research and Development Agreement) with the sponsor, and other public information on the systems and facilities for treatment of narcotic addiction, as well as projections of the market potential for the product were considered in the determination. All data were calculated as of the date of the orphan designation application.

The factual basis on which this decision was made was information provided by the sponsor. The information in the designation application is not disclosed prior to market approval. After market approval, disclosure excludes financial information and other confidential information submitted. The sponsor has not made the information public and has indicated to FDA that it wishes such information to be kept confidential as commercial confidential information.

Until a product is approved, it is not possible to determine the remaining patent exclusivity on a particular product. If the product is approved, orphan product designation will provide market exclusivity of seven years.

With respect to market exclusivity and preclusion of competition from bioequivalent products, the provisions of 21 U.S. C. § 360cc provide as follows:

“(a) Except as provided in subsection (b), if the Secretary—

(1) approves an application filed pursuant to section 505(b),

(2) issues a license under section 351 of the Public Health Service Act for a drug designated under section 526 for a rare disease or condition, the Secretary may not approve another application under section 505 or issue another license under section 351 of the Public Health Service Act for such drug for such disease or condition for a person who is not the holder of such approved application, of such certification, or of such license until the expiration seven years from the date of the approval of the approved application, the issuance of the certification or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

(b) If an application filed pursuant to section 505(b) is approved for a drug designated under section 526 for a rare disease or condition, if a certification is issued under section 507 for such a drug or if a license is issued under section 351 of the Public Health Service Act for such a drug, the Secretary may, during the seven-year period beginning on the date of the application approval, of the issuance of the certification under section 507, or of the issuance of the license, approve another application under section 505(b), issue another certification under section 507, or, issue a license under section 351 of the Public Health Service Act, for such drug for such disease or condition for a person who is not the holder of such approved application, of such certification, or of such license if—

(1) the Secretary finds, after providing the holder notice and opportunity for the submission of views, that in such period the holder of the approved application, of the certification, or of the license cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated; or

(2) such holder provides the Secretary in writing the consent of such holder for the approval of other applications, issuance of other certifications, or the issuance of other licenses before the expiration of such seven-year period.”

(Note: The phrases “of such certification” and “the issuance of the certification” are probably meant to be deleted as section 125 of Pub. L. 105-115 repealed sections 506 and 507.)

11. Buprenorphine was developed under a Cooperative Research and Development Agreement with NIDA. Can you provide a narrative description of this agreement, specifically including the terms and conditions agreed to by the product sponsor and the NIDA? How much money has NIDA spent under the terms of this agreement? In what manner, if any, was the federal share of the costs of development included by the product sponsor in the grant of orphan status? Were the sponsor's costs of developing buprenorphine for any other purpose than heroin addiction included in any way in the determination of development costs?

Buprenorphine and buprenorphine combined with naloxone are being developed under a Cooperative Research and Development Agreement (CRADA) between NIDA and Reckitt & Colman Pharmaceuticals, Inc. The terms and conditions of the CRADA specified that Reckitt & Colman would collaborate in the development of buprenorphine and buprenorphine combined with naloxone. Reckitt & Colman was required to produce all dosage forms, collaborate on the design of clinical trials and participate in joint analysis of clinical trial data, permit investigators to publish the results of their studies, produce New Drug Application (NDA) reports as required by the FDA, and file NDAs as warranted by the study results.

NIDA's role was to provide access to a clinical trials network suitable for undertaking trials acceptable to the FDA under its Good Clinical Practices Guidelines, monitoring the trials and reporting adverse events to the FDA, to participate in meetings with investigators and the FDA, and to participate as appropriate in publications resulting from the studies. Under the terms of a CRADA, no federal funds are provided to the outside collaborator.

NIDA estimates that it provided in kind services (clinical pharmacology, analytical resources, and clinical trial support) related to the development of the buprenorphine products of approximately \$26 million over a five year period, or about \$5 million per year. It is important to note that the pharmaceutical industry estimates the cost of bringing a new medication to market at approximately \$500 million (source: Pharmaceutical Research and Manufacturers Association). Therefore, the expenditure of these funds, in pursuit of an orphan medication, and in view of the fact that two new dosage forms were developed and tested to potential NDA status is very reasonable. It is also important to note that without the support of Reckitt & Colman, the cost to the Federal Government would have been substantially higher.

NIDA was pleased to have Reckitt & Colman as the sponsor in the development and marketing of these products, especially given the reluctance of pharmaceutical companies to invest in the development of pharmacotherapies for drug abuse and addiction. This is mainly due to the lack of market incentives and the societal stigma that companies perceive can be created if one of their products is approved for use in the treatment of drug abuse and addiction. This reluctance by the private sector to develop anti-addiction medications is the main reason why NIDA's medications development program was created by Congress in 1988 (P.L. 100-690 and P.L. 102-321). (For a full analysis of factors discouraging industry, see *The Development of Medications for the Treatment of Opiate and Cocaine Addictions: Issues for the Government and Private Sector*; National Academy Press, Washington, D.C., 1995. A copy is being forwarded under separate cover.)

12. Buprenorphine is intended to treat heroin addiction. Can you provide an analysis of all addictions that lead to an increase in morbidity and mortality in the United States? Please include information available to you regarding trends, socioeconomic status, race and ethnic factors, and other measures used by public health officials to assess and evaluate public health issues and public policy responses to them. Vice President Gore recently was the keynote speaker at a NIDA sponsored National Research Forum. He is quoted in "NIDA Notes" as saying that "nicotine is a drug—a dangerous, highly addictive drug, and we should treat it as a drug...nicotine is a highly addictive drug—as addictive as heroin or cocaine." Your analysis should specifically include nicotine. Does S. 324 address any of these other addictions?

Extensive information on various addictions in the U.S. population is provided as an attachment to this letter.

FDA has provided a comprehensive discussion of nicotine addiction in its Nicotine Regulation Documents. These include references to the available literature and FDA's concerns with nicotine addiction, particularly in children. These documents are too voluminous to be replicated in this letter, however, they are readily available on FDA's Web site. The web site address is www.fda.gov. Once that site is accessed simply click on the icon "Children & Tobacco: Regulations & Information." The available documents include "Tobacco Regulations and Related Federal Register Documents" which contain the information referred to above.

The language provided in S. 324 is that the provisions would apply to any narcotic drugs or combination of drugs in schedule IV or V which are approved for use in maintenance or detoxification treatment, if certain other conditions are met. The terms "maintenance treatment" and "detoxification treatment" are defined in the Controlled Substances Act. Sections 102 (29) and (30) (21 U.S. C. § 802) define these terms. Since S. 324 would amend the Controlled Substances Act, these definitions would be applicable.

13. Does the Administration have an effort under way to study and demonstrate the use of anti-addictive medicines, particularly buprenorphine, in non-clinical settings? Please describe this activity and indicate what impact, if any, S. 324 would have on the substance and timing of this effort. Please describe in terms of efficacy, diversion, and other relevant health and safety considerations the differences between the administrative program already under way and the program contemplated by S. 324. In view of your existing administrative efforts, is legislation needed?

The NIDA-VA study 1008, the pivotal efficacy and safety trial for the buprenorphine and buprenorphine/nx tablets, was performed in a non-methadone clinic setting (i.e., outpatients in VA medical centers). The efficacy of buprenorphine and buprenorphine/nx was demonstrated in this study. Additionally, O'Connor et al (attached) evaluated buprenorphine in a primary care medical setting versus a traditional methadone clinic.

Expanding on this, NIDA intends to undertake a study of buprenorphine/nx in a variety of non-clinic settings to gather information on the use of this medication in

special populations, such as adolescents. Although the proposed study is not required for the basic NDA and is not relevant to the safety and efficacy data required for approval of the product, it may provide additional information to FDA that may be helpful in development of recommended labeling for the product. It will also provide Public Health Service agencies the opportunity to evaluate physician-training materials. Not only will this study provide valuable information, but it will be in compliance with a Congressional mandate that all National Institutes of Health research studies include children and adolescents when relevant and feasible. Additionally, the study report could be presented as part of the data package from the Office of the Secretary, HHS in determining whether buprenorphine treatments have been effective forms of maintenance and detoxification as called for in S. 324.

The enactment of S. 324 would have no impact on this study. S. 324 would permit the introduction of buprenorphine and buprenorphine/nx, if approved by the FDA, in a limited and controlled manner, to settings other than traditional methadone clinics. It is widely recognized (see Federal Regulation of Methadone Treatment; National Academy Press, Washington, D.C. 1995) that meaningful further expansion of the present methadone clinic system is not probable under the current weight of Federal, state, and local regulations. The experience with the introduction of LAAM, an orphan product approved in 1993, into this clinic system is highly instructive. It took the majority of States three years beyond Federal approval to approve the use of LAAM in their clinic systems. Moreover, each clinic needed to be registered on an individual basis. Only one fourth of the extant narcotic treatment programs have ordered LAAM. Because all treatment with methadone and LAAM must be provided through these clinics, virtually no expansion of treatment has occurred. In other words, the same 180,000 clients per year are receiving either methadone or LAAM (of which approximately 5,000 are LAAM patients). As a public health matter, the limited number of methadone clinics in this country is the rate limiting factor in providing additional pharmacological treatment for heroin addiction. This is occurring at a time when, as you note, heroin use is rising, and the burden of infectious diseases such as HIV, hepatitis, and tuberculosis is rising concurrently.

Because buprenorphine combined with naloxone will be the product utilized in outpatient treatment, its diversion potential is expected to be much lower than that of either methadone or LAAM. The Drug Enforcement Administration has recognized as much. A copy of the letter of July 14, 1998, from Thomas A. Constantine, Administrator, Drug Enforcement Administration, to the Honorable Bill McCollum concerning its views on this matter is forwarded with these comments.

In our view, to consign new treatment medications, with enhanced safety and less diversion potential solely into the existing methadone clinic system would be a serious public health mistake. S. 324 would permit incremental treatment expansion to proceed in a manner which is not overburdened by Federal, state, and local requirements as is the case with methadone clinic regulation. This treatment expansion cannot occur if new anti-addiction drug products are only permitted to be dispensed through the existing methadone clinic system, because it is a limited and closed capacity system.

It is important to point out that buprenorphine or buprenorphine/nx is not expected to replace methadone. In fact, methadone and LAAM clinics would remain an important part of the treatment system. Clinics are likely to receive referrals for patients who do not do well on buprenorphine and buprenorphine/nx or who need specialized services provided in clinics; and clinics may wish to move some of their patients to buprenorphine and buprenorphine/nx, either for maintenance or detoxification. This could mean that methadone clinics could admit additional patients, currently on waiting lists, for whom methadone or LAAM is the most appropriate treatment choice.

Question 12:

Buprenorphine is intended to treat heroin addiction. Can you provide an analysis of all addictions that lead to an increase in morbidity and mortality in the United States? Please include information available to you regarding trends, socioeconomic status, race and ethnic factors, and other measures used by public health officials to assess and evaluate public health issues and public policy responses to them. Vice President Gore recently was the keynote speaker at a NIDA sponsored National Research Forum. He is quoted in "Nida Notes" as saying that "nicotine is a drug—a dangerous, highly addictive drug, and we should treat as a drug... nicotine is a highly addictive drug—as addictive as heroin or cocaine." Your analysis should specifically include nicotine. Does S. 324 address any of these other addictions?

Answer:

According to a special study of causes of death in 1990, tobacco accounted for 38 percent, the greatest proportion of preventable deaths in the United States.

(McGinnis & Foege. "Actual Causes of Death in the United States." Journal of the American Medical Association 270(18):2207-2212. The others are listed below:

Actual Causes of Preventable Deaths in the United States

Cause	Estimated Number	Percentage of Total
Total	1,060,000	100
Tobacco	400,000	37.7
Diet/Activity Patterns	300,000	28.3
Alcohol	100,000	9.4
Toxic agents	90,000	8.5
Microbial agents	60,000	5.7
Firearms	35,000	3.3
Sexual Behavior	309,000	2.8
Motor Vehicles	25,000	2.4
Illicit use of drugs	20,000	1.9

With regard to the use of alcohol, cigarettes and other drugs for the U.S. population age 12 and older:

Prevalence of Past-Month Alcohol, Cigarette, and Other Drug Use U.S. Population, Age 12 and Older, 1997*

Substance	Number Using (1,000s)	Percent Using
Alcohol	111,071	51.4
Cigarettes	64,056	29.6
Any illicit drug	13,904	6.4
Marijuana	11,109	5.1
Non-medical use of psychotherapeutics	2,665	1.2
Cocaine	1,505	0.7
Hallucinogens	1,632	0.8
Inhalants	883	0.4
Heroin	325	0.2

*From Preliminary Results from the 1997 National Household Survey on Drug Abuse.

Of important note here is that the prevalence of past-month use of heroin in the US Population, age 12 and older, has been steadily increasing since 1993 when the number of estimated past month users was at 68,000.

If we look at the age break out of those who have used alcohol, cigarettes or other drug during the past month we get the following picture:

Age Intervals
Past Month Use 1997*
[In percent]

Substance	12-17	18-25	26-34	35 and older
Alcohol Use (Any)	20.5	58.4	60.2	52.8
Alcohol Use (Heavy)	3.1	11.1	7.5	4.0
Cigarettes	19.9	40.6	33.7	27.9
Any illicit drug	11.4	14.7	7.4	3.6
Marijuana	9.4	12.8	6.0	2.6
Cocaine	1.0	1.2	0.9	0.5
Heroin	0.4	0.6	0.2	0.1

*From Preliminary Results from the 1997 National Household Survey on Drug Abuse.

You also asked for information on use by race and ethnic groups. Attached are several tables which indicate demographic characteristics of the populations using any illicit drug, marijuana, cocaine, alcohol, and cigarettes which you will find informative. Also attached are tables summarizing trends since 1979 with regard to any illicit drug, marijuana, cocaine, alcohol and cigarettes.

With regard to heroin, we are transmitting with these responses a paper prepared by the Office of Applied Studies in SAMHSA entitled "Heroin Abuse in the United States."

The final question asked here is whether S. 324 address any of these other addictions? S. 324 focuses on schedule IV and V drugs used for the treatment of opiate addiction. Thus it does not apply to any medications that would address cocaine, marijuana, inhalant, hallucinogenics, or any other drug, nor does it focus on alcohol abuse or cigarettes addiction.

DEPARTMENT OF PHARMACOLOGY
THE UNIVERSITY OF MICHIGAN MEDICAL SCHOOL
3 June 1999

The Honorable JOHN DINGELL
United States House of Representatives
Room 2328
Rayburn House Office Building
Washington, DC 20515-2216

DEAR REPRESENTATIVE DINGELL

It is my understanding that the Commerce Subcommittee on Health and the Environment of the House of Representatives will soon take up consideration of S. 324, the Drug Addiction Treatment Act of 1999, sponsored by Senators Hatch, Levin, and Moynihan. I strongly endorse this bill. I believe it will have a highly salutary effect on narcotic addiction through the appropriate use of medication. One of the important aspects of the bill is the use of buprenorphine by well-trained physicians to treat narcotic addiction from their offices. Thus, S. 324 has the potential to attract and treat effectively sizable populations of currently untreated addicts. A major by-product of this increased treatment, of course, will be a reduction in the demand for illicit narcotics in the United States.

In my career in experimental medicine at the University of Michigan, I have worked a great deal with buprenorphine in preclinical research in primates. I have published over a dozen scientific articles on buprenorphine and its potential as a pharmacotherapy for narcotic addiction. It is remarkably nontoxic and long-lasting relative to other drugs (e.g., methadone) and should be very attractive to illicit opioid users who are wary of the stigmatization associated with current approaches to pharmacotherapy of narcotic addiction. S. 324 is both an important step toward appropriate use of a new medication and new, physician-based approach to dealing with addiction. I am very hopeful that you will urge that S. 324 be given careful and urgent consideration by the Commerce Committee.

I have been very pleased to help Senator Levin and his staff in his efforts in dealing with drug abuse issues (Congressional Record, 28 January 1999, S. 1091). I was very proud to have been given the opportunity to show Senator Levin our laboratories at the University of Michigan and to talk about our efforts toward developing a new pharmacotherapy for cocaine addiction. This approach utilized a cocaine catalytic antibody, a way of immunizing an individual against the effects of cocaine. This work continues to be very promising, and we are beginning the long process of convincing the scientific community of its worth.

Incidentally, I have also had the good fortune on a number of occasions of working with your brother, Jim, when he was at the National Institute on Drug Abuse. I enjoyed the interaction.

Thank you for your attention to S. 324, and I hope you, too, will become enthusiastic about its worth.

Yours sincerely,

JAMES H. WOODS, PH.D.
Professor

MPHA
July 29, 1999

The Honorable CARL LEVIN
United States Senate
459 Russell Senate Office Building
Washington, D.C.

DEAR SENATOR LEVIN: I am pleased to advise you of the support of the Michigan Public Health Association with your S. 324, the Drug Addiction Treatment Act of 1999. The Michigan Public Health Association is an advocate of a variety of sub-

stance abuse treatment programs that meet the particular needs of individuals, including methadone and buprenorphine treatment in the treatment of opiate addiction through physician offices. Substance abuse creates psychological, social, and familial problems.

Estimates from the Institute of Medicine (Institute of Medicine, 1990), a Robert Wood Johnson Foundation report, calculates that there are about five million users of illicit drugs, but a fourth of them receive treatment (Institute for Health Policy, 1993). The costs of substance abuse use problems are great. Substance abuse affects health care, costs, mortality, workers' compensation claims, reduced productivity, crime, suicide, domestic violence, and child abuse. Additionally, there are costs of unnecessary health care, extra law enforcement, motor vehicle crashes, crime, and lost productivity due to substance use. Substance abuse interventions that provide an avenue to regaining a healthy life are critical.

"The Michigan Public Health Association believes the use of the new medication buprenorphine in the treatment of opiate addiction through physician offices will provide access to treatment for heroin addicted users. Buprenorphine will allow drug addicted individuals to maximize everyday life activities, and participate more fully in work day and family activities while seeking the needed counseling to become drug free. Individuals who are substance-abuse free have less physical and sexual abuse, less criminal activity, fewer days lost from work/school that adds up to tremendous cost savings for society. The overall goal is to reduce drug use and the risk of the spread of HIV/AIDS, hepatitis B and C. Access to drug addiction treatment will increase the potential of physical and mental health for many people in the community."

Please let me know if the Michigan Public Health Association can be of further assistance to you with the passage of this important legislation. My telephone number is (313) 874-3084.

Sincerely,

STEPHANIE MEYERS SCHIM, PhD, RN,
President of the Michigan Public Health Association

cc: Mohammad N. Akhter, MD, MPH
Executive Director
American Public Health Association

Mr. BILIRAKIS. Thank you very much, Senator. Your remarks were well said certainly.

Do you agree that the legislation that was submitted in the House, actually was prepared and introduced by Chairman Bliley, is essentially a companion of yours and essentially the same? So you certainly endorse it.

Senator LEVIN. Absolutely.

Mr. BILIRAKIS. Over in the Senate you haven't had any opposition?

Senator LEVIN. None. In fact, we have a great deal of bipartisan support, and I have also statements of Senators Moynihan and Biden which I would submit for the record in support of the bill.

[The prepared statements of Hon. Daniel P. Moynihan and Hon. Joseph R. Biden, Jr. follow:]

PREPARED STATEMENT OF HON. DANIEL P. MOYNIHAN, A U.S. SENATOR FROM THE
STATE OF NEW YORK

Mr. Chairman, thank you for the opportunity to participate in this hearing to address the issue of the availability of new medications, such as buprenorphine, to block the craving of addictive substances, such as heroin.

Determining how to deal with the problem of addictive substances is not a new topic. Just over a decade ago when we passed the Anti-Drug Abuse Act of 1988, I was assigned by our then-Leader Robert Byrd, with Sam Nunn, to cochair a working group to develop a proposal for drug control legislation. We worked together with a similar Republican task force. We agreed, at least for a while, to divide funding under our bill between demand reduction activities (60 percent) and supply reduction activities (40 percent). And we created the Director of National Drug Control Policy (section 1002); next, "There shall be in the Office of National Drug Control Policy a Deputy Director for Demand Reduction and a Deputy Director for Supply Reduction."

We put demand first. I made the case, if you have any illusion that you can ever interdict the supply of drugs, well, don't let the National Institute of Mental Health find that out because they might well take a closer examination. There's no possibility.

I have been intimately involved with trying to eradicate the supply of drugs into this country. It fell upon me, as a member of the Nixon Cabinet, to negotiate shutting down the heroin traffic that went from central Turkey to Marseilles to New York—"the French Connection"—but we knew the minute that happened, another route would spring up. That was a given. The success was short-lived. What we needed was demand reduction, a focus on the user. And we still do.

Demand reduction requires science and it requires doctors. I see the science is becoming available, and the bill we are here to discuss offers us an important step in allowing doctors to make use of it.

Congress and the public continue to fixate on supply interdiction and harsher sentences (without treatment) as the "solution" to our drug problems, and adamantly refuse to acknowledge what various experts now *know* and are telling us: that addiction is a chronic, relapsing disease; that is, the brain undergoes molecular, cellular, and physiological changes which may not be reversible.

What we are talking about is not simply a law enforcement problem, to cut the supply; it is a public health problem, and we need to treat it as such. We need to stop filling our jails under the misguided notion that such actions will stop the problem of drug addiction.

PREPARED STATEMENT OF HON. JOSEPH R. BIDEN, JR., A U.S. SENATOR FROM THE
STATE OF DELAWARE

Nearly ten years ago, in December 1989, I released a Senate Judiciary Committee Report entitled "Pharmacotherapy: A Strategy for the 1990s." In this report I argued that there was scientific promise for medicines that might lessen an addict's craving for cocaine and heroin, as well as to reduce their enjoyment of those drugs.

This report asked the question: "If drug abuse is an epidemic, are we doing enough to find a medical 'cure'?"

At the time, despite the efforts of myself and other members of Congress, the answer to that question was as clear as it was distressing: the nation was doing far too little to find medicines that treat the disease of drug addiction.

To address this shortfall, I authored, along with Senator Kennedy, the Pharmacotherapy Development Act—which passed into law in 1992. The cornerstone of this Act was its call for a ten year, \$1 billion effort to research and develop anti-addiction medications.

I cannot think of a more worthwhile investment. There is no other disease that effects so many, directly and indirectly. We have 14 million drug users in this country, four million of whom are hardcore addicts. We all have a family member, neighbor, colleague or friend who has become addicted. We are all impacted by the undeniable correlation between drugs and crime—an overwhelming 80 percent of the 1.8 million men and women behind bars today have a history of drug and alcohol abuse or addiction or were arrested for a drug-related crime. It only makes sense to unleash the full powers of medical science to find a "cure" for this social and human ill.

Ten years ago, the question was: "Are we doing enough to find a 'cure'?" Unfortunately that question is still with us. But today we also have another question: "Are we doing enough to get the 'cures' we have to those who need them?" We have an enormous "treatment gap" in this country. Only two million of the estimated 4.4 to 5.3 million people who need drug treatment are receiving it. Licensing qualified doctors to prescribe Schedule IV and V medications from their offices is a significant step toward bridging the treatment gap.

Right now we have some highly effective pharmacotherapies to treat heroin addiction and we are still working on developing similar medications for cocaine addiction. Access to currently available medications such as methadone and LAAM (Levo-Alpha Acetylmethadol) has been strangled by layers of bureaucracy and regulation. As a result, only 22 percent of opiate addicts are now receiving pharmacotherapy treatment. General McCaffrey is leading the charge to fix that problem and I applaud his efforts.

The difficulties of distributing treatment medications to addicts not only hurts those who are not getting the treatment they need, but it also stifles private research. I have often bemoaned the fact that private industry has not aggressively developed pharmacotherapies. As we increase access to these drugs, we increase incentives for private investment in this valuable research.

I am proud to be a cosponsor of “The Drug Addiction Treatment Act of 1999” because it ensures that the product gets to market. By allowing certain doctors to dispense Schedule IV and V drugs from their offices, the bill expands treatment flexibility and access and encourages others to develop similar medications.

Mr. Chairman, I am encouraged that you have convened this hearing today to discuss the House version of this bill. I look forward to working with you on this most important matter.

Senator LEVIN. And I very much support the companion bill here, which I understand is similar or the same to ours.

One final important point, States can opt out of this. If a State does not want to permit this, it has 3 years to opt out. It is a very important provision because there is an argument that a State may want to opt out of this provision, and we give that opportunity to the States.

Mr. BILIRAKIS. Thank you very much, sir. I know the Senator has a vote taking place in the Senate. He seems to be patient enough