

DRUG ADDICTION TREATMENT ACT OF 1999

NOVEMBER 3, 1999.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BLILEY, from the Committee on Commerce,
submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 2634]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 2634) to amend the Controlled Substances Act with respect to registration requirements for practitioners who dispense narcotic drugs in schedule IV or V for maintenance treatment or detoxification treatment, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Drug Addiction Treatment Act of 1999”.

SEC. 2. AMENDMENT TO CONTROLLED SUBSTANCES ACT.

(a) IN GENERAL.—Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) is amended—

(1) in paragraph (2), by striking “(A) security” and inserting “(i) security”, and by striking “(B) the maintenance” and inserting “(ii) the maintenance”;

(2) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively;

(3) by inserting “(1)” after “(g)”;

(4) by striking “Practitioners who dispense” and inserting “Except as provided in paragraph (2), practitioners who dispense”; and

(5) by adding at the end the following paragraph:

“(2)(A) Subject to subparagraphs (D) and (I), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule IV or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

“(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before dispensing narcotic drugs in schedule IV or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

“(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

“(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

“(iii) In any case in which the practitioner is not in a group practice, the total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 40, except that the Secretary may by regulation change such total number.

“(iv) In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 40, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.

“(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule IV or V or combinations of such drugs are as follows:

“(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.

“(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such

treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

“(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

“(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

“(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

“(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

“(ii) The Secretary shall assign a unique identifier to each notification under subparagraph (B), and shall provide to the Attorney General all information contained in such notifications.

“(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule IV or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

“(ii)(I) A practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule IV or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary.

“(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

“(F)(i) With respect to the dispensing of narcotic drugs in schedule IV or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

“(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

“(G) For purposes of this paragraph:

“(i) The term ‘group practice’ has the meaning given such term in section 1877(h)(4) of the Social Security Act.

“(ii) The term ‘qualifying physician’ means a physician who is licensed under State law and who meets one or more of the following conditions:

“(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

“(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

“(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

“(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

“(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule IV or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

“(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide

maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

“(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for three years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

“(H) During the 3-year period beginning on the date of the enactment of the Drug Addiction Treatment Act of 1999, any law or regulation of a State or political subdivision of a State that is in conflict with this paragraph is superseded by this paragraph. If before the expiration of such period a State or political subdivision of a State enacts such a law, then upon the expiration of the period this paragraph ceases to supersede the law.

“(I)(i) This paragraph takes effect on the date of the enactment of the Drug Addiction Treatment Act of 1999, and remains in effect thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).

“(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on the date of the enactment of the Drug Addiction Treatment Act of 1999, make determinations in accordance with the following:

“(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

“(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule IV or V or combinations of such drugs are being dispensed or possessed in violation of this Act; and may make a determination of whether such waivers have adverse consequences for the public health.

“(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that this paragraph should not remain in effect, this paragraph ceases to be in effect 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.”.

(b) CONFORMING AMENDMENTS.—Section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended—

(1) in subsection (a), in the matter after and below paragraph (5), by striking “section 303(g)” each place such term appears and inserting “section 303(g)(1)”; and

(2) in subsection (d), by striking “section 303(g)” and inserting “section 303(g)(1)”.

SEC. 3. ADDITIONAL AUTHORIZATION OF APPROPRIATIONS REGARDING DEPARTMENT OF HEALTH AND HUMAN SERVICES.

For the purpose of assisting the Secretary of Health and Human Services with the additional duties established for the Secretary pursuant to the amendments made by section 2, there are authorized to be appropriated, in addition to other authorizations of appropriations that are available for such purpose, such sums as may be necessary for fiscal year 2000 and each subsequent fiscal year.

PURPOSE AND SUMMARY

The purpose of H.R. 2634, the Drug Addiction Treatment Act of 1999, is to amend certain Controlled Substances Act (21 U.S.C. 823) registration requirements for practitioners who dispense narcotic drugs in schedule IV or V for maintenance treatment or detoxification treatment. It frees qualified physicians to treat their addicted patients using schedule IV or V drugs, promises to speed the further development and approval of schedule IV and V narcotic drugs suitable for addiction treatment purposes, and offers the prospect of medical treatment for the many Americans for whom other treatment programs are out of reach.

Under existing law, physicians must register with the Drug Enforcement Administration (DEA) in order to dispense controlled substances. If physicians wish to dispense narcotic controlled substances for maintenance and detoxification treatment, the physicians must have the additional prior approval of the DEA, as well as the endorsement of State and local regulatory authorities, and the drugs used in treatment must have been approved by the Food and Drug Administration (FDA). The bill waives the additional approval process for qualified physicians who comply with the waiver procedure. For three years following enactment, the bill supersedes any conflicting State or local law or regulation.

The waiver procedure only extends to physicians registered to dispense controlled substances and qualified by training or experience to treat opiate-dependent patients. Physicians activate the waiver mechanism by notifying the Secretary of Health and Human Services (the Secretary) in writing of their intention to begin treatments and documenting their qualifications. The waiver is available for treatment involving schedule IV or V controlled substances, alone or in combination, and unless the number is adjusted by the Secretary, for the treatment of no more than forty patients at any one time.

The bill relies on several safeguards against abuse of the waiver procedure. The Secretary may deny access to the waiver mechanism in the case of treatments using a particular drug or combination of drugs should the Secretary determine that the drug or drugs warrant either more demanding physician qualification standards or more narrowly defined restrictions on the quantities that may be dispensed for unsupervised use.

Physicians risk the loss of their registration to dispense controlled substances and in serious cases criminal prosecution, if they dispense schedule IV or V controlled substances absent either the existing approval procedure or the bill's mechanism waiving the requirements of that procedure.

Finally, within three years following enactment, the Secretary and the Attorney General may end availability of the waiver. The Secretary's decision may turn upon determinations whether (1) the treatments provided under the waiver mechanism have been effective forms of clinical treatment; (2) the waivers have increased the availability of treatment; or (3) the treatments have had adverse public health consequences. The Attorney General's decision may likewise be grounded upon (1) the waiver mechanism's adverse public health consequences; (2) the extent to which the numerical

limitations on patients under treatment have been breached; or (3) the extent to which the waiver mechanism has contributed to an increase in violations of the Controlled Substances Act that involve schedule IV or V drugs.

BACKGROUND AND NEED FOR LEGISLATION

Opiate dependency is a large and growing problem in the United States. Current estimates suggest that nearly 600,000 people need treatment for heroin addiction alone. Research conducted by the Office of National Drug Control Policy suggests a shift from injecting heroin to snorting or smoking heroin because of increased purity and the misconception that these forms of use will not lead to addiction. It is these latter forms of heroin abuse that have led to a significant increase of heroin abuse among American high school students.

Heroin abuse is associated with serious health conditions, including fatal overdose, spontaneous abortion, collapsed veins, and infectious diseases, including HIV/AIDS and hepatitis. The short-term effects of heroin abuse appear soon after a single dose and disappear in a few hours. After an injection of heroin, the user reports feeling a surge of euphoria accompanied by a warm flushing of the skin, a dry mouth, and heavy extremities. Following this initial euphoria, mental functioning becomes clouded due to the depression of the central nervous system.

Heroin has costs that can never be adequately calculated: family breakups, battering and abuse, neglect, malnutrition, HIV and hepatitis infections, violence, crime, and deadly accidents. No family or community should have to pay the price demanded by heroin addiction. Congress has taken action to make available treatments for heroin addiction, but must do more in light of newer and better treatments under the rubric of the Controlled Substances Act.

The Controlled Substances Act provides much of the framework for Federal and State regulation of the manufacture and distribution of substances that are subject to abuse but that may have beneficial medicinal uses. The Controlled Substances Act assigns substances to one of five schedules according their potential for abuse, addiction, and medical utility. Thus, for instance, schedule I substances (such as heroin) have a high potential for abuse, no accepted medical use, and are unsafe for use even under medical supervision. Schedule II substances (such as methadone) are characterized by a high potential for abuse, the prospect of severe addiction following abuse, but under tight restrictions have accepted medical uses. Schedules III, IV and V substances have accepted medical uses, but are less prone to abuse and less likely to be addictive. Thus, schedule III is reserved for substances with accepted medical utility, whose potential for abuse is less than schedule I or II substances, whose abuse may lead to moderate or low levels of addiction, such as Tylenol with codeine. Schedule V houses medically beneficial substances with the least potential for abuse and addiction.

Medical practitioners may not administer or dispense schedule I controlled substances, and they must be registered with DEA to administer or dispense controlled substances on other schedules. For each controlled substance, DEA insists on a level of security, record

keeping, and inspections consistent with the schedule to which the substance has been assigned.

Methadone has been a mainstay of opiate addiction treatment for over thirty years. Methadone, however, is itself subject to abuse and is both a narcotic and a schedule II controlled substance. Congress enacted the Narcotic Addict Treatment Act, cognizant of the dangers and possible benefits of methadone treatment. The Narcotic Addict Treatment Act and its implementing regulations establish the minimum specifications for programs that treat opiate addiction with narcotic drugs such as methadone.

The Narcotic Addict Treatment Act compels practitioners who dispense narcotic drugs for maintenance treatment or detoxification treatment to obtain a separate, specific registration from DEA every year. The regulations augment this basic requirement with an array of instructions that one commentary describes in following encapsulated terms:

Program approval and structure:

- Submission of applications (to FDA and state authorities);
- Compliance with special DEA security requirements;
- Organizational structure (e.g., primary facility, medication unit, program sponsor, medical director); and,
- Notification of FDA and state authorities of changes in organizational structure.

Use of "narcotic drugs"

- Designation of approved medications;
- Security of drug stocks (standards as required by the DEA);
- Dosing (initial dose, justification for high doses, who may dispense, form and route of medication, packaging or take-home doses); and,
- Hospital detoxification treatment.

Clinical standards and required services

- Admission standards (addiction history, physiologic dependence, voluntary participation, informed consent; exceptions if coming from penal or chronic care institutions, pregnant patients, previously treated patients; limitations if under 18 years of age);
- Admission evaluation (psychologic and sociologic background);
- Medical services (e.g., confirm patient suitability, medical evaluations, laboratory studies, countersign orders and treatment plans, justify take-home medications, physician review of treatment plan);
- Contents of medical evaluation (including history, physical examination, laboratory examinations);
- "Initial treatment plan" and "periodic treatment plan evaluation" (describes treatment and rehabilitative service needs);
- Referral to vocational rehabilitation, education, and employment services;
- Minimal frequency of attendance (quantity of take-home medication); and,
- Drug testing.

Administrative

- Clinical and administrative record keeping;
- Staffing pattern considerations; and,
- Conduct of research.

Special populations

- Services for pregnant patients;
- Special standards for short-term detoxification treatment; and,
- Special standards for long-term detoxification treatment.¹

Before the FDA will consider a program application, it must have the endorsement of the State authorities in the locale where the program is to operate. State prerequisites must be at least as rigorous as the Federal standards, many are more so. Federal regulations, for instance, limit programs to the treatment of patients who have been addicted for at least a year. It is not uncommon for a State to raise the bar so that only patients who have been addicted for at least two years may be treated.

These multiple layers of protection are not inconsequential. They dictate treatment by “program” rather than by individual physician. Programs are largely found in urban areas. In several States, there are no programs at all. They chill the development of alternative medication. Only methadone and another schedule II substance, levo-alpha-acetyl-methadol (LAAM), have been approved for program use. The FDA approved LAAM, which unlike methadone need not be taken daily, in 1993. Yet, largely due to regulatory delays at the Federal level and difficulties associated with implementation within State regulatory schemes, far fewer than half of the treatment programs have been authorized to dispense LAAM.

The United States has an estimated 810,000 opiate-dependent individuals. The most frequently used agent in medically supervised opiate withdrawal and maintenance treatment is methadone. Combined methadone and LAAM treatment programs reach approximately 180,000 opiate-dependent Americans.

Methadone’s half-life is approximately 24 hours and leads to a long duration of action and once-a-day dosing. Its long duration of action and its slow onset of action blunts its euphoric effect, making it unattractive as a principal drug of abuse. LAAM, a less commonly used opiate agonist, has a longer half-life and may prevent withdrawal symptoms for up to 96 hours.

Research and testing led by the National Institute on Drug Abuse suggest that at least one substance, buprenorphine (expected to be approved by FDA as a schedule V drug for the treatment of opiate addiction), particularly in conjunction with naloxone, will be an effective supplement for methadone/LAAM treatment. Buprenorphine has proven to be a very effective treatment for detoxification and maintenance in Europe, and is expected to be approved for detoxification and maintenance use in the United States in the near future.

Buprenorphine, although expected to be in the least dangerous class of controlled substances for treatment of addicts, is a narcotic

¹Strain & Stitzer, Methadone Treatment for Opioid Dependence, Table 2.1. Program Aspects Required or Described by U.S. Federal Regulations (DHHS, FDA, 21 CFR Part 291) for Methadone, 18 (1999).

drug and as such would be subject to the same regulatory regime as methadone and LAAM. In order to encourage the development of such schedule IV and V addiction medication, the Drug Addiction Treatment Act creates an alternative regulatory pathway, one more compatible with the less addictive and less abuse prone substances that populate schedules IV and V. To do so, it must navigate a new route around the forbidding Federal and State regulations promulgated many years ago to address the much more dangerous schedule II drugs like methadone.

According to a July 14, 1999, letter to Ranking Minority Member John D. Dingell from Secretary of Health and Human Services Donna Shalala, buprenorphine (and buprenorphine/naloxone in combination) "has very limited euphorogenic effects, and has the ability to precipitate withdrawal in individuals who are highly dependent on other opiates. Thus, buprenorphine and buprenorphine/nx products are expected to have low diversion potential." The Secretary also states that these drugs should "increase the amount of treatment capacity available and expand the range of treatment options that can be used by physicians," and that:

* * * 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).

The simple words of a witness at the July 30, 1999, hearing held by the Subcommittee on Health and Environment convey how deeply important enactment of the Drug Addiction Treatment Act of 1999 would be to men and women struggling with heroin addiction. Mr. Odis Rivers, a patient at the Jefferson Avenue Treatment Research Program in Detroit, Michigan, introduced himself to the Subcommittee with the following testimony:

I am a recovering heroin addict enrolled in a treatment research project at the Wayne State University School of Medicine. I have been addicted to heroin since 1970. I am a three year veteran of the U.S. Army where I served overseas in South Korea. I became addicted to heroin when I returned from the army in 1970 the same year that I was diagnosed with diabetes. I have made many attempts to overcome my heroin addiction but have always relapsed. Today I am proud to say that I have been drug free for over 6 months and feel increasingly confident that I can stay that way.

The medication, buprenorphine, that I have received at the Jefferson Avenue Treatment Research Program has been one of the most important parts of my recovery. Six months ago when I came to the Research Clinic I was separated from my wife and over the 29 years that I was a heroin addict I had lost the respect of my family. Today I am back with my wife and am looking forward to making up for all of the time I lost with her when I was addicted. I am also very lucky to have a family who has seen that

I am attempting to turn my life around. It feels good to have their respect and I can be a big brother again to my sister. That means a lot to me and I know having this respect will help me in my recovery.

HEARINGS

The Subcommittee on Health and Environment held a hearing on H.R. 2634, the Drug Addiction Treatment Act of 1999, on July 30, 1999. The Subcommittee received testimony from: The Honorable Orrin Hatch, Senator, State of Utah, and The Honorable Carl Levin, Senator, State of Michigan; Dr. Alan I. Leshner, Director, National Institute on Drug Abuse, accompanied by Dr. Frank J. Vocci, Director, Medications Development Division, National Institute on Drug Abuse; Dr. H. Westley Clark, Director, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration; Dr. Charles Schuster, Director Clinical Research Division on Substance Abuse, Wayne State University, Detroit, Michigan, accompanied by Mr. Odis Rivers, Citizen, State of Michigan; Dr. Larry L. Alexander, Emergency Room Physician, Baylor Medical Center at Irving; Mr. Robert E. Anderson, Director, Research and Program Applications, National Association of State Alcohol and Drug Abuse Directors; Ms. Jenny Collier-McColl, Director of National Policy, Legal Action Center; and Dr. Thomas Kosten, President, American Academy of Addiction Psychiatry.

COMMITTEE CONSIDERATION

On September 30, 1999, the Subcommittee on Health and Environment met in open markup session and approved H.R. 2634 for Full Committee consideration, amended, by a voice vote. On October 13, 1999, the Full Committee met in open markup session and ordered H.R. 2634 reported to the House, amended, by a voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 2634 reported. An amendment by Mr. Bliley to authorize such sums as may be necessary for FY 2000 and each subsequent fiscal year for carrying out the purposes of the legislation was agreed to by a voice vote. A motion by Mr. Bliley to order H.R. 2634 reported to the House, amended, was agreed to by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a legislative hearing and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM OVERSIGHT FINDINGS

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2634, the Drug Addiction Treatment Act of 1999, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

While the Committee adopts the CBO estimate submitted pursuant to section 402 of the Congressional Budget Act for those costs subject to appropriation, the Committee believes that CBO's estimates with respect to direct spending are significantly overstated. For this reason, the Committee adopts its own estimate.

	By fiscal years, in millions of dollars—				
	2000	2001	2002	2003	2004
CHANGE IN SPENDING SUBJECT TO APPROPRIATION					
SAMHSA:					
Authorization Level	5	5	5	5	5
Estimated Outlays	3	5	5	5	5
CHANGE IN DIRECT SPENDING					
Medicaid:					
Estimated Budget Authority	(1)	(1)	(1)	(1)	(1)
Estimated Outlays	(1)	(1)	(1)	(1)	(1)

¹ Less than \$500,000.

Basis of estimate

There is no Federal requirement that Medicaid programs pay for maintenance or detoxification programs for opiate dependency. Secretary of Health and Human Services Donna Shalala recognized this fact when she was asked in writing by Representative John D. Dingell about “the expenditure of resources by any agency of the federal government” in order to implement S. 324, the Senate companion to H.R. 2634. The Secretary responded in a letter on July 14, 1999, stating that “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.” (reproduced in “Drug Addiction Treatment Act of 1999,” Hearing Before the Subcommittee on Health and Environment of the Committee on Commerce, House of Representatives, page 11, Serial No. 106–45). The Department does not anticipate that Medicaid will bear any significant costs due to this legislation.

On September 28, 1999, the CBO provided an estimate of S. 486, the Methamphetamine Anti-Proliferation Act of 1999, to the Senate Committee on the Judiciary. S. 486 contained the language of S. 324, the Senate companion to H.R. 2634. In that estimate, CBO estimated that direct spending would not exceed \$500,000 in any given year.

The Committee believes that the original estimate of this legislation by CBO was correct. CBO estimated the number of individuals who will benefit from the introduction of buprenorphine will ultimately be 100,000, but the Committee believes that this will not take place in a five-year period. According to an internal memorandum prepared by the company with marketing rights of Suboxone (the commercial name of buprenorphine), the number of patients enrolled in buprenorphine programs after the passage of this legislation would start at very modest levels and would increase over time, reaching 38,000 to 45,000 patients by year 5 and growing each subsequent year to a plateau of some 100,000 in the out years. The estimates contained in the table below are based on Subutex tablet usage data from France, a country with the highest penetration of buprenorphine treatment for its opioid-addicted population.

Fiscal year	2000	2001	2002	2003	2004
Number of Patients	4,000	16,000	27,000	33,000	45,000
Effect of H.R. 2634 (in percent)	100	25	12	8	4
Number Due to H.R. 2634	4,000	4,000	3,240	2,640	1,800

When a new drug is approved for the use of treating addicts, regulations are promulgated under the Controlled Substances Act for that purpose and for that drug. Each regulatory regime is unique. H.R. 2634, however, would allow certain physicians to dispense an entire class of drugs (Schedule IV and V drugs) approved for that indication by the FDA without having to wait for the new regulations. The Committee has been diligent in working with the Administration for over a year to promulgate regulations as soon as buprenorphine is approved by FDA, which the Committee expects will occur in December 1999. The Committee estimates that the regulations for buprenorphine may be promulgated and finalized as late as one year from the date of FDA drug approval.

Because H.R. 2634 brings this drug to market in advance of the regulations under the Controlled Substances Act, CBO estimates that H.R. 2634 would accelerate the availability of the drug and would lead to 10 percent more people receiving the drug than if this legislation had not been enacted.

The 10 percent effect of the bill on the number of people being treated, however, is not a linear relationship, as the CBO estimate describes it. The Committee believes that the number of patients enrolled in a buprenorphine program will be 100 percent due to H.R. 2634 in the first year because Schedule IV or V medication prescribed in advance of the regulations would be solely due to H.R. 2634. Allowing for uncertainty that regulations will be finalized for the second year after FDA approval, the Committee estimates that as many as 25 percent of the patients enrolled in treatment could be ascribed to the legislation. The probability that any patients enrolled in buprenorphine treatment programs solely due

to H.R. 2634 will decline markedly over the next few years, with a residual 4 percent probability in year 5.

CBO estimates that the average annual cost of treatment with buprenorphine would be about \$4,300 per person in the year 2000, evenly divided between the cost of the drug itself and the cost of related medical and mental health services. The Committee believes that CBO erred in ascribing mental health services to the cost of H.R. 2634. Any patient who is enrolled in a drug treatment program for opioid addiction is already receiving these ancillary services; substituting one drug treatment program for a less effective one will have no impact on the consumption of ancillary services like mental health counseling. The Committee believes it is an appropriate estimate that the buprenorphine treatments will cost approximately \$2,150 for a twelve month period.

CBO also estimated that in 1992 about 12 percent of all methadone treatment was paid for by Medicaid, and assumed that a similar share of the buprenorphine market would be paid for by Medicaid. The Committee believes that CBO overestimated those numbers. Methadone treatment is largely reserved for those who have been addicted to relatively high levels of opioids (generally heroin) for a relatively long period of time. Typically, an addict cannot enroll in a methadone program until he or she has been addicted for a year, by which time the drug has done its damage and the addict can no longer work productively. Long-term drug addiction is a major cost driver in public assistance programs.

In the July 14th letter to Representative John D. Dingell, "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 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)." Those patients enrolled in methadone treatment programs have a greater propensity to be Medicaid eligible (oftentimes, due to their addiction) than those who would be appropriate for buprenorphine treatment. The Committee believes that Medicaid eligible addicts will comprise as much as 9 percent of those patients for whom buprenorphine treatment would be appropriate. For this estimate, the Committee believes that CBO is correct in assuming that 57 percent of Medicaid costs will be reimbursed by the Federal government.

For the aforementioned reasons, the Committee believes that its estimate more accurately reflects the costs associated with the enactment of H.R. 2634 than the CBO estimate reprinted below.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 29, 1999.

Hon. TOM BLILEY,
*Chairman, Committee on Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2634, the Drug Addiction Treatment Act of 1999.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Cyndi Didzinski (for costs to the Substance Abuse and Mental Health Services Administration); Dorothy Rosenbaum (for Medicaid costs); Lisa Cash Driskill (for the state and local impact); and John Harris (for the private-sector impact).

Sincerely,

BARRY B. ANDERSON
(For Dan L. Crippen, Director).

Enclosure.

H.R. 2634—Drug Addiction Treatment Act of 1999

Summary: H.R. 2634 would amend the Controlled Substances Act of 1970 to enable qualifying practitioners who wish to dispense narcotic drugs in schedule IV or V for detoxification treatment to apply to the Secretary of Health and Human Services (HHS) for a waiver of the Drug Enforcement Administration's (DEA's) registration requirements. The program would be implemented by the Substance Abuse and Mental Health Services Administration (SAMHSA). The bill would authorize the appropriation of such sums as may be necessary for fiscal year 2000 and each subsequent year to pay for implementing the program and processing the waiver application, but specifies that no more than \$5 million per year may be obligated for this activity. Assuming appropriation of the necessary amounts, CBO estimates that implementing H.R. 2634 would cost the federal government about \$80 million over the 2000–2004 period—\$23 million in administrative costs for SAMSHA and \$30 million in additional Medicaid spending. Because the bill would affect direct spending, pay-as-you-go procedures would apply.

H.R. 2634 contains an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA), but CBO estimates that the costs would not be significant and would not exceed the threshold established in that act (\$50 million in 1996, adjusted annually for inflation). This bill would impose no new private-sector mandates as defined in UMRA.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 2634 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal years, in millions of dollars—				
	2000	2001	2002	2003	2004
CHANGE IN SPENDING SUBJECT TO APPROPRIATION					
SAMHSA:					
Authorized Level	5	5	5	5	5
Estimated Outlays	3	5	5	5	5
CHANGE IN DIRECT SPENDING					
Medicaid:					
Estimated Budget Authority	(¹)	5	5	10	10
Estimated Outlays	(¹)	5	5	10	10

¹ Less than \$500,000.

Basis of estimate: Under current law, physicians wishing to dispense narcotic drugs to treat narcotic dependence must first apply to HHS, which determines whether they are qualified to provide such treatment. Qualified physicians must then apply to DEA to be registered separately to dispense (not prescribe) such narcotic drugs in treatment. H.R. 2634 would permit physicians to dispense and prescribe narcotic drugs in schedule IV or V (the drugs rated the lowest risk for abuse) for maintenance or detoxification treatment, under certain conditions, instead of obtaining a separate DEA registration.

Under the waiver program in H.R. 2634, interested qualified practitioners would notify the Secretary of HHS, in writing, of their intent and certify that they meet the conditions in the bill relating to state licensing, training and experience, and other requirements. Physicians would proceed to provide such treatment unless they were notified otherwise by the Secretary. The bill would also authorize the Secretary to establish, by regulation, criteria for determining the necessary training and experience for qualified physicians. At any time during the three-year period following the enactment of this legislation, the Secretary, in consultation with the Attorney General, would be able to publish a decision to terminate the program based on specific adverse findings. If such a decision were published, the program would be eliminated within 60 days.

Spending subject to appropriation action

H.R. 2634 would create several new responsibilities for SAMHSA. Based on information from SAMHSA, CBO estimates that \$5 million per year would be required to fund the additional staff to formulate and publish regulations, establish an appropriate training curriculum, design practice guidelines, oversee practitioners, set up data base containing the names of practitioners who receive waivers, process providers' applications, and assess their qualifications. In addition, during the first three years, SAMHSA would collect data and provide information to the Attorney General to evaluate the impact of the program and make a determination of adverse use. Provided the program is not terminated, the provisions in H.R. 2634 would increase discretionary spending by a total of \$23 million over fiscal years 2000 through 2004. This estimate assumes that the necessary amounts would be appropriated for each fiscal year and that outlays would follow historical spending rates for similar activities.

Direct spending

Medicaid. CBO estimates that enacting H.R. 2634 would increase federal Medicaid spending by \$30 million over the 2000–2004 period because more Medicaid beneficiaries would receive new schedule IV and V narcotics over that period than under current law. Currently, no schedule IV or V narcotics are approved for outpatient maintenance or detoxification treatment. Methadone, a schedule II narcotic, is the principal narcotic currently used in treating opiate addiction. The distribution of methadone is regulated so that only certain providers who are registered with DEA may dispense it, and the daily doses usually must be provided in clinical settings and combined with counseling and other treatment services.

Later this year, the Food and Drug Administration (FDA) is expected to approve a new substance, buprenorphine, for the treatment of opiate addiction. According to HHS, buprenorphine is likely to be approved as a schedule IV or V narcotic because it has been found to have limited euphorogenic effects and therefore low desirability for sale on the street. Under current law, it is unclear exactly how buprenorphine will be distributed. Assuming FDA approves the drug, HHS and DEA will develop regulations to govern its distribution. Many experts believe that it would be appropriate to allow physicians to prescribe the drug from their office-based settings and to distribute it through commercial pharmacies, but final decisions and regulations will probably take about a year. Furthermore, under current law, many states have their own regulations governing the distribution of narcotics.

H.R. 2634 would specifically waive the DEA registration requirement that would otherwise apply to physicians who wish to prescribe buprenorphine and would allow physicians to prescribe that drug from their office-based settings. In addition, the bill would supersede state regulations for three years. CBO expects that enacting the bill would lead to somewhat wider distribution of buprenorphine than would otherwise occur—for two reasons. First, implementation of office-based distribution would probably occur faster than under current law and, second, the regulations that the Administration would issue under current law would probably be more restrictive than the procedures allowed by the bill.

Based on information from the National Institute on Drug Abuse, CBO estimates that ultimately about 100,000 individuals will receive buprenorphine each year if it is distributed through office-based settings. CBO expects that enactment of the bill would speed up the penetration of buprenorphine by one to two years and would ultimately lead to 10 percent more people receiving the drug. CBO further estimates that the average annual cost of treatment with buprenorphine would be about \$4,300 per person in 2000, evenly divided between the cost of the drug itself and the cost of related medical and mental health services. According to a report by the Institute of Medicine, in 1992 about 12 percent of all methadone treatment was paid for by Medicaid. For this estimate, CBO assumes that the same proportion of buprenorphine treatment would be covered by Medicaid, and that 57 percent of those costs would be reimbursed by the Federal Government. In addition, CBO estimates that one quarter of the costs of buprenorphine treatment

under the bill either would occur under current law or would be offset by reduced use of other medical or mental health services.

Drug Enforcement Administration. CBO estimates that implementing H.R. 2634 would have a negligible effect on the DEA. The agency collects a fee—\$70 a year, or \$210 every three years—from each practitioner for dispensing controlled substances (including narcotics) and uses these collections to fund its registration activities. Because most, if not all, practitioners will dispense some controlled substances that are not covered by the waiver provided by the bill, enacting H.R. 2634 would probably not affect the amount of collections. The bill’s effect on DEA’s spending for registration activities would be very small because relatively few practitioners are expected to apply for the waiver.

Pay-as-you-go considerations: The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The net changes in outlays and governmental receipts that are subject to pay-as-you-go procedures are shown in the following table. For the purposes of enforcing pay-as-you-go procedures, only the effects in the current year, the budget year, and the succeeding four years are counted.

SUMMARY OF PAY-AS-YOU-GO EFFECTS OF H.R. 2634

	By fiscal years, in millions of dollars—									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Changes in outlays	0	5	5	10	10	10	5	5	5	5
Changes in receipts	Not Applicable									

Estimated impact on state, local, and tribal governments: H.R. 2634 contains an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA). The bill would preempt, for three years, a state’s ability to regulate the distribution of certain narcotic drugs for detoxification treatment. If, within that period, a state enacted a law in conflict with the bill, that law would go into effect at the end of the three-year period. Because states would not be required to take any action, however, CBO estimates the cost of this preemption would be insignificant.

Because the bill would increase the number of Medicaid beneficiaries that receive new schedule IV and V narcotics for detoxification treatment, CBO estimates that Medicaid spending by states would increase by about \$20 million over the 2000–2004 period.

Estimated impact on the private sector: This bill would impose no new private-sector mandates as defined in UMRA.

Previous CBO estimates: In September 1999, CBO provided an estimate of S. 486, the Methamphetamine Antiproliferation Act of 1999. That bill contained provisions similar to those in H.R. 2634. In that estimate, CBO did not include the costs to the Medicaid program of changing the law to make schedule IV and IV narcotics more easily distributed.

Estimate prepared by: Federal Costs: Substance Abuse: Cyndi Dudzinski; Medicaid: Dorothy Rosenbaum; and Drug Enforcement Administration: Mark Grabowicz. Impact on State, Local, and Trib-

al Governments: Lisa Cash Driskall. Impact on the Private Sector: John Harris.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides the short title of the Act, the “Drug Addiction Treatment Act of 1999.”

Section 2. Amendment to Controlled Substances Act

Section 2 amends section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) to permit a waiver of the separate registration required before practicing physicians may administer narcotic drugs for maintenance treatment or detoxification treatment purposes. The section establishes a waiver procedure that allows practitioners to treat addicted patients with narcotic drugs in schedule IV or V but without the encumbrances that accompany treatment with schedule II narcotic drugs.

Section 2(a)(1) redesignates subsection 303(g) of the Controlled Substances Act as paragraph 303(g)(1) and makes other technical and conforming changes consistent with preservation of the separate registration procedure for methadone and LAAM treatment programs.

Paragraph 2(a)(2) establishes the new waiver mechanism for schedule IV or V treatment programs and places it in paragraph 303(g)(2). The waiver is available to qualified physicians for maintenance treatment and detoxification treatment using approved schedule IV or V narcotic drugs, either alone or in combination.

Physicians who wish to use the waiver must notify the Secretary of their intentions, certifying (1) that they meet one or more of the training and experience demands defined in section 303(g)(2)(G); (2) that they have the capacity to refer patients to counselling and other ancillary services as appropriate; and (3) that they will honor the limitations placed on the number of patients they may treat at any one time. Subject to regulatory adjustment by the Secretary, neither sole practitioners nor any collection of physicians practicing as a group may treat more than 40 patients at any one time. In the case of group practices, the Secretary has the authority to set different numerical ceilings according to the number of practitioners in the group.

The waiver extends only to drugs, or drugs in combinations, approved for maintenance and detoxification treatment either by virtue of the Federal Food, Drug and Cosmetic Act or section 351 of the Public Health Service Act (42 U.S.C. 262) (relating to the regulation of biological products). The Secretary, in consultation with the Attorney General, may narrow the range of drugs or combinations approved for treatment upon an adverse determination, announced in the Federal Register, based upon the conclusion that they should be subject to more demanding practitioner qualification standards or to more stringent standards with respect to the amounts dispensed for unsupervised use.

Notification of an intent to claim the waiver must be in writing and identify the physician, his or her DEA controlled substance registration, and for group practitioners, the names and DEA registrations of the members of the group. The Secretary assigns a unique identifier to each notification. The Secretary also shares the information from the notifications with Attorney General.

A practitioner who fails to comply with the waiver requirements runs the risk of losing his or her registration to dispense controlled substances. Unless a physician holds a separate registration under section 303(g)(1) (the existing narcotics treatment program procedure), the Attorney General may consider it inconsistent with the public interest for a practitioner to dispense narcotic drugs in schedule IV or V, alone or in combination, for maintenance or detoxification treatment while failing to comply with the waiver provisions of section 303(g)(2). The Attorney General may deny a registration to dispense controlled substances generally upon a determination that "issuance of such registration would be inconsistent with the public interest." A charge of failure to comply with the waiver procedures, however, is subject to a good faith defense, as long as the breach is not contrary to a physician-qualification-drug-quantity, adverse determination appearing in the Federal Register at least 30 days prior to filing of the practitioner's notification of intent.

Physicians may elect to treat patients with schedule IV or V narcotic drugs under either the registration procedure of section 303(g)(1) or the waiver mechanism of section 303(g)(2). The waiver mechanism cannot be construed to alter any of the features of the registration procedure including limits on the number of patients who may be treated at one time. The definition of group practice is drawn from paragraph 1877(h)(4) of Social Security Act (42 U.S.C. 1395nn(h)(4)(A)).

Qualified physicians for purposes of a waiver include only those who: (1) hold an American Board of Medical Specialties subspecialty board certification in addiction psychiatry; (2) hold an American Society of Addiction Medicine addiction certification; (3) hold an American Osteopathic Association subspecialty board certification in addiction medicine; (4) have completed at least eight hours of training opiate-dependent patient treatment and management provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization designated by the Secretary; (5) have been an investigator in a clinical trial leading to approval of a schedule IV or V narcotic drug for maintenance or detoxification treatment; (6) have such training or experience as the State medical licensing board considers sufficient to evidence an ability to treat and manage opiate-dependent patients; or (7) have such other training or experience as the Secretary considers sufficient to evidence such ability. This section clarifies that Federal regulations only apply to practitioners who do not comply with the qualifications in paragraphs I-VII, and that the Secretary's criteria must be established by regulations that sunset after three years.

Section 303(g)(2) supersedes any conflicting State or local law or regulation during the three years following enactment. State or local provisions enacted during that period become effective when it expires.

At any time during the three years following enactment, the Attorney General or the Secretary, each after consulting with the other, may terminate the waiver mechanism after announcing their decision in the Federal Register. The Secretary's determination must be based on whether treatments under the waiver procedure have been effective in a clinical environment, whether the waiver mechanism has significantly increased the availability of treatment, and whether it has adversely affected the public health. The Attorney General's determination must consider the extent to which the limitations on the number of patients a physician may treat have been exceeded, the extent to which the mechanism has contributed to the possession and dispensing of schedule IV or V narcotic drugs in violation of the Controlled Substances Act, and the extent to which the waiver procedure has adversely affected the public health.

Paragraph 2(b) of the bill provides conforming amendments in section 304 of the Controlled Substances Act (21 U.S.C. 824) to reflect continuation of the registration procedure and establishment of the waiver mechanism.

Section 3. Additional authorization of appropriations regarding department of Health and Human Services

Section 3 authorizes appropriations for such sums as are necessary to carry out the purposes of the Act in addition to other authorizations of appropriations that are available for such purpose.

EXCHANGE OF COMMITTEE CORRESPONDENCE

HOUSE OF REPRESENTATIVES,
COMMITTEE ON THE JUDICIARY,
Washington, DC, October 25, 1999.

Hon. TOM BLILEY,
*Chairman, House Commerce Committee, House of Representatives,
Rayburn House Office Building, Washington, DC.*

DEAR CHAIRMAN BLILEY: I am writing to you concerning the bill H.R. 2634, the Drug Addiction Treatment Act of 1999.

As you know, this bill contains language which falls within the Rule X jurisdiction of this committee relating to the Controlled Substances Act. I understand that you would like to proceed expeditiously to the floor on this matter. I am willing to waive our committee's right to mark up this bill. However, this, of course, does not waive our jurisdiction over the subject matter on this or similar legislation, or our desire to be conferees on this bill should it be subject to a House-Senate conference committee.

I would appreciate your placing this exchange of letters in the Congressional Record. Thank you for your cooperation on this matter.

Sincerely,

HENRY J. HYDE,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
Washington, DC, October 21, 1999.

Hon. HENRY HYDE,
*Chairman, Committee on the Judiciary, House of Representatives,
Rayburn House Office Building, Washington, DC.*

DEAR CHAIRMAN HYDE: Thank you for your letter regarding your Committee's jurisdictional interest in H.R. 2634, the Drug Addiction Treatment Act of 1999.

I acknowledge your committee's jurisdiction over this legislation and appreciate your cooperation in moving the bill to the House floor expeditiously. I agree that your decision to forego further action on the bill will not prejudice the Judiciary Committee with respect to its jurisdictional prerogatives on this or similar legislation, and will support your request for conferees on those provisions within the Committee on the Judiciary's jurisdiction should they be the subject of a House-Senate conference. I will also include a copy of your letter and this response in the Committee's report on the bill and the Congressional Record when the legislation is considered by the House.

Thank you again for your cooperation.

Sincerely,

TOM BLILEY,
Chairman.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

* * * * *

TITLE II—CONTROL AND ENFORCEMENT

* * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * *

REGISTRATION REQUIREMENTS

SEC. 303. (a) * * *

* * * * *

(g)(1) **【Practitioners who dispense】** *Except as provided in paragraph (2), practitioners who dispense* narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

【(1)】 (A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

【(2)】 (B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting **【(A) security】** (i) *security* of stocks of narcotic drugs for such treatment, and **【(B) the maintenance】** (ii) *the maintenance* of records (in accordance with section 307) on such drugs; and

【(3)】 (C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) *Subject to subparagraphs (D) and (I), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule IV or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).*

(B) *For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before dis-*

dispensing narcotic drugs in schedule IV or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) In any case in which the practitioner is not in a group practice, the total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 40, except that the Secretary may by regulation change such total number.

(iv) In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 40, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule IV or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the

practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

(ii) The Secretary shall assign a unique identifier to each notification under subparagraph (B), and shall provide to the Attorney General all information contained in such notifications.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule IV or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

(ii)(I) A practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule IV or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule IV or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term "group practice" has the meaning given such term in section 1877(h)(4) of the Social Security Act.

(ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situa-

tions, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule IV or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for three years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(H) During the 3-year period beginning on the date of the enactment of the Drug Addiction Treatment Act of 1999, any law or regulation of a State or political subdivision of a State that is in conflict with this paragraph is superseded by this paragraph. If before the expiration of such period a State or political subdivision of a State enacts such a law, then upon the expiration of the period this paragraph ceases to supersede the law.

(I)(i) This paragraph takes effect on the date of the enactment of the Drug Addiction Treatment Act of 1999, and remains in effect thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on the date of the enactment of the Drug Addiction Treatment Act of 1999, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a deter-

mination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule IV or V or combinations of such drugs are being dispensed or possessed in violation of this Act; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that this paragraph should not remain in effect, this paragraph ceases to be in effect 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

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DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this title or title III;

(2) has been convicted of a felony under this title or title III or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 303 inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1128(a) of the Social Security Act.

A registration pursuant to [section 303(g)] *section 303(g)(1)* to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General

upon a finding that the registrant has failed to comply with any standard referred to in ~~section 303(g)~~ *section 303(g)(1)*.

* * * * *

(d) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in ~~section 303(g)~~ *section 303(g)(1)* may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

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ADDITIONAL VIEWS

This bill is born of a concern that potential new opiate addiction treatment medications will be regulated in a manner that will limit their availability and use. The current paradigm for regulation of opiate addiction medications is based on methadone and ORLAAM (a methadone alternative) and includes rigorous federal regulations as well as a variety of state and local restrictions.

The only known medications that would be affected by the bill are buprenorphine and a combination product, buprenorphine/naloxone. These products have been developed under a Cooperative Research and Development Agreement (CRADA) between the National Institute on Drug Abuse (NIDA) and Reckitt & Colman.

According to NIDA's Buprenorphine Update, "[t]here are no current regulations which address the use of buprenorphine or buprenorphine/naloxone for the treatment of opiate dependence because these products are not yet approved for this purpose by the FDA." NIDA goes on to state that "[t]he regulatory burden should be determined based on a review of the risks to individuals and society of this medication being dispensed by prescription and commensurate with its safety profile, as is the case with evaluation of all controlled substances."

The Federal agency responsible for establishing guidelines for opiate addiction treatment is the Substance Abuse and Mental Health Services Administration (SAMHSA). At a hearing on this legislation and in other communications on this subject, SAMHSA has said that it is in the process of drafting a proposed regulation for buprenorphine. The agency has not argued that the rigorous regulatory paradigm for methadone would be appropriate for buprenorphine. Indeed, SAMHSA has already published a proposal to revise the methadone regulations.

The bill exempts "qualifying physicians" at a time when buprenorphine has not been approved by FDA, and therefore before labeling information important to its use is known. According to NIDA, "[t]he safety and effectiveness profiles for buprenorphine and buprenorphine/naloxone suggest they could be dispensed under controlled circumstances that would be delineated in the product labeling and associated rules and regulations." It may be premature to exempt anyone from yet to be written regulations for a yet to be approved and labeled drug.

The bill preempts state and local laws that are "in conflict with" it. The National Association of State Alcohol and Drug Abuse Directors (NASADAD) has stated its opposition to the bill's preemption language. We still do not have an accounting of what state and local laws will be affected by the preemption language of this bill.

Finally, the bill does not provide any resources for patient access to buprenorphine. Although the rigor of current narcotic addiction treatment regulations may be a barrier to treatment, evidence pre-

sented at the hearing on this bill clearly showed that financial resources are a critical element of access to treatment and to development of effective addiction treatment medications. It is important to note that most persons in the treatment gap lack access to financial resources for treatment. Insurance coverage often does not provide "parity" for substance abuse treatment, and the Medicaid programs of twenty-five states do not pay for methadone treatment. The cost of methadone is less than one dollar per day. Some estimates for the daily cost of buprenorphine are as high as ten dollars per day. Thus, most heroin addicts in the treatment gap will not be able to afford the office based treatment contemplated by the bill.

Buprenorphine is expected to be effective for the treatment of mild to moderate heroin addiction. A majority of heroin addicts are severely addicted. Thus, many persons who are in the treatment gap will not benefit from the bill for pharmacological reasons. Their lack of access to treatment is not addressed by the bill.

In sum, the bill may ultimately help some heroin addicts to receive treatment, but this number will be a fraction of those who are in the treatment gap. These will be mild to moderately addicted persons with the financial resources to obtain access to a physician or other health care provider who will either dispense or prescribe the medication. The bill does not address the needs of most heroin addicts; namely, those who are severely addicted or who lack the financial resources to see a doctor. Some members have strongly urged the majority to address these aspects of the treatment gap that are not included in H.R. 2634. A good first step would be to move legislation to reauthorize the programs administered by the Substance Abuse and Mental Health Services Administration, which provide the bulk of federal resources for substance abuse prevention and treatment.

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