



Federal Enforcement of the Controlled Substances Act: Striking a Balance Between Enforcement and the Regulation of Medical Practice

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Federal Enforcement of the Controlled Substances Act:
Striking a Balance Between Enforcement and the Regulation of
Medical Practice

Whitney Washington
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Abstract

In the Controlled Substances Act of 1970, Congress made the conscious decision to vest the regulation and control of drugs in two executive branch departments. The Attorney General, through the DEA, is responsible for law enforcement. The Department of Health and Human Services, through the FDA, is responsible for the regulation of all commercially available drugs. This paper presents a brief historical overview of the shared regulatory authority over drugs by examining the Controlled Substances Act and federal treatment of controlled substances since 1970. The paper discusses the events surrounding the creation of the current structure of regulation, the workings of the structure and the criticisms of it, with a focus on the decision by Congress to divide authority. This paper does not endorse specific proposals for change, but rather seeks to inform the discussion on the current regulation of drugs and other controlled substances.

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Introduction

In the Controlled Substances Act, Congress made the conscious decision to vest the regulation and control of drugs in two executive branch departments. The Attorney General, through the DEA, is responsible for law enforcement. The Department of Health and Human Services, through the FDA, is responsible for the regulation of all commercially available drugs. At times, such as with the scheduling of drugs, the two departments are to consult one another, coming to a decision that represents the collective thoughts of the two bodies. At other times, however, the agencies have distinct roles and little interaction. As a result of the differing goals and functions of the two departments, some commentators have criticized the system of consultation and shared regulation that governs controlled substances.

This paper presents a brief historical overview of the shared regulation of drugs by examining the Controlled Substances Act and federal treatment of controlled substances since the 1970. This overview discusses the events surrounding the creation of the current structure of regulation, the workings of the structure and the criticisms of it, with a focus on the decision by Congress to vest the Attorney General with law enforcement authority, subject to the binding input of the Secretary of Health and Human Services (“Secretary”). The paper, however, does not provide recommendations for change. Rather, it serves as a point of departure for further commentary in the field.

This text proceeds in five parts. Part I provides a historical background to the Controlled Substances Act (CSA). Part II provides an explanation of the federal regulatory scheme for controlled substances. Part III examines the debate over the current regulatory scheme and the roles of DOJ and HHS within it, touching on the origins of the debate as well. Part IV focuses on enforcement of the CSA, highlighting again the tension between the roles of the Department of Justice and the Department of Health and Human Services in the prosecution of physicians prescribing controlled substances. Part V examines proposals for change to the current regulatory scheme.

Part I: Historical Background

Prior to the creation of the Drug Enforcement Agency (DEA), two federal offices had control over drug enforcement.¹ The Bureau of Narcotics in the Department of Treasury was responsible for the monitoring and control of marijuana and narcotics—drugs produced in whole or in part from opium or opiates, poppy straw, coca leaves, and cocaine.² The Bureau of Drug Abuse Control in the Department of Health, Education and Welfare (HEW) was responsible for controlling “dangerous drugs,” including depressants, stimulants such as barbiturates and amphetamines, and hallucinogens, such as LSD.³ In response to growing use of illegal drugs in America, President Johnson introduced legislation in 1968 to combine the Bureau of Narcotics and the Bureau of

¹ Allgov.com, U.S. Drug Enforcement Administration (DEA), http://www.allgov.com/Agency/U_S_Drug_Enforcement_Administration_DEA (last visited April 24, 2009).

² See 21 USC 802(17) (2007). for current definition, which was in effect prior to the CSA as well.

³ *Id.*

Drug Abuse Control into one agency.⁴ Reorganization Plan No. 1 of 1968, effective April 8 of that year, created the Bureau of Narcotics and Dangerous Drugs (BNDD) in the Department of Justice (DOJ), which was responsible for preventing illicit traffic in narcotic, stimulant, and depressant drugs and controlling the manufacture of those drugs for medicinal purposes.⁵

In 1969 President Nixon announced that the Attorney General, John N. Mitchell, was preparing a comprehensive measure to combine existing federal laws addressing narcotics and drugs into a single statute in order to better address the narcotics and drugs problems at the federal level.⁶ This effort would lead to Reorganization Plan No. 2 of 1973, which established the DEA in the Department of Justice.⁷

In furtherance of creating a unified enforcement policy for controlled substances, Congress enacted the Controlled Substances Act (CSA) in 1970 as titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The creation of the CSA resulted in a comprehensive federal scheme for regulation of controlled substances to combat both drug abuse and illegal drug trafficking. To bolster its position that comprehensive action was necessary, Congress made a number of findings relating to controlled substances. One finding in particular stated, “the illegal importation,

⁴ Allgov.com, *supra* note 1.

⁵ Reorganization Plan No. 1 of 1968, 33 F.R. 5611 (1968); Robert Matchette et al., *Records of the Drug Enforcement Agency*, Guide to Federal Records in the National Archives of the United States, National Archives and Records Administration (1995) <http://www.archives.gov/research/guide-fed-records/groups/170.html>.

⁶ Matchette, *supra*.

⁷ *Id.*.

manufacture, distribution, possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.”⁸

President Nixon signed the Comprehensive Drug Abuse Prevention and Control Act into law on October 27, 1970. In his signing statement, President Nixon expressed a deep concern about the effects drug use had on crime and the increasing prevalence of drug use among teenagers.⁹ Known as a proponent of taking a tough stance on drug abuse¹⁰ after declaring a war on drugs shortly after taking office in 1969,¹¹ President Nixon, interestingly, did not stress DOJ’s predominant role in enforcement.¹² He mentioned instead the importance of treatment programs to help the addicted end their dependence.¹³ President Nixon did also highlight the increased jurisdiction of the Attorney General and

⁸ Emily Farr. Comment, *The Medical Necessity Defense as an Exception to the Controlled Substances Act*. 53 S.C.L.Rev 439, 449 (2002) (quoting 21 U.S.C.A. 801(2) (West 2001)).

⁹ Richard Nixon. Remarks on Signing the Comprehensive Drug Abuse Prevention and Control Act of 1970. (October 27, 1970) available at <http://www.presidency.ucsb.edu/ws/index.php?pid=2767>.

¹⁰ President Nixon was very much opposed to legalizing marijuana. In a meeting with Mayor Daley of Chicago in 1971 he remarked, “Now my position is flat-out on that. I am against legalizing marijuana...the point is, once you cross that line, from the straight society to the drug society – marijuana, then speed, then it’s LSD, then it’s heroin, etc. then you’re done. We’ve got to take a strong stand.” Ontheissues.com, On The Issues: Richard Nixon on Drugs, http://www.ontheissues.org/Celeb/Richard_Nixon_Drugs.htm (quoting White House tapes: meeting with Mayor Richard Daley, May 13, 1971) (last visited April 24, 2009).

¹¹ See *Gonzales v. Raich*, 545 U.S. 1, 10 (2005) (noting in the opinion the historical background to the marijuana laws).

¹² Nixon, *supra* note 9.

¹³ *Id.*

the additional enforcement officers the bill would enable,¹⁴ but not as much as one might have anticipated.

Part II: Federal Oversight Scheme for Controlled Substances

The DEA and the Food and Drug Administration (FDA) both have a role in enforcing federal law pertaining to drugs. The DEA enforces the CSA, which establishes criminal and civil sanctions for the unlawful possession, manufacturing, or distribution of certain dangerous substances, including prescription drugs that share these properties.¹⁵ The FDA regulates all commercially available drugs for safety and effectiveness under the Federal Food, Drug and Cosmetic Act (FDCA).

The Attorney General has the authority to add or remove drugs from the schedules of controlled substances established by the CSA. The CSA divided controlled substances into 5 schedules, for which differing levels of control are applied. The substances range from Schedule I substances, which are found to have a very high potential for abuse, to Schedule 5 substances, which have the lowest potential for abuse of any controlled substance and lead to the least physical or psychological dependence of any drug if abused.¹⁶ Schedule I substances are those that have no accepted medical use in the United States and have a high abuse potential.¹⁷ Examples of schedule I substances are

¹⁴ *Id.*

¹⁵ Jody Feder, *Legal Issues Related to Prescription Drug Sales on the Internet*. Congressional Research Service. (March 5, 2004).

<http://digital.library.unt.edu/govdocs/crs/permalink/meta-crs-5776:1>

¹⁶ 21 U.S.C. §812(b)(1) (2007).

¹⁷ 21 U.S.C.A. §812(b)(1)(A) (2007).

heroin, marijuana and other hallucinogenic substances.¹⁸ Schedule II substances are considered to have a high abuse potential plus severe psychic or physical dependence liability, but to have a currently accepted medical use in treatment in the US or a currently accepted medical use with severe restrictions unlike schedule I.¹⁹ Examples of Schedule II drugs are opium and opiates, methadone, coca leaves, and any liquid substances containing methamphetamine.²⁰

Drugs and other substances in Schedules III-V all have a currently accepted medical use in treatment in the United States and have decreasing potentials for abuse and physical or psychological dependence. Schedule III substances are those that have a potential for abuse less than the Schedule I and II drugs and substances, and may lead to moderate or low physical dependence or high psychological dependence if abused. These drugs and substances include anabolic steroids, codeine and hydrocodone with aspirin or Tylenol, as well as some barbiturates and their derivatives.²¹ Schedule IV consists of drugs or other substances with a lower potential for abuse than Schedule III and that lead to limited physical dependence or psychological dependence if abused, relative to the drugs or other substances in schedule III. This category includes drugs like Valium and Xanax. Finally, Schedule V drugs or other substances have a low potential for abuse relative to the drugs or substances in Schedule IV, and abuse of the drug or substance may lead to limited physical or psychological dependence relative to drugs or other substances in

¹⁸ U.S. Drug Enforcement Agency, *Drugs of Abuse Publication, Chapter 1*, <http://www.usdoj.gov/dea/pubs/abuse/1-csa.htm> (last visited April 24, 2009).

¹⁹ 21 U.S.C. §812(b)(2)(A) (2007).

²⁰ U.S. Drug Enforcement Agency, *supra* note 17

²¹ *Id.*

Schedule IV. Schedule V consists of medications like cough medicines that contain codeine.²²

The DEA regulates the manufacture, sale and distribution of controlled substances. Any person who handles or intends to handle controlled substances must obtain a registration issued by the DEA,²³ and parties that distribute controlled substances must keep extensive records. For Schedule I and II substances, the supplier must receive a special order form from the customer to supply the drug.²⁴ The special order form contains the pre printed address of the customer and is created by the DEA.²⁵ For drugs in the other three schedules no registration form is required, but the supplier is responsible for ensuring the purchaser has a valid registration to handle controlled substances.²⁶

The five schedules of drugs are subject to differing distribution rules. Schedule I drugs are to be used in the US only in research situations. Schedule II prescription orders must be written and signed,²⁷ Schedule III and IV prescription orders may be oral or written, and Schedule V drugs and substances do not require a prescription but do require a showing of identification and recordation in a pharmacist's log.²⁸ The DEA limits the quantities of Schedule I and II substances that may be produced in the US in any given

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ See <http://www.accessbutler.com/abc/WAButler/ProductsandServices/deaform222.pdf> for a sample order form.

²⁶ U.S. Drug Enforcement Agency, *supra* note 17

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

year, but does not do so for the other schedules. As a result, scheduling decisions are of importance to drug manufacturers, users, and the medical practitioners that prescribe drugs.

While at first glance it seems that the DEA alone handles scheduling decisions, the FDA, and a couple other agencies in the Department of Health and Human Services (HHS) have input into the scheduling decisions of the Attorney General. When deciding whether to add or remove a drug from the schedule, the Attorney General is required to first ask the Secretary of HHS for her recommendation. The Secretary's recommendations are binding on the Attorney General, insofar as they concern the scientific and medical matters relating to the appropriate schedule under which such drug or substance should be listed, if any.

The statute provides that,

The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection c and any scientific or medical considerations involved in paragraphs (1), (4) and (5). . . The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the

Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.²⁹

The Secretary mentioned in the above section of the statute is the Secretary of Health and Human Services—the Secretary of Health, Education and Welfare in the original bill. The factors listed in paragraphs (2), (3), (6), (7) and (8) to be considered are: scientific evidence of a drug’s pharmacological effect; if known, the state of current scientific knowledge regarding the drug; what risks the drug poses to public health; the psychic or physiological dependence liability; and whether the substance is an immediate precursor of a substance already controlled under the title.³⁰

The DEA or HHS, or any interested person through petition, may initiate proceedings to add, delete or change the schedule of a drug or other substance. Interested persons include “the manufacturer of a drug, a medical society or association, a pharmacy association, a public interest group concerned with drug abuse, a state or local government agency, or an individual citizen.”³¹ When the DEA receives a petition, it begins its investigation of the drug.³² The DEA may also begin an investigation into a drug at any time based upon information it receives from government laboratories, local and state law enforcement and regulatory agencies, or other sources of information.³³

²⁹ 21 U.S.C. 811(b) (2007).

³⁰ 21 U.S.C. 811(c) (2007).

³¹ Drug Enforcement Agency, *supra* note 17.

³² *Id.*

³³ *Id.*

In practice the DEA administrator does much of the administrative work around scheduling that is statutorily delegated to the Attorney General by the CSA. The Department of Justice describes the process as the following,

Once the DEA has collected the necessary data, the DEA Administrator, by authority of the Attorney General, requests from the Department of Health and Human Services a scientific and medical evaluation and recommendation as to whether the drug or other substance should be controlled or removed from control. This request is sent to the Assistant Secretary of Health for HHS. HHS solicits information from the Commissioner of the Food and Drug Administration (FDA), evaluations and recommendations from the National Institute on Drug Abuse, and on occasion from the scientific and medical community at large. The Assistant Secretary, by authority of the Secretary compiles the information and transmits back to the DEA a medical and scientific evaluation regarding the drug or other substance, a recommendation as to whether the drug should be controlled, and in what schedule it should be placed.³⁴

Any additions, deletions or changes made by the DEA to the schedules must be made pursuant to the notice and comment rulemaking procedures set forth in Title 5 Chapter 5 of the US code.³⁵ However, the statute exempts the Attorney General from conducting the findings necessary to schedule a drug or substance and observing the notice and comment proceedings if he or she is placing an immediate precursor in the same schedule

³⁴ *Id.*

³⁵ *See* 5 U.S.C. 553 (2001).

the controlled substance of which it is an immediate precursor is already in or in any schedule with a higher numerical designation.³⁶

As noted above, aside from the exception for treatment of precursors, the FDA and the National Institute on Drug Abuse give their input into the scheduling of drugs, which is made binding on the Attorney General. The FDA has other roles related to the regulation of controlled substances as well. The agency also monitors the abuse potential of drugs. Pursuant to the statute “if, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary [of HHS] to the Attorney General.”³⁷ As discussed above, HHS may initiate proceedings to add, delete or change the schedule of a drug or other substance. The FDA—the agency tasked with reviewing and deciding upon all new drug applications—has a primary role in suggesting whether a drug or substance for which a new drug application has been filed should be added to the list of controlled substances.

The Attorney General also defers to the FDA and the FDCA with respect to over the counter drugs. He is instructed to promulgate regulations excluding from the application of the CSA any non-narcotic drug that contains a controlled substance if the drug may, under the Food, Drug and Cosmetic Act be lawfully sold over the counter without a prescription.³⁸ The Attorney General may promulgate a regulation exempting any

³⁶ 21 U.S.C. §811(e) (2007).

³⁷ 21 U.S.C. §811(f) (2007).

³⁸ 21 U.S.C. §811(g) (2007).

compound, mixture, or preparation containing a controlled substance that contains an anabolic steroid if the Secretary of HHS makes such a recommendation.³⁹

The federal scheme regulating controlled substances thus grants the Attorney General, acting through the DEA, and HHS, acting through the FDA and other agencies, competency to address the monitoring and regulation of controlled substances. Though it has been in existence for almost 40 years, this system in which the law enforcement agency enforces the law subject to the binding input of the medical and public health agency has drawn criticism from multiple sides, as detailed below. To understand the criticism, it helps to understand why Congress gave the HHS input into scheduling and where the desire for a balance between enforcement and medical and scientific decision-making originates. The first step will be to look to the debates in Congress.

Part III: Congressional Debates over the Cross Competencies of DEA and HHS

In the findings and declarations section of the CSA, Congress stated that many of the drugs included within the “title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.”⁴⁰ Despite the useful purposes of many of the listed drugs, “illegal importation, manufacture, distribution, and possession and improper use of controlled substances” were held to have a “substantial and detrimental effect on the health and general welfare of the American people.”⁴¹ As a result, federal control of the intrastate and interstate manufacture and distribution of controlled substances was necessary. Given the legitimate medical

³⁹ *Id.*

⁴⁰ 21 U.S.C. §801(1) (2007).

⁴¹ 21 U.S.C. §801(2) (2007).

purpose of many of the drugs included on the list, debate has been ongoing as to how much of the approach to drugs and other controlled substances should be focused on enforcement and how much should be focused on prevention, rehabilitation and treatment.

A quick glance at the schedules of controlled substances reveals that some very recognizable and commonly prescribed substances can be found on the lists. The drug Xanax is commonly prescribed for the treatment of anxiety and panic disorders.⁴² Valium is used for a number of purposes including the treatment of anxiety, acute alcohol withdrawal, and seizures.⁴³ It is also used to relieve muscle spasms and provide sedation before medical procedures.⁴⁴ Both of these commonly prescribed drugs are listed as schedule IV substances on the CSA's schedules. A schedule III substance that is commonly prescribed is hydrocodone, which is the main ingredient in the drugs Vicodin, Lortab and Lorcet.⁴⁵ Hydrocodone is a cough suppressant and analgesic used for treatment of moderate to moderately severe pain, and studies have indicated that it is as effective or more effective than codeine for cough suppression and nearly as powerful as morphine in managing pain.⁴⁶ Congress understood the importance of drugs such as these in the maintenance of the health and welfare of the American people and did not

⁴² First DataBank, Inc., Xanax (Alprazolam) Drug Information, <http://www.rxlist.com/xanax-drug.htm> (last visited April 24, 2009).

⁴³ Rxlist.com, Valium (Diazepam Tablets) Drug Information. <http://www.rxlist.com/valium-drug.htm> (last visited April 24, 2009).

⁴⁴ *Id.*

⁴⁵ U.S. Drug Enforcement Agency, Drug Information, Hydrocodone <http://www.usdoj.gov/dea/concern/hydrocodone.html> (last visited April 24, 2009).

⁴⁶ *Id.*

intend to deprive medical practitioners and patients in need of these useful substances. Their use, however, was to be balanced with the need for enforcement.

During the consideration of the Comprehensive Drug Abuse Prevention and Control Act (CDAPCA), a debate arose related to whether the Act should stress the importance of stronger law enforcement or should note Congress' desire to use educational and rehabilitative measures to address the use and abuse of controlled substances. The debate on the Senate floor of Amendment 1026 proposed by Iowa Senator Harold Hughes provided a good example of the tension between enforcement and rehabilitation. Senator Roman Hruska in his statement before the floor on the Act described it as a measure "that would go very extensively into the field of rehabilitation, education, prevention, and matters of that kind."⁴⁷ He argued that adding the amendment to the Act would "impair many of the law enforcement features contained in Title II of the bill."⁴⁸ Senator Hruska and others were further concerned that in the congressional findings of the amendment one finding stated that drug dependence is an illness or disease. In their view, such a statement could lead to the use of drug dependence as an affirmative defense to criminal prosecution.⁴⁹ This would be problematic in a bill geared toward law enforcement.

Another provision in the Hughes amendment that Senator Hruska and others were concerned about was the authority granted to the Department of Health, Education and Welfare to classify substances. Senator Hruska argued that the use of the word

⁴⁷ 116 CONG. REC. S17395 (daily edition Oct, 7, 1970) (statement of Sen. Hruska on Amendment 1026).

⁴⁸ *Id.*

⁴⁹ *Id.*

“classification” in section 112(k) of the amendment implicitly authorized the Secretary of HEW to classify controlled substances for rehabilitation and treatment purposes.⁵⁰

Conferring upon HEW the ability to classify would lead to a duplication of that activity, according to Senator Hruska, and would only create conflicts for the investigators and prosecutors important to the enforcement of the law.⁵¹ What was needed immediately was a “strict and very effective law enforcement program.”⁵² Once that was accomplished consideration could be made of the need for prevention, treatment and rehabilitation measures.⁵³

Senator Dodd shared Senator Hruska’s views, similarly declaring his concerns about the amendment. He argued that it was a mistake to add to the CSA rehabilitation, research and education and information aspects of the matter.⁵⁴ Further, he remarked that doing so “will hamper the enforcement of this good narcotics law which we can pass.”⁵⁵

The Hughes amendment failed, but the debate would come up again. In December of 1970 after the CDAPCA had been signed into law, the International Protocol on Psychotropic Substances was brought before the Senate for a vote. The Protocol is a treaty of the United Nations that was designed to combat the increased use of psychotropic substances, such as amphetamines and barbiturates, by creating a regulatory framework that included scheduling and controlling these drugs. Debate on the protocol

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ 116 CONG. REC S.17377 (daily edition Oct. 7, 1970) (remarks of Sen. Dodd).

⁵⁵ *Id.*

presented another opportunity for discussion of rehabilitation and enforcement in the federal approach to controlled substances. Senator Hughes, the chair of the special subcommittee on alcoholism and narcotics explicitly addressed the prior debate on the issue. Hughes stated the following:

One of the most basic issues—to my mind the most basic issue—to come up when the Comprehensive Drug Abuse Prevention and Control Act of 1970 was being considered had to do with the relative responsibilities of the Department of Health, Education and Welfare and the Department of Justice over the scheduling of drugs for control purposes. The original administration bill indicated that control responsibilities lay with Justice and that HEW could give Justice their views, but that the Department of Health, Education and Welfare views were in no way binding. The compromise bill, however, changed this so that while Justice still had the ultimate decisionmaking authority as to control, scientific and medical determinations were made by HEW and these latter determinations were made binding upon Justice.⁵⁶

The Nixon administration's initial proposal gave the Department of Justice full responsibility to schedule controlled substances. Senator Hughes worried in his testimony that the executive branch was holding to its initial position and extending it to

⁵⁶ 116 CONG. REC S20849 (daily edition Dec. 19, 1970) (Sen. Hughes remarks).

the international realm.⁵⁷ Under the draft protocol of the International Protocol on Psychotropic Substances, the United Nations Commission on Narcotic Drugs—the UN’s drug enforcement policy arm—was to amend the schedules from time to time after considering the views of the World Health Organization, but the views of the WHO were not to be binding.⁵⁸ Although Senator Hughes’ statements related to an international proposal, a primary underlying issue, the scheduling of controlled substances, remained the same. The fact that Senator Hughes expressed his concerns about the balance between enforcement and scientific knowledge and study shows that the debate over how much enforcement should occur without medical input was ongoing.⁵⁹

Senators Hughes continued his testimony with more concerns about the level of health and science input that would enter law enforcement decisions, directly addressing the debate over the Controlled Substances Act.

As you know, Mr. President, when the Comprehensive Drug Abuse Prevention and Control Act of 1970 was being discussed and debated, there were a number of other issues like the specific one which I have just mentioned which arose and which involved aspects of this larger question of the relative health and scientific input and involvement on the one hand, and law enforcement input on the other. I am equally concerned about those issues as well—issues which involved such matters as control of research, confidentiality of patient records, confidentiality for research subjects, and

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *See* 116 CONG. REC S20849 (daily edition Dec. 19, 1970) (Sen. Hughes remarks).

maximum permissible freedom for doctors and researchers to use therapeutic drugs with only reasonable interference by enforcement personnel.⁶⁰

Senator Hughes's concern about the role enforcement would play in the ability of doctors to use therapeutic drugs has become a major issue, as illustrated in the discussion below.

Part IV: Enforcement of the CSA

A. Law Enforcement Post CSA passage

In 1971, President Nixon commissioned the National Commission on Marijuana and Drug Abuse and appointed Robert Shafer, a former Governor of Pennsylvania to head the commission.⁶¹ Known as the Shafer Commission, the commission was comprised of four members of Congress and nine members of the public—practitioners in fields ranging from the medicine to public broadcasting—and issued reports in 1972 and 1973.⁶² No more than five of the public members could be from the same political party.

The commission presented empirical data and made a number of recommendations to the President and Congress regarding suggested responses to marijuana use in the United States. The commission recommended that, “possession for personal use in private and

⁶⁰ 116 CONG. REG. S20850 (daily edition Dec. 9, 1970).

⁶¹ Pennsylvania Historical and Museum Commission. Pennsylvania Governors Past to Present: Governor Raymond Philip Shafer. <http://www.phmc.state.pa.us/bah/dam/governors/shafer.asp?secid=31>, (last visited April 24, 2009).

⁶² *Id.*

casual not-for-profit sales in private not be made criminal offenses.”⁶³ Shafer stated in his testimony before Congress that the commission “unanimously agreed that [marijuana] use is not a desirable behavior and . . . that society should discourage use. Nevertheless . . . placed in proper perspective with other societal problems, citizens should not be criminalized or jailed merely for private possession or use.”⁶⁴ The commission further concluded that “the criminal law is too harsh a tool to apply to personal possession even in the effort to discourage use The actual and potential harm of the use of the drug is not great enough to justify intrusion by the criminal law into private behavior, a step which our society takes with greatest reluctance.”⁶⁵

The commission’s recommendations included medical recommendations for the government’s approach to marijuana. It recommended that there be increased support of studies that evaluate the efficacy of marijuana in the treatment of physical impairments and disease. The promotion of community-based treatment facilities was also recommended to assist in caring for problem drug users, which would allow utilization of existing health centers when possible and appropriate.⁶⁶

President Nixon was not satisfied with the report and reportedly refused to read it.⁶⁷

Thus, the Nixon administration ignored the report’s findings and decided to pursue its

⁶³ 118 CONG REC. H2408 (daily edition March 22, 1972) (statement of Rep. Koch).

⁶⁴ *Id.* (quoting Shafer).

⁶⁵ *Id.*

⁶⁶ 118 CONG REC. H2410.

⁶⁷ Dean Kuipers. *Interview with Dr. Thomas Ungerleider*, LOS ANGELES CITYBEAT Mar. 29, 2007, available at http://www.lacitybeat.com/cms/story/detail/dr_thomas_ungerleider/5238/

drug enforcement policy,⁶⁸ creating the DEA in 1973 and consolidating enforcement within it.

Since the CSA's passage in 1970 there have been three amendments to the bill, but the general enforcement scheme has stayed substantially the same. The CSA was amended in 1978 to meet obligations under the Convention on Psychotropic Substances. The 1978 amendment added to the classification and scheduling procedure a provision enabling communication with the WHO related to the international scheduling of controlled substances, to provide for consistency between the US controlled substances schedules and the Convention on Psychotropic Substances schedules.⁶⁹ The 1984 amendment specified penalties for manufacture, use or distribution of controlled substances and updated provisions regarding compounds.⁷⁰ The 2004 amendments added to the definition of and penalty treatment for anabolic steroids.⁷¹

B. Litigation over the CSA

Pursuant to the CSA, enforcement of drug laws has remained the province of the DEA, while HHS has acted to provide scientific input related to controlled substances and has regulated and monitored the practice of medicine. Though DOJ and HHS have worked together on the sharing of information on and the scheduling of drugs and other controlled substances, there have been points of tension. One particular point of tension is illuminated by the controversy over the DOJ's regulation of physician authorization to

⁶⁸ *Id.*

⁶⁹ See 21 U.S.C. §811(d)(2)(A) (2007).

⁷⁰ See 21 U.S.C. §841 (2007).

⁷¹ See 21 U.S.C. §801 (2007),

distribute drugs. The question of the proper role of DOJ in the enforcement of medical decisions was at the forefront in *Gonzales v. Oregon*.⁷²

In *Gonzales*, a directive issued by the Attorney General was the basis for the legal controversy. Attorney General John Ashcroft had issued a directive advising doctors in Oregon that they would be subject to deregistration and criminal prosecution if they were to use controlled substances to carry out Oregon's death-with-dignity law.⁷³ Oregon's death-with-dignity law was enacted in 1994 by Oregon voters and allows Oregon residents to request a diagnosis from their "attending physician that they have an incurable and irreversible disease, that within reasonable medical judgment, will cause death within six months."⁷⁴ After receipt of the request, the requesting patient is required to obtain a determination by the attending physician that the request was made voluntarily and secure confirmation of the attending physician's diagnosis by a second consulting physician. Only at that point can the attending physician dispense or issue a prescription for the requested drug, but not administer it.⁷⁵ The drugs that physicians prescribed and dispensed to hasten death are controlled substances, which subjects them to the requirements of the CSA.

The CSA imposes strict, mandatory registration requirements for physicians seeking to dispense or prescribe controlled substances. A medical practitioner is required to register

⁷² *Gonzales v. Oregon*, 546 U.S. 243 (2006).

⁷³ Dispensing of Controlled Substances to Assist Suicide, 21 C.F.R. Part 1306 (2001)

⁷⁴ *Gonzales v. Oregon*, 546 U.S. at 252 (2006) (citing ORE. REV.STAT. §§127.815, 127.800(12) (2003)).

⁷⁵ ORE. REV.STAT §§127.815(1)(L), 127.880 (2003).

with the Attorney General and obtain a certificate of registration with the DEA if she intends to prescribe or dispense a controlled substance.⁷⁶ One of the amendments made to the CSA in the 1984 bill authorized the Attorney General to deny a practitioner's application for DEA registration if the Attorney General determined that the issuance of such registration would be inconsistent with the public interest.⁷⁷ Relevant to *Gonzales*, the DEA Administrator found that assisting suicide is not a legitimate medical purpose and that prescribing, dispensing or administering federally controlled substances to assist suicide violates the CSA.⁷⁸ Such conduct by a physician registered to dispense controlled substances could render his registration inconsistent with the public interest and subject him to the suspension or revocation of his registration.⁷⁹

Although prior Attorney General Janet Reno determined that the DEA could not prosecute or revoke CSA registration of Oregon physicians who assisted suicide because the CSA did not authorize the DEA to replace the states as primary regulators of the medical profession, Attorney General John Ashcroft's administration overturned this determination. Attorney General Ashcroft determined that assisting suicide was not a "legitimate medical purpose within the meaning of 21 CFR §1306.04, and that prescribing, dispensing, or administering federally controlled substances to assist suicide

⁷⁶ 21 U.S.C. §823(b) (2007).

⁷⁷ Dispensing of Controlled Substances to Assist Suicide, 21 CFR Part 1306.

⁷⁸ *Id.*

⁷⁹ *Id.*

violates the CSA.”⁸⁰ The Attorney General found that this conclusion holds even if state law authorizes or permits such conduct by practitioners or others.⁸¹

The Supreme Court rejected Attorney General Ashcroft’s assertion in *Gonzales* and found that he did not have authority under the CSA to preempt Oregon’s death-with-dignity law. The Court held that the CSA “allocates decisionmaking powers among statutory actors so that medical judgments . . . are placed in the hands of the Secretary.”⁸² Further, in the CSA’s provisions on regulation of medical practice with respect to drug rehabilitation, the Secretary determines the appropriate methods of professional practice in medical treatment of narcotic addiction, after consultation with the Attorney General.⁸³ The Court additionally references the Congressional record for the statement that Congress intended for all decisions of a medical nature to be made by the Secretary, whereas the Attorney General would make all decisions “respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs.”⁸⁴

One important element of the Supreme Court’s decision was that the Attorney General did not have the authority to regulate the practice of medicine. The Court found from looking through the Congressional Record that the congressional intent in creating the CSA and adopting the statutory provisions related to physician prescribing and dispensing controlled substances was to allow the DEA to enforce drug law to the extent

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Gonzales v. Oregon*, 546 U.S. at 265.

⁸³ *Id.*

⁸⁴ *Id.* (referencing H.R. REP. NO. 93-884, at 6 (1974)).

that enforcement did not interfere with the practice of medicine. Congress intended that the Secretary of HHS make all decisions that were medical in nature.

As is seen by the testimony of some of the Senators who debated and passed the CSA, giving the Secretary input into medical and health decisions was of great importance to Congress. Though some senators objected to adding preventive, rehabilitative and treatment-based provisions to the CSA,⁸⁵ it was important that the opinions of the health professionals in the health policy and regulatory agency of the federal government influenced enforcement policy. From the binding nature of HHS's input into scheduling decisions to HHS's regulation of practice for physicians prescribing controlled substances, it was to be the agency with primary competence.

That said, in the event of violation of the Controlled Substances Act, even if by a practicing physician, the Court has affirmed the statutory authority of DEA to enforce the CSA's punishments. In *US v. Moore* the Supreme Court interpreted the CSA to criminalize the misuse of controlled substances.⁸⁶ Dr. Moore had acted improperly in the prescription and disbursement of controlled substances. He had failed to give adequate examinations, provided drugs as frequently and in quantities as great as the patient desired, and charged fees based on the amount of drugs prescribed.⁸⁷

⁸⁵ See 116 CONG. REC S20849 (daily edition Dec. 19, 1970) (Sen. Hughes remarks).

⁸⁶ *U.S. v. Moore*, 423 U.S. 122, 142-43 (1975).

⁸⁷ *Id.* at 126-27.

The Court said that because Dr. Moore’s conduct exceeded the bounds of professional conduct he could be criminally prosecuted.⁸⁸ Dr. Moore argued that he could not be prosecuted because his conduct was authorized by the CSA, but the Court was not persuaded. Dr. Moore had only a valid registration to dispense methadone for detoxification purposes,⁸⁹ but had acted as a “large scale pusher” in the eyes of the Court, dispensing methadone for more than just detoxification.⁹⁰ Congress in enacting the CSA was concerned that drug laws not impede legitimate research and physicians be allowed reasonable discretion in treating patients.⁹¹ As a result, it gave the Secretary the task of determining the appropriate methods of professional practice in medical treatment of narcotic addiction.⁹² This also means, however, that physicians who go beyond the approved practices are subject to serious criminal penalties.⁹³

The Supreme Court approved of DEA enforcement of the CSA against consumers of controlled substances in *Gonzales v. Raich*. California’s Compassionate Use Act authorizes doctors to prescribe a limited amount of marijuana for medicinal purposes.⁹⁴ The plaintiffs in the case, Ms. Raich and Ms. Monson, were California residents who suffered from serious medical conditions and used marijuana as medication pursuant to recommendations from their respective doctors.⁹⁵ Ms. Monson cultivated marijuana, a

⁸⁸ *Id* at 142-43.

⁸⁹ *Id*, at 144.

⁹⁰ *Id*, at 143.

⁹¹ *Id*, at 144.

⁹² *Id*.

⁹³ *Id*.

⁹⁴ *U.S. v. Raich*, 545 U.S. 1 (2005).

⁹⁵ *Id*. at 6.

schedule I drug, until federal DEA agents came to her house and destroyed her six cannabis plants.⁹⁶

The plaintiffs argued that enforcing the CSA against them would violate the Commerce Clause, the Process Clause of the Fifth Amendment, the Ninth and Tenth Amendments, but the Court found that the CSA could properly be enforced against them.⁹⁷ The Court found that a primary purpose of the CSA is to control the supply of controlled substances in both lawful and unlawful markets.⁹⁸ The regulation of the production of marijuana for home consumption has a substantial impact of the supply and demand for marijuana in interstate commerce and is within Congress' commerce power.⁹⁹ Thus, locally cultivated marijuana is properly subject to federal regulation and prohibition by the CSA.¹⁰⁰

Further, the CSA would impose controls beyond those of California law, including requiring a provider to obtain federal approval before marijuana could be dispensed.¹⁰¹

Though the Supreme Court prevented the enforcement of the CSA against doctors in Oregon, it showed in *Moore* and *Raich* that where the CSA is being expressly violated, whether by physician or consumer, federal controlled substances laws will be enforced. It is not difficult to see that the line between enforcement of violation of the CSA and control over the practice of medicine is quite blurry, however. The Attorney General does not have the authority to regulate the practice of medicine, and medical judgments

⁹⁶ *Id.* at 7.

⁹⁷ *Id.* at 8.

⁹⁸ *Id.* at 18.

⁹⁹ *Id.* at 19.

¹⁰⁰ *Id.* at 33.

¹⁰¹ *Id.* at 27-8.

are left to HHS, but where medical judgments have been made and rules have been adopted implementing them, the Attorney General has the authority to enforce the law and prosecute medical practitioners. Given the blurriness of this line, calls have been made to reform this system of shared authority.

Part V: Calls For Reform

A. Recent Legislative Action

Though Congress has settled parts of the debate as to how much authority the Attorney General should have over matters related to the practice of medicine, for some the debate is ongoing. Critics of parts of the statutory scheme see a need for change of the regulatory scheme as it is. One of the most recent proposals for change to the current balance between the Attorney General and HHS came in the form of legislation proposed in 2005.

Virginia representative Frank R. Wolf introduced legislation in 2004 proposing that the DEA be given authority to review, and potentially block, the sale of all new prescription narcotics.¹⁰² The legislation was attached to an omnibus appropriations bill, and passed with little notice during the 2004 session.¹⁰³ In 2005, when the bill was to be renewed, the FDA, a number of drug makers, and doctors who treat patients for pain objected to

¹⁰² Mark Kaufman. *Drug Enforcement Agency Stripped of Role on New Painkillers*. WASHINGTON POST, Nov. 5, 2005, at A13.

¹⁰³ *Id.*

renewing the provision.¹⁰⁴ Representative Wolf’s legislation was subsequently stripped from the bill.

Opponents of the provision argued that it was an “unwarranted intrusion by a law enforcement agency into the FDA’s drug review process.”¹⁰⁵ Pain specialists opposed to the bill argued that DEA reviews of new prescription drugs “could jeopardize the development of new drugs needed by patients with chronic pain.”¹⁰⁶ Congressman Wolf’s office commented that in declining to renew the provision, Congress “missed an opportunity to better control the sale of powerful new narcotic painkillers.”¹⁰⁷

The dispute over the Wolf provision is another chapter in the debate over the role the DEA should play in the regulation of medical practice and handling scientific information. In this situation, the focus is on new prescription drugs. As part of its enforcement regime, the DEA has with increased frequency arrested doctors, pharmacists, and other health-care workers accused of negligence or willful diversion in dispensing prescription narcotics that were later abused.¹⁰⁸ (An example is the Moore case above). A concern of Congress when it was enacting the CSA was that the threat of enforcement would make doctors refuse to treat patients with narcotics addictions.¹⁰⁹ This threat would also deter doctors from conducting research into and experimenting with new treatments for narcotics addicts. Such deterrence would be detrimental to the

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ See 116 CONG. REC S17395 (daily edition Oct. 7, 1970) (Sen. Hughes remarks).

public health because narcotics addicts would not get the treatment they needed at all or would not have access to new and more effective treatments being developed by medical professionals.

The FDA, drug makers and doctors were all concerned about Representative Wolf's bill because of the effect it could have on the practice of medicine. The Wolf bill gave to the DEA a function that was previously, and now currently, statutorily assigned to HHS and administered by the FDA. Not only does the bill take power away from the FDA, it weighs the need for enforcement over the need for medical study, treatment and rehabilitation. While it does have investigatory functions, the DEA's primary concern is to enforce the law relating to narcotics. With enforcement as the primary goal, concerns over the potential for abuse of a drug might be given too much weight where a new narcotic could be a promising tool in the treatment of addiction or the management of pain.

Congressman Wolf's office was primarily concerned with control of the sale of new painkillers, which is an important concern. It is not hard to find stories about people who have become addicted to painkillers after being prescribed them to deal with pain associated with a surgery or a medical condition, and have had a great deal of trouble defeating the addiction. For example, future hall of fame NFL quarterback Brett Favre admitted to the public that he became addicted to painkillers after using them to manage the pain that arose from successive injuries and surgeries.¹¹⁰ Abuse of narcotics is a real

¹¹⁰Michael Bauman, *The quarterback's challenge*, SPORTING NEWS, May 27, 1996.

issue, but many would argue that stemming abuse should not jeopardize the discovery of new medical treatments or interfere with the practice of medicine. Discussion of the bill highlights the tension between currents who believe narcotics should be met primarily with enforcement and others that feel that baseline decisions on drugs should be left to medical practitioners.

B: Existing Weaknesses in Federal Enforcement

While detractors from the current balance, like Congressman Wolf, argue that the DOJ should have authority to review all new drugs, DEA's critics argue that it already has a less than effective enforcement program. In 2005 DEA agents seized a total of \$1.4 billion in illegal drug trade related assets and \$477 million worth of drugs according to a DEA produced publication highlighting their year 2005 accomplishments.¹¹¹ These large numbers appear to indicate that the DEA has management of the illegal drug trade well under control. According to statistics from the White House Office of Drug Control Policy, however, the total value of all drugs sold in the US is as much as \$64 billion a year.¹¹² Given the comparatively small volume of drugs that the DEA seizes, some critics argue that the DEA's programs do not effectively deal with the drug problem.

Others argue that for the gains that the DEA makes in its seizure of drugs and enforcement of drug law, there are greater burdens placed on local law enforcement

¹¹¹ Allgov.com, U.S. Drug Enforcement Administration, http://www.allgov.com/Agency/U_S_Drug_Enforcement_Administration_DEA (last visited April 24, 2009).

¹¹² *Id.*

officials.¹¹³ The argument asserts that local law enforcement is increasingly burdened because higher prices will be charged for drugs to compensate for the increased risk of having the drugs seized, which will lead to increased crime by addicts trying to secure more money to pay the higher prices.¹¹⁴ Thus, the gains in the amount of illegal drugs seized really should be offset by the greater attention law enforcement will have to devote to street crime.

These two criticisms relate mainly to the DEA's handling of narcotics that enter into the US from abroad while discussions above have touched on the DEA's enforcement of laws related to narcotics manufactured here in the US. The DEA's role in the scheduling of substances and the monitoring of controlled substances manufactured and distributed in the US is closely related to its role in stopping the flow of controlled substances that enter the US without regard for the intricate scheme regulating these substances. The DEA spends a good amount of its time and budget on seizing illegal drugs and stopping the flow of unregulated drugs such that if there were less input by HHS into scheduling or DEA was tasked with direct review of new drugs, resource constraints might prevent it from effectively conducting its current duties.

One might think that given the questions as to the DEA's effectiveness, HHS, perhaps FDA in particular, should be given more input or control in regulation. It appears that the FDA's regulation of legal drugs is not without its flaws either, however. In looking at one of its functions, monitoring of and decision-making related to postmarket drugs, the

¹¹³ *Id.* (citing Milton Friedman).

¹¹⁴ *Id.*

Government Accountability Office (GAO) found that the FDA has some notable shortcomings.¹¹⁵ The FDA struggles in postmarket monitoring because it does not have authority in many cases to require postmarket studies from drug sponsors, does not have the resources to partner in conducting clinical trials or conduct its own, and the adverse events reporting system it uses has limits because of its inability to accurately measure frequency of events.¹¹⁶ These data constraints have contributed to FDA's shortcomings. Moreover they have led to controversy and in at least one case the pulling of a drug from the market. Perhaps in light of this reality and the FDA's struggle to monitor prescription drugs currently on the market, HHS cannot afford to take on responsibilities that will further constrain its resources.

Conclusion

This paper has presented a brief overview of the history of the Controlled Substances Act and the federal regulatory scheme for controlled substances. It has detailed the split of authority that exists between the Department of Justice and the Department of Health and Human Services in the regulation of these substances, the reasons for the shared responsibility, and the tensions that arise between the competing goals of enforcement and physician and scientist control over the practice of medicine. Though critics of the regulatory system argue for reform, this paper has not endorsed any of the proposals for change that are being discussed in the public sphere. Instead, the goal of this paper is to present the situation as it is and remind us of how we got here as we think about change.

¹¹⁵ U.S. GOV'T ACCOUNTABILITY OFFICE, FDA POSTMARKET DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 24 (March 2006).

¹¹⁶ *Id.*

Perhaps this reminder will be helpful in thinking about how to balance competing goals of enforcement and protecting the full practice of medicine in the future.