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Dispensing Controlled Substances for the Treatment of Pain; Notice

Issuance of Multiple Prescriptions for Schedule II Controlled Substances; Proposed Rule

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–286P]

Dispensing Controlled Substances for the Treatment of Pain

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Policy Statement.

SUMMARY: On January 18, 2005, DEA published in the **Federal Register** a solicitation of comments on the subject of dispensing controlled substances for the treatment of pain. Many of the comments that DEA received asked the agency to elaborate on the legal requirements and agency policy relating to this subject. This document provides such information.

DATES: September 6, 2006.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Background

On January 18, 2005, the DEA published in the **Federal Register** a Solicitation of Comments on the subject of dispensing controlled substances for the treatment of pain. 70 FR 2883. Many of the comments sought further information about the legal requirements and agency policy relating to the prescribing of controlled substances for the treatment of pain. DEA stated in the Solicitation of Comments that it would be issuing a document providing such information after reviewing the comments. Accordingly, this policy statement provides practitioners with a recitation of the pertinent principles under the Controlled Substances Act (CSA) and DEA regulations relating to the dispensing of controlled substances for the treatment of pain.

Extent of Abuse in the United States of Controlled Prescription Drugs

The abuse (nonmedical use) of prescription drugs is a serious and growing health problem in this country.[1] As the Administration has announced, recent data indicate that prescription drug abuse, particularly of opioid pain killers, has increased at an alarming rate over the past decade.[2] Statistics published in the National Survey on Drug Use and Health (NSDUH) by the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), demonstrate that prescription drugs account for the second-most commonly abused category of drugs, behind marijuana and ahead of cocaine, heroin, methamphetamine, and other drugs.[3]

One of the areas of concern is the number of persons who have recently begun abusing prescription controlled substances. In its NSDUH Report published in June 2006,[4] SAMHSA states: ''In 2004, among persons aged 12 or older, 2.4 million initiated nonmedical use of prescription pain relievers within the past year. This is more than the estimated number of initiates for marijuana (2.1 million) or cocaine (1.0 million).'' Overall, according to the NSDUH report: ''An estimated 31.8 million Americans have used pain relievers nonmedically in their lifetimes, up from 29.6 million in 2002.''

Another source of data presented by SAMHSA is that collected by the Drug Abuse Warning Network (DAWN), which provides national estimates of drug related visits to hospital emergency departments. According to DAWN, for 2004:

- Nearly 1.3 million emergency department (ED) visits in 2004 were associated with drug misuse/abuse. Nonmedical use of pharmaceuticals was involved in nearly half a million of these ED visits.
- Opiates/opioid analgesics (pain killers), such as hydrocodone, oxycodone, and methadone, and benzodiazepines, such as alprazolam and clonazepam, were present in more than 100,000 ED visits associated with nonmedical use of pharmaceuticals in 2004.[5]

A measure of the problem among young people is the 2005 Monitoring the Future (MTF) survey conducted by the University of Michigan.[6] The MTF survey is funded by the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), and measures drug abuse among 8th, 10th, and 12th graders. NIDA stated: ''While the 2005 survey showed a continuing general decline in drug use, there are continued high rates of non-medical use of prescription medications, especially opioid pain killers. For example, in 2005, 9.5 percent of 12th graders reported using Vicodin in the past year, and 5.5 percent of these students reported using OxyContin in the past year.'' [7] In announcing the latest MTF survey results, NIH Director Dr. Elias Zerhouni said that ''the upward trend in prescription drug abuse is disturbing.'' [8]

Purposes and Structure of This Document

One of the chief purposes of this document is to make clear that the longstanding requirement under the law that physicians may prescribe controlled substances only for legitimate medical purposes in the usual course of professional practice should in no way interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment. DEA also wishes to dispel the mistaken notion among a small number of medical professionals that the agency has embarked on a campaign to ''target'' physicians who prescribe controlled substances for the treatment of pain (or that physicians must curb their legitimate prescribing of pain medications to avoid legal liability).

To achieve these aims, this document begins with a general summary of the relevant legal principles and an explanation of the role of DEA with respect to regulation of controlled substances. The document then addresses specific issues and questions that have been raised on a recurring basis by physicians who seek guidance on the subject of dispensing controlled substances for the treatment of pain.

It should be understood that the legal standard under the Controlled Substances Act (CSA) for prescribing controlled substances to treat pain is the same as that for prescribing controlled substances generally: The prescription must be issued for a legitimate medical purpose by a registered physician acting within the usual course of professional practice. The reason this document focuses on the prescribing of controlled substances for the treatment of pain is that there has been considerable interest among members of the public in having DEA address this specific issue.

[1] National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005). (available at *http://www.drugabuse.gov/PDF/RRPrescription.pdf*).

[2] Office of National Drug Control Policy (ONDCP) press release, March 1, 2004.

[3] 2006 Synthetic Drug Control Strategy (available at *http://www.whitehousedrugpolicy.gov/publications/synthetic_drg_control_strat/synth_strat.pdf*).

[4] The NSDUH report is available at *http://www.oas.samhsa.gov/2k6/pain/pain.pdf*. The report extracted data from the 2004 National Survey on Drug Use and Health.

[5] *http://dawninfo.samhsa.gov/files/TNDR07EDvisitsNonmedicalUseForWeb.pdf*.

[6] *http://monitoringthefuture.org*.

[7] NIDA news release, December 19, 2005 (available at *http://www.nida.nih.gov*).

[8] *Id*.

The Statutory Role of DEA in Regulating the Prescribing of Controlled Substances

DEA is the agency within the Department of Justice responsible for carrying out the functions assigned to the Attorney General under the CSA.[9] These functions include enforcing and administering the CSA provisions governing the prescribing, administering, and dispensing of controlled substances. Thus, the scope of DEA's authority is delineated by the extent to which Congress itself regulated controlled substances through the enactment of the CSA and assigned certain functions under the Act to the Attorney General.

While the CSA is one component of the overall regulation of the practice of medicine in the United States,[10] it bears emphasis that the CSA does *not* regulate the practice of medicine as a whole. Therefore, although DEA is the agency responsible for administering the CSA, DEA does *not* act as the Federal equivalent of a State medical board overseeing the general practice of medicine. *State* laws and *State* licensing bodies (such as medical licensing boards) collectively regulate the practice of medicine.[11] In contrast, the scope of the CSA (and therefore role of DEA) is much narrower. The CSA regulates only the segment of medical practice involving the use of controlled substances, and DEA is correspondingly responsible for ensuring that controlled substances are used in compliance with Federal law.

In particular, DEA's role under the CSA is to ensure that controlled substances are prescribed, administered, and dispensed only for legitimate medical purposes by DEA-registered practitioners acting in the usual course of professional practice and otherwise in accordance with the CSA and DEA regulations. Each State also has its own laws (administered by State agencies) requiring that a prescription for a controlled substance be issued only for a legitimate medical purpose by State-licensed practitioners acting in the usual course of professional practice.

There is nothing new in this arrangement of responsibilities between the Federal and State governments. For more than 90 years (starting with the Harrison Narcotic Act of 1914, which was superseded by the CSA in 1970) Federal law has placed certain restrictions on the medical use of federally controlled substances while, at the same time, the States have regulated the practice of medicine generally. In this respect, there has long been a certain amount of overlap between the Federal and State oversight of controlled substances. Beginning in the 1930s and through to the present, States have adopted uniform controlled substance laws that were designed to promote standards that are consistent from State to State and in harmony with Federal law.[12] One such standard that has always been a fundamental part of these uniform State laws is the requirement that controlled substances be dispensed only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice—a requirement first articulated in the Harrison Narcotic Act. Accordingly, it has been the case for more than 70 years that a practitioner who dispenses controlled substances for other than a legitimate medical purpose, or outside the usual course of professional practice, is subject to legal liability under both State and Federal law.[13]

The Meaning of the ''Legitimate Medical Purpose'' Requirement

As stated above, the core legal standard is that a controlled substance may only be prescribed, administered, or dispensed for a legitimate medical purpose by a physician acting in the usual course of professional practice. This requirement has been construed to mean that the prescription must be ''in accordance with a standard of medical practice generally recognized and accepted in the United States.'' [14] However, Federal courts have long recognized that it is not possible to expand on the phrase ''legitimate medical purpose in the usual course of professional practice,'' in a way that will provide definitive guidelines that address all the varied situations physicians might encounter. As one court explained:

> There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts.[15]

Similarly, another court stated:

> A majority of cases [in which physicians were alleged to have dispensed controlled substances without a legitimate medical purpose] have dealt with facts which were so blatant that a statement of clear-cut criteria in a form useful in other cases would have been superfluous to the decision. We are, however, able to glean from reported cases certain recurring concomitance of condemned behavior.[16]

The foregoing quotation makes a particularly important point: that the types of cases in which physicians have been found to have dispensed controlled substances improperly under Federal law generally involve facts where the physician's conduct is not merely of questionable legality, but instead is a glaring example of illegal activity.

Specific Areas of Interest to the Commenters

The comments DEA received covered a variety of issues related to the dispensing of controlled substances for the treatment of pain. While some of the viewpoints expressed in the comments were in sharp contrast with other viewpoints, taken as a whole, the comments indicate there is significant interest (among those physicians and members of the public who submitted comments) in having DEA address the following topics:

[9] 21 U.S.C. 871(a); 28 CFR 0.100.

[10] As the United States Supreme Court stated in an early decision under the CSA, ''provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits.'' *United States* v. *Moore*, 423 U.S. 122, 141–142 (1975). In *Gonzales* v. *Oregon*, 126 S.Ct. 904, 925 (2006), the Court continued to cite *Moore* with approval and for the proposition that the legitimate medical purpose requirement in the CSA ''ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' The Court further stated: ''As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Id*

[11] Medical specialty boards also play a crucial role in providing information to the public, the government, and the medical profession concerning issues involving specialization and certification in medicine. Specialty boards maintain the quality of medical care in the United States by developing and utilizing professional and educational standards for the evaluation and certification of physician specialists.

[12] The first such uniform act was the Uniform Narcotic Drug Act of 1932, which was eventually adopted by every state. That act was replaced in 1970 by the Uniform Controlled Substances Act, which has been adopted by all but two states (New Hampshire and Vermont).

[13] Congress expressly intended that there would be a dual system of Federal-state regulation of controlled substances by including in the CSA a preemption provision, 21 U.S.C. 903, which reflects that this field of regulation was to be shared by the Federal and state governments. Section 903 states: ''No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State * * *.'' At the same time, this provision reiterates what is inherent in the supremacy clause of the United States Constitution—that no state may enact a law relating to controlled substances that presents a ''positive conflict'' with the CSA.

[14] *Moore*, 423 U.S. at 139 (quoting jury instruction).

[15] *United States* v. *August*, 984 F.2d 705, 713 (6th Cir. 1992).

[16] *United States* v. *Rosen*, 582 F.2d 1032 (5th Cir. 1978).

- The extent and consequences of the undertreatment of pain in the United States.
- The extent and consequences of excessive use of opioids to treat nonsevere pain.
- Providing medical and legal guidance on prescribing opioids for pain.
- Elaborating on DEA's policy regarding the investigation of physicians for improper prescribing of controlled substances for pain.
- Having DEA provide reassurance that it is not targeting physicians who prescribe controlled substances for pain.

Each of these topics is addressed in this document.[17]

Comments Regarding the Use of Opioids

The comments reflect two distinct points of emphasis among physicians who specialize in the treatment of pain. For some, of paramount concern is what they describe as the undertreatment of acute and chronic pain. Illustrative of this viewpoint, one commenter has stated:

> The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in State pain policies. Circumstances that contribute to the prevalence of undertreated pain include: (1) Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes.[18]

One group representing several organizations of physicians who specialize in treating pain commented that it agrees with the following statement made by DEA in the November 16, 2004, Interim Policy Statement published in the **Federal Register** (69 FR 67170): ''[C]hronic pain is a serious problem for many Americans. It is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified.'' However, this group expressed the view that the Interim Policy Statement would have ''the exact opposite effect'' by discouraging some practitioners from properly treating pain. The group therefore urged DEA to readdress the subject in a way that will promote proper dispensing of controlled substances for pain. Similar views were expressed in comments submitted by many other organizations whose missions relate to the treatment of pain. For example, an organization representing health care professionals and patient advocates for those with cancer pain stated: ''We respectfully request that the DEA reaffirm its support for areas of the law that support the appropriate use of opioid analgesics for pain control and thereby reduce the fears and uncertainties of health care professionals who treat patients in pain.'' With regard to this point, NIDA has stated in a recent report: ''Many healthcare providers underprescribe opioid pain relievers, such as morphine and codeine, because they overestimate the potential for patients to become addicted.'' [19]

A few other commenters focused primarily on what they believe is the overprescribing of opioids by some physicians to treat pain. For example, one physician who specializes in pain treatment stated that ''the majority of high dose narcotic prescribing is for chronic 'non-malignant' pain,'' that ''the growth of this practice has been exponential,'' and that ''there have been many problems associated with this practice, including the tremendous rise in abuse of prescription drugs in all segments of the population, especially the youth.'' Along similar lines, another physician commented there has been an ''epidemic'' of deaths and addiction resulting from the illicit use of prescription narcotics, which, according to this commenter, is due in large part to the prescribing of narcotics to ''a much wider class of chronic noncancer patients, including those with moderate subjective ailments such as bursitis, neuralgia, arthritis, headaches, and lower back pain.'' Another physician stated the large increase in the use of prescription narcotics and deaths related thereto ''seem to be coincident with growing advocacy for use of opioid pain medications in chronic benign pain syndromes'' and ''also coincide with the marketing of expensive new opioid drug preparations which are aggressively promoted by the drug manufacturers, and with the growth of professional and accrediting organizations that seem determined to promote the use of opioid pain medications.''

The two distinct areas of emphasis reflected in the comments—the commenters' views about the undertreatment of pain and what some perceive as overprescribing of opioids for nonsevere ailments—are not necessarily mutually exclusive. To the contrary, the comments taken collectively suggest that there may be some physicians who ''undertreat'' pain and others who improperly prescribe opioids ostensibly for the treatment of pain. (DEA presumes, however, that most physicians provide appropriate amounts of pain medication.) The comments also reflect that there is a lack of consensus among physicians as to all the circumstances that warrant the use of opioids to treat pain.[20] On this latter point, one physician who specializes in pain treatment commented: ''The treatment of chronic nonmalignant pain syndromes with narcotic medications remains a controversial area with the mainstream medical community.'' This commenter suggested there is a need for randomized, double-blind, controlled clinical trials to fully evaluate this issue. As explained below, it is not DEA's role to issue medical guidelines specifying patient characteristics that warrant the selection of a particular opioid or other medication or regimen for the treatment of pain.

Requests for Guidance on Treating Patients for Pain

Many commenters expressed the view that it would be beneficial if physicians had a single document providing clear guidelines on the use of controlled substances for the treatment of pain. Some believe such a document would remedy their concerns about the undertreatment of pain by giving

[17] Also of chief concern to commenters was the issuance by physicians of multiple schedule II prescriptions. DEA addressed this issue in detail in the August 26, 2005, **Federal Register** document titled ''Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances.'' 70 FR 50403. In addition, DEA is today publishing in the **Federal Register** a notice of proposed rulemaking (Docket No. DEA–287N) that would revise the DEA regulations to allow for the issuance of multiple schedule II prescriptions under certain circumstances.

[18] Federation of State Medical Boards of the United States, Model Policy for the Use of Controlled Substances for the Treatment of Pain (2004).

[19] National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (available at *http://www.drugabuse.gov/PDF/RRPrescription.pdf*).

[20] One indication of the lack of consensus among physicians on this point is the following. The American Medical Association, in a published policy statement (D–120.999) (''Use of opioids in chronic noncancer pain''), states: ''Further controlled trials [should] be conducted on opioid therapy in patients with chronic noncancer pain in an effort to identify best practice with regard to selection of both medication and treatment regimens [to] identify patient characteristics that predict opioid responsiveness [and to] provide support for guidelines on appropriate precautions, contraindications, and the degree of monitoring required in such patients.''

physicians assurance that they can avoid scrutiny by Federal and State regulatory authorities as long as they follow those guidelines when prescribing opioids. More specifically, it has been suggested that these guidelines should take the form of a series of questions and answers to be adopted by DEA. Among the questions that have been proposed for inclusion in these guidelines are:

- What should be the goals of pain management?
- How can a clinician assess a patient's pain?
- When should a primary care physician turn to a pain medicine specialist to manage a patient's pain?
- How are opioids used to manage chronic pain?

It is certainly appropriate for physicians and medical oversight boards to explore these types of questions. However, for the following reasons, it is not appropriate for DEA to address these questions in the form of a guidance document (or to endorse such a guidance document prepared by others).

First, one cannot provide an exhaustive and foolproof list of ''dos and don'ts'' when it comes to prescribing controlled substances for pain or any other medical purpose. As discussed above, the fundamental principle under both Federal and State law is that a controlled substance must be dispensed by a physician for a legitimate medical purpose in the usual course of professional practice. Throughout the 90 years that this requirement has been a part of United States law, the courts have recognized that there are no definitive criteria laying out precisely what is legally permissible, as each patient's medical situation is unique and must be evaluated based on the entirety of the circumstances. DEA cannot modify or expand upon this longstanding legal requirement through the publication or endorsement of guidelines.

Second, as stated earlier in this document, DEA's authority under the CSA is not equivalent to that of a State medical board. DEA does not regulate the general practice of medicine. The responsibility for educating and training physicians so that they make sound medical decisions in treating pain (or any other ailment) lies primarily with medical schools, post-graduate training facilities, State accrediting bodies, and other organizations with medical expertise. Some states also have continuing medical education requirements for licensing. Physicians also keep abreast of the latest findings by reading peer-reviewed articles published in medical and scientific journals. DEA, however, has neither the legal authority nor the expertise to provide medical training to physicians or issue guidelines that constitute advice on the general practice of medicine.[21]

For these reasons, DEA is not proposing any medical guidelines on prescribing controlled substances for the treatment of pain.

Whether To Form an Advisory Committee

Several members of the public have suggested that DEA form an advisory committee, panel, or working group to develop and publish guidelines on the use of controlled substances for the treatment of pain. An agency may not utilize an advisory committee (or panel or working group) to provide advice to the agency or prepare a document for (or in conjunction with) the agency unless all of the procedural requirements of the Federal Advisory Committee Act (FACA) are satisfied.[22] Compliance with FACA ensures, among other things, that persons selected by the agency to serve on the committee constitute a balanced membership that represents a fair cross-section of viewpoints.

If DEA were to conclude that compelling considerations necessitated the formation of an advisory committee subject to FACA, the agency would seek to do so in accordance with the law and Executive Branch directives.[23] At this time, DEA does not believe that such considerations exist warranting the formation of such an advisory committee to address the dispensing of controlled substances for the treatment of pain. However, there are other means available to an agency to obtain valuable public input. Within the bounds permissible by law, DEA remains firmly committed to obtaining the ongoing input of the medical community, law enforcement officials, and other interested members of the public. Toward this end, the agency welcomes written submissions from the public on this document and will continue to explore other legally appropriate means of hearing the views of interested members of the public.

The Number of Physicians Who Prescribe Controlled Substances in Violation of the CSA Is Extremely Small and There Is No DEA ''Crackdown'' on Physicians

DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes. In fact, the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by Federal or State law enforcement officials. Contrary to the impression of some commenters, DEA has not modified its criteria for investigating physicians or increased its emphasis on physicians as part of the agency's overall mission. *In any given year, including 2005, fewer than one out of every 10,000 physicians in the United States (less than 0.01 percent) lose their controlled substance registrations based on a DEA investigation of improper prescribing.*[24] This figure alone should correct any mistaken notions about a supposed DEA ''crackdown'' on physicians. Moreover, as mentioned above, the responsibility for monitoring and preventing controlled substance abuse is shared by State and Federal governments. Even in the rare cases where a physician loses his/her DEA registration for improper prescribing, it is often State officials—not DEA—who initiate the investigations.

DEA always had, and continues to have, a legal obligation to investigate the extremely small fraction of physicians who use their DEA registration to commit criminal acts or otherwise violate the CSA. DEA takes this obligation seriously because even just one physician who uses his/her DEA registration for criminal purposes can cause enormous harm. In the words of one commenter: ''It takes only a few untrained or unscrupulous physicians to create large pockets of addicts.'' But DEA takes just as seriously its obligation to ensure that there is no interference with the dispensing of controlled

[21] As stated above, DEA does have the authority and the expertise to investigate and determine whether a prescription for a controlled substance was issued for a legitimate medical purpose in the usual course of professional practice within the meaning of the CSA and DEA regulations.

[22] As set forth in FACA, a charter must be enacted before an advisory committee can meet. 5 U.S.C. App. 2 § 9(c). For an agency committee, the charter must be filed with the head of the agency, the appropriate Senate and House of Representatives standing committees, the Library of Congress, and the General Services Administration Secretariat, 41 CFR 102–3.70. The charter must contain certain information, including, among other things, the following: the advisory committee's official designation; objectives and the scope of the advisory committee's activity; the time necessary to carry out the advisory committee's purposes; a description of the duties for which the advisory committee is responsible; the estimated annual costs; the estimated frequency of the advisory committee's meetings; and the planned termination date.

[23] *See* Executive Order 12838 (''Termination and Limitation of Federal Advisory Committees'').

[24] The majority of cases in which physicians lose their DEA registrations result from actions by state medical boards to revoke or suspend the physicians' state medical licenses.

substances to the American public in accordance with the sound medical judgment of their physicians. It would be a disservice to many patients if exaggerated statements regarding the likelihood of a DEA investigation resulted in physicians mistakenly concluding that they must scale back their patients' use of controlled substances to levels below that which is medically appropriate.

Furthermore, DEA does not apply a greater level of scrutiny to the prescribing of controlled substances to treat pain as compared to other ailments. Regardless of the ailment, DEA applies evenhandedly the requirement that a controlled substance be prescribed for a legitimate medical purpose in the usual course of professional practice. The idea that prescribing opioids to treat pain will trigger special scrutiny by DEA is false.

Types of Cases in Which Physicians Have Been Found To Have Prescribed or Dispensed Controlled Substances for Other Than a Legitimate Medical Purpose or Outside the Usual Course of Professional Practice

Bearing in mind that there are no criteria that will address every conceivable instance of prescribing, the following examples of cases are provided to explain how Federal courts and DEA have applied the requirement that a controlled substance be dispensed for a legitimate medical purpose in the usual course of professional practice.

Application of the Requirement by Federal Courts

As noted above, the Supreme Court recently stated, in *Gonzales* v. *Oregon*, that the legitimate medical purpose requirement in the CSA ''ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' [25] The Court further stated: ''As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' [26]

Consistent with those views, some years ago, the United States Court of Appeals for the Fifth Circuit summarized the reported cases in which physicians had been found to have violated the requirement that a prescription for a controlled substance be issued only for a legitimate medical purpose in the usual course of professional practice. In this decision, *United States* v. *Rosen*, 582 F.2d 1032 (5th Cir. 1978), the court looked at the case law and found the following recurring patterns indicative of diversion and abuse:

(1) An inordinately large quantity of controlled substances was prescribed.

(2) Large numbers of prescriptions were issued.

(3) No physical examination was given.

(4) The physician warned the patient to fill prescriptions at different drug stores.

(5) The physician issued prescriptions knowing that the patient was delivering the drugs to others.

(6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.

(7) The physician involved used street slang rather than medical terminology for the drugs prescribed.

(8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.

(9) The physician wrote more than one prescription on occasions in order to spread them out.

The same fact patterns listed by the *Rosen* court remain prevalent today among the cases in which physicians have been found to have improperly prescribed controlled substances. This does not mean that the existence of any of the foregoing factors will automatically lead to the conclusion that the physician acted improperly. Rather, each case must be evaluated based on its own merits in view of the totality of circumstances particular to the physician and patient. For example, what constitutes ''an inordinately large quantity of controlled substances'' (factor (1) listed by the *Rosen* court) can vary greatly from patient to patient. A particular quantity of a powerful schedule II opioid might be blatantly excessive for the treatment of a particular patient's mild temporary pain, yet insufficient to treat the severe unremitting pain of a cancer patient.

Again, rather than focusing on any particular factor, it is critical to bear in mind that (i) the entirety of circumstances must be considered, (ii) the cases in which physicians have been found to have prescribed controlled substances improperly typically involve facts that demonstrate blatant criminal conduct, and (iii) the percentage of physicians who prescribe controlled substances improperly (or are investigated for doing so) is extremely small.

Application of the Requirement by DEA

Any final decision by DEA to revoke or deny a DEA registration is published in the **Federal Register**. The following are three examples from 2005 in which DEA revoked physicians' DEA registrations for unlawfully prescribing or dispensing controlled substances. (The complete final orders are published in the **Federal Register** and are available online.)

- *Robert A. Smith, M.D.* (70 FR 33207)—Dr. Smith gave one patient seven to ten prescriptions of OxyContin per visit on a weekly basis. The prescriptions were written in the patient's name as well as the names of the patient's father and her fiancé. Each visit, the patient paid Dr. Smith a $65 fee for the office visit plus an additional $100 for the fraudulent prescriptions. Dr. Smith also asked the patient for sexual favors during office visits. The patient declined, but, as a substitute, paid another woman $100 to perform a sexual act on Dr. Smith. Dr. Smith's office assistant also provided the patient with blank prescriptions, in return for which the office assistant demanded from the patient $40 and OxyContin tablets.

Another patient would give Dr. Smith a list of fictitious names and types of controlled substances he desired, and Dr. Smith would issue three prescriptions under each name, usually for Percocet, OxyContin, and Xanax, at the same time. Dr. Smith issued between nine and fifteen fraudulent prescriptions per visit and received $100 for each set of three prescriptions. The patient then sold the prescriptions to a third party who, in turn, sold the drugs on the street, all with the knowledge of Dr. Smith.

Another individual visited Dr. Smith three times in less than a three-week period, obtaining fraudulent prescriptions each time. The individual paid Dr. Smith $500 for 15 prescriptions for Xanax, OxyContin, and Percocet, which were written under five different fictitious patient names.

- James S. Bischoff, M.D. (70 FR 12734)—Dr. Bischoff took a 16-year-old high school student to an out-of-town physician specialist for emergency medical treatment after the boy's hand was cut in an accident. When the specialist did not recommend treatment with a controlled substance, Dr. Bischoff wrote the boy a prescription for 100 OxyContin, which Dr. Bischoff personally took to a pharmacy to be filled. Dr. Bischoff delivered only 20 tablets to the boy, unlawfully diverting the remaining 80 tablets. Around the same time, Dr. Bischoff wrote another prescription in the boy's name for 120 Adderall tablets. Dr. Bischoff also filled this prescription himself at a pharmacy but never delivered the tablets to the boy. Later, Dr. Bischoff wrote another prescription in the name of the boy for 120 Adderall tablets. The boy's stepmother learned that the boy was taking the medication only after she

[25] 126 S.Ct. at 925.

[26] *Id.*

discovered the bottle a couple of weeks later. She then checked with the pharmacy and discovered that Dr. Bischoff had written and personally filled multiple fraudulent prescriptions for controlled substances in the names of the boy's family members, telling pharmacists that he was a close friend and that the purported patients were too busy to get to the pharmacy. In addition, Dr. Bischoff ordered approximately 46,000 dosage units of schedule III and IV controlled substances from a supplier, and he was unable to account for 32,000 dosage units.

• *John S. Poulter, D.D.S.* (70 FR 24628)—Local law enforcement authorities were called after Dr. Poulter was observed parked in front of a convenience store injecting himself with Demerol. Dr. Poulter failed a field sobriety test, admitted to injecting himself with Demerol, and later pleaded guilty to State felony charges of unlawful possession of a controlled substance. The plea was held in abeyance for three years pending Dr. Poulter's successful completion of a monitoring program for impaired professionals. In addition to the criminal proceedings, his State professional licensing board took action based on the Demerol incident and several instances of improper use of Fentanyl. Dr. Poulter entered into a five-year probationary agreement with the State board, agreeing to abstain from personal use of mood-altering substances. Before completing these probationary periods, Dr. Poulter was involved in an automobile accident in which he drove his car off the road after having injected himself with Fentanyl and Demerol. Responding officers and medical personnel found him ''incoherent and very confused,'' and there were visible needle marks on his arm and hands. A search of the automobile revealed a used syringe and a plastic container holding Demerol and Fentanyl.

These three recent cases provide illustrations of some of the most common behaviors that result in loss of DEA registration: Issuing prescriptions for controlled substances without a bona fide physician-patient relationship; issuing prescriptions in exchange for sex; issuing several prescriptions at once for a highly potent combination of controlled substances; charging fees commensurate with drug dealing rather than providing medical services; issuing prescriptions using fraudulent names; and self-abuse by practitioners.

In another recent case, *United States* v. *Singh,* 390 F.3d 168 (2d Cir. 2004), a physician who claimed to specialize in pain management was convicted following a jury trial of improperly prescribing a controlled substance in violation of the CSA. The court of appeals, which upheld the conviction, described the nature of the physician's prescribing practice as follows (*id.* at 176):

> Singh developed a scheme that enabled nurses to see patients alone, to issue prescriptions for schedule II controlled substances, and to bill for such services. He and the other physicians would pre-sign the triplicate forms and provide them to non-physician personnel to use during patient visits. These employees, although not trained or legally authorized to do so, filled in all the required prescription information—drug type, dosage, and quantity—and provided the prescriptions to the patients.
>
> It appears that the physicians at the practice, including Singh, signed entire books of triplicate prescription forms in blank without even knowing the identities of the patients to whom the prescriptions would be issued or the nature or dosage of the drug to be prescribed. * * *
>
> Data extracted from Singh's office records revealed that the nurses issued prescriptions for at least 76,000 tablets of schedule II controlled substances when Singh was not present in the practice suite.

Thus, *Singh* is another example of a prosecution based on blatant criminal conduct by a physician, and it should cause no concern for any legitimate pain specialist or other physician who properly prescribes controlled substances.

Commencement of Investigations

On the subject of when DEA might commence an investigation of possible improper prescribing of controlled substances, several commenters sought elaboration on DEA's statements in the November 16, 2004 Interim Policy Statement. In that document, DEA stated, among other things:

> [I]t is a longstanding legal principle that the Government ''can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not.'' *United States* v. *Morton Salt Co.,* 338 U.S. 632, 642–643 (1950). It would be incorrect to suggest that DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the [CSA].

The foregoing is a correct statement of the law, and DEA is not unique in this regard. All law enforcement agencies—Federal and State—have long been governed by this same principle. The reason DEA mentioned this longstanding maxim in the Interim Policy Statement was to correct an earlier publication attributed to DEA that embodied a contrary view.

While those who commented on the subject of investigations generally acknowledged that DEA had properly stated the law, some asserted that, by doing so, the agency might have caused some physicians to fear the prospect of being investigated and thereby discouraged them from providing proper pain treatment. DEA believes, however, physicians will understand that correctly stating the legal standard which has historically applied to regulatory agencies is no cause for alarm. DEA does not use its investigatory authority in an arbitrary manner. Further, as DEA has repeatedly stated in this document and elsewhere, there is no ''crackdown'' or increased emphasis on investigating physicians, and the statistics bear that out. In 2005, as in prior years, only a tiny fraction of physicians (less than one in ten thousand) lost their registration based on a DEA investigation of improper prescribing of controlled substances.

One commenter suggested DEA should announce it will only commence an investigation when it has evidence that the physician is prescribing in a manner outside of accepted medical standards. To adopt such a standard would conflict with longstanding law, as previously noted. In addition, from a practical perspective, such a standard would be impossible to apply because the agency cannot know—prior to commencing an investigation—whether the activity was proper or improper. Gathering preliminary information is essential to determining whether a full-scale investigation is—or is not—warranted. By stating the governing law, however, DEA is not suggesting that it investigates every instance of prescribing in order to rule out the possibility of illegal activity. To the contrary, the agency recognizes that nearly every prescription issued by a physician in the United States is for a legitimate medical purpose in the usual course of professional practice.

Other Recurring Questions

What is fueling the recent increase in prescription drug abuse?

There are a variety of factors that may be contributing to the increase in prescription drug abuse. The Director of NIDA recently testified before Congress:

> The recent increase in the extent of prescription drug abuse in this country is likely the result of a confluence of factors, such as: Significant increases in the number of prescriptions; significant increases in drug availability; aggressive marketing by the pharmaceutical industry; the proliferation of illegal Internet pharmacies that dispense these medications without proper prescriptions and surveillance; and a greater

social acceptability for medicating a growing number of conditions.[27]

• *Increased availability of prescription drugs and sharing among family and friends*—The United States Government Accountability Office (GAO) published a report in 2003 on the abuse of the most prescribed brand name narcotic medication for treating moderate-to-severe pain.[28] The report states: ''The large amount of [the drug] available in the marketplace may have increased opportunities for abuse and diversion. Both DEA and [the manufacturer of the drug] have stated that an increase in a drug's availability in the marketplace may be a factor that attracts interest by those who abuse and divert drugs.''

The 2006 Synthetic Drug Control Strategy states:

> Preliminary data suggest the most common way in which controlled substance prescriptions are diverted may be through friends and family. For example, a person with a lawful and medical need for some amount of a controlled substance uses only a portion of the prescribed amount. Then a family member complains of pain, and the former patient shares excess medication. Alternatively, for a family member addicted to controlled prescription drugs, the mere availability of unused controlled substance prescriptions in the house may prove to be an irresistible temptation.

• *Ease of access via the Internet*—It is becoming increasingly easy for persons of any age to obtain controlled substances illegally by means of the Internet. Numerous Web sites based in the United States and abroad sell controlled substances to anyone willing and able to provide a credit card number. Some of these Web sites do not require a prescription. Others will provide the buyer with an illegitimate prescription simply by having the buyer fill out an online questionnaire without seeing a physician. As the 2006 Synthetic Drug Control Strategy states, ''the anonymity of the Internet and the proliferation of Web sites that facilitate illicit transactions for controlled substance prescription drugs have given drug abusers the ability to circumvent the law as well as sound medical practice.''

• *Improper prescribing*—As the 2006 Synthetic Drug Control Strategy states: ''The overwhelming majority of prescribing in America is conducted responsibly, but the small number of physicians who overprescribe controlled substances—carelessly at best, knowingly at worst—help supply America's most widespread drug addiction problem. Although the problem exists, the number of physicians responsible for this problem is a very small fraction of those licensed to prescribe controlled substances in the United States.''

• *Drug formulation and marketing*—One of the recommendations in the 2006 Synthetic Drug Control Strategy is to ''[c]ontinue to support the efforts of firms that manufacture frequently diverted pharmaceutical products to reformulate their products so as to reduce diversion and abuse,'' and to ''[e]ncourage manufactures to explore methods to render * * * pain control products, such as OxyContin, less suitable for snorting or injection.'' Whether the marketing of certain opioids has contributed to abuse and diversion has also been an area of discussion.[29]

What are some of the common methods and sources of diversion?

Diversion of prescription drugs containing controlled substances occurs on a variety of levels. Some controlled substances are stolen directly from manufacturers and distributors. Diversion also occurs at the retail level with thefts from, and robberies of, pharmacies. In one survey of over 1,000 pharmacists nationwide, 28.9 percent reported that they had experienced a theft or robbery at their pharmacies within the past five years.[30] A very small percentage of physicians also contribute to the problem of diversion by intentionally, or unintentionally, providing controlled substances to those who are themselves drug abusers or who sell the drugs for profit.

Prescription fraud is another common source of diversion. This occurs whenever prescriptions for controlled substances are obtained under false pretenses, including when prescriptions are forged or altered, or when someone falsely claiming to be a physician calls in the prescription to a pharmacy.

''Doctor shopping'' is another traditional method by which diversion occurs. Some drug abusers visit multiple physicians' offices and falsely present complaints in order to obtain controlled substances.

What are the potential signs to a physician that a patient might be seeking drugs for the purpose of abuse or diversion?

Many physicians have requested a list of the possible indicators that a patient might be seeking controlled substances for the purpose of diversion or abuse. DEA has provided this type of list in various publications over the years. While not an exhaustive list, the following are some of the common behaviors that might be an indication the patient is seeking drugs for the purpose of diversion or abuse:

- Demanding to be seen immediately;
- Stating that s/he is visiting the area and is in need of a prescription to tide her/him over until returning to the local physician;
- Appearing to feign symptoms, such as abdominal or back pain, or pain from kidney stones or a migraine, in an effort to obtain narcotics;
- Indicating that nonnarcotic analgesics do not work for him/her;
- Requesting a particular narcotic drug;
- Complaining that a prescription has been lost or stolen and needs replacing;
- Requesting more refills than originally prescribed;
- Using pressure tactics or threatening behavior to obtain a prescription;
- Showing visible signs of drug abuse, such as track marks.

What are the general legal responsibilities of a physician to prevent diversion and abuse when prescribing controlled substances?

In each instance where a physician issues a prescription for a controlled substance, the physician must properly determine there is a legitimate medical purpose for the patient to be prescribed that controlled substance and the physician must be acting in the usual course of professional practice.[31] This is the basic legal requirement discussed

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[27] The NIDA testimony, which was presented July 26, 2006, before the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, appears in full on NIDA's Web site at *http://www.drugabuse.gov/Testimony/7-26-06Testimony.html.*

[28] The GAO report, ''Prescription Drugs OxyContin Abuse and Diversion and Efforts to Address the Problem,'' GAO–04–110 (December 2003), is available at *http://www.gao.gov/new.items/d04110.pdf.*

[29] A detailed discussion of this issue is contained in the above-referenced GAO report, ''Prescription Drugs OxyContin Abuse and Diversion and Efforts to Address the Problem.'' The manufacturer's statement to Congress in response to the GAO report is available at *http://reform.house.gov/UploadedFiles/9-13-2005%20Purdue%20Testimony.pdf.* In 2001, FDA announced that it had worked with the manufacturer of OxyContin to make changes to the drug's labeling, including a ''black box warning,'' which FDA states is ''intended to lessen the chance that OxyContin will be prescribed inappropriately for pain of lesser severity than the approved use or for other disorders or conditions inappropriate for a schedule II narcotic.'' FDA Talk Paper: ''FDA Strengthens Warnings for OxyContin'' (July 25, 2001), available at *http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01091.html.*

[30] The survey was conducted by the National Center on Addiction and Substance Abuse at Columbia University, which published the results in a comprehensive report on prescription drug abuse entitled: ''Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.'' (available at *http://www.casacolumbia.org/absolutenm/articlefiles/380-under_the_counter_-_diversion.pdf).*

[31] 21 CFR 1306.04(a); *United States* v. *Moore, supra.*

above, which has been part of American law for decades. Moreover, as a condition of being a DEA registrant, a physician who prescribes controlled substances has an obligation to take reasonable measures to prevent diversion.[32] The overwhelming majority of physicians in the United States who prescribe controlled substances do, in fact, exercise the appropriate degree of medical supervision—as part of their routine practice during office visits—to minimize the likelihood of diversion or abuse. Again, each patient's situation is unique and the nature and degree of physician oversight should be tailored accordingly, based on the physician's sound medical judgment and consistent with established medical standards.

What additional precaution should be taken when a patient has a history of drug abuse?

As a DEA registrant, a physician has a responsibility to exercise a much greater degree of oversight to prevent diversion and abuse in the case of a known or suspected addict than in the case of a patient for whom there are no indicators of drug abuse. Under no circumstances may a physician dispense controlled substances with the knowledge they will be used for a nonmedical purpose or that they will be resold by the patient. Some physicians who treat patients having a history of drug abuse require each patient to sign a contract agreeing to certain terms designed to prevent diversion and abuse, such as periodic urinalysis. While such measures are not mandated by the CSA or DEA regulations, they can be very useful.

Can a physician be investigated solely on the basis of the number of tablets prescribed for an individual patient?

The Supreme Court has long recognized that an administrative agency responsible for enforcing the law has broad investigative authority,[33] and courts have recognized that prescribing an ''inordinately large quantity of controlled substances'' can be evidence of a violation of the CSA.[34] DEA therefore, as the agency responsible for administering the CSA, has the legal authority to investigate a suspicious prescription of any quantity.

Nonetheless, the amount of dosage units per prescription will never be a basis for investigation for the overwhelming majority of physicians. As with every other profession, however, among the hundreds of thousands of physicians who practice medicine in this country in a manner that warrants no government scrutiny are a handful who engage in criminal behavior. In rare cases, it is possible that an aberrant physician could prescribe such an enormous quantity of controlled substances to a given patient that this alone will be a valid basis for investigation. For example, if a physician were to prescribe 1,600 (sixteen hundred) tablets per day of a schedule II opioid to a single patient, this would certainly warrant investigation as there is no conceivable medical basis for anyone to ingest that quantity of such a powerful narcotic in a single day. Again, however, such cases are extremely rare. The overwhelming majority of physicians who conclude that use of a particular controlled substance is medically appropriate for a given patient should prescribe the amount of that controlled substance which is consistent with their sound medical judgment and accepted medical standards without concern that doing so will subject them to DEA scrutiny.

Can methadone be used for pain control?

Methadone, a schedule II controlled substance, has been approved by the FDA as an analgesic. While a physician must have a separate DEA registration to dispense methadone for maintenance or detoxification, no separate registration is required to prescribe methadone for pain. However, in a document entitled ''Methadone-Associated Mortality: Report of a National Assessment,'' SAMHSA recently recommended that ''physicians need to understand methadone's pharmacology and appropriate use, as well as specific indications and cautions to consider when deciding whether to use this medication in the treatment of pain.'' [35] This recommendation was made in light of mortality rates associated with methadone.

Obtaining Further Input From Physicians and Other Health Care Professionals

In developing policies and rules relating to the use of controlled substances in the treatment of pain, DEA is firmly committed to obtaining input on an ongoing basis from physicians and other health care professionals authorized to prescribe and dispense controlled substances, as well the views of Federal and State agencies, professional societies, and other interested members of the public. DEA welcomes the written comments that any such persons might wish to submit in response to this document. DEA will also continue to evaluate whether it would be beneficial to obtain the additional views of physicians through in-person meetings, to the extent permissible under FACA.

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Michele M. Leonhart,

Deputy Administrator.

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[32] 21 U.S.C. 823(f).

[33] *Morton Salt,* 338 U.S. at 642–643 (''an administrative agency charged with seeing that the laws are enforced'' may ''investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not.'').

[34] *United States* v. *Rosen,* 582 F.2d at 1036.

[35] SAMHSA Publication No. 04–3904. Available at *http://dpt.samhsa.gov/reports/index.htm.*