

PAIN & POLICY STUDIES GROUP



WHO Collaborating Center
for Policy and Communications
in Cancer Care

March 11, 2005

DEA Headquarters, Deputy Administrator
Attention: DEA Federal Register Representative/CCD
2401 Jefferson-Davis Highway
Alexandria, VA 22301

Re: Docket No. DEA-261
Comment on Dispensing of Controlled Substances for the Treatment of Pain

Dear Ms. Leonhart:

The Pain & Policy Studies Group (PPSG) respectfully submits the attached document to the United States Drug Enforcement Administration (DEA) and to the Department of Justice (DOJ). These comments are in reference to the Interim Policy Statement of November 16, 2004 (Docket No. DEA-258S) "Dispensing of Controlled Substances for the Treatment of Pain" and the Solicitation of Comments of January 18, 2005 (Docket No. DEA-261).

We believe that healthcare professionals, law enforcement and regulatory personnel share a responsibility to ensure that prescription pain medications are available to the patients who need them while also preventing these drugs from becoming a source of harm or abuse. This can be accomplished only when health professionals who treat pain also understand and avoid knowingly contributing to diversion, and when law enforcement and regulators who deal with diversion also understand and do not interfere in pain management. Although most practitioners are not sources of diversion, significant efforts have been undertaken by the pain community in cooperation with law enforcement and regulatory experts to inform and educate pain practitioners about risk assessment and mitigation.

The PPSG has worked with DEA's Office of Diversion Control to address these goals. This work has resulted in a joint statement with DEA and 21 health organizations called "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act" in 2001. This statement was subsequently endorsed by over 40 organizations. This document and the developing collaborative relationships culminated in the jointly authored "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel" (FAQ) in August 2004. Soon thereafter, DEA abruptly withdrew its support, issued an Interim Policy Statement and then a Solicitation of Comments.

We believe that DEA needs to carefully review its approach to working with pain and palliative care groups, and recommit to a meaningful effort to work with law enforcement and regulators at all levels of government to avoid statements and actions that have the potential to interfere in

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pain management. In addition, many organizations would be willing to work with DEA to dispel fears of inappropriate investigation among practitioners, if DEA is able to clarify that it and its law enforcement partners do not randomly investigate practitioners, and that the indicators used to detect law violation cannot be confused with legitimate practices.

We are requesting several positive formal actions that can ease the fears and concerns of practitioners and also provide needed guidance to federal, state and local investigators and prosecutors. We ask that DEA consider these recommendations, and bring them to the attention of the DOJ and the state Attorneys General because of the applicability of these matters to the prosecution of criminal cases relating to controlled substances under both federal and state statutes.

The DEA should:

- (1) Reaffirm its previous interpretations of law to permit practitioners to issue a series of prescriptions marked “do not fill” until a later date.
- (2) Reassure practitioners that DEA uses appropriate indicators of diversion that cannot be confused with legitimate practice, and that its approach to investigation of practitioners is not a threat to law-abiding practitioners and patients.
- (3) Clarify what constitutes unlawful conduct under the Controlled Substances Act and regulations.
- (4) Avoid sending messages of fear to the community of law-abiding practitioners.
- (5) Following clarification of the above policies and procedures, the DEA and the DOJ should a) affirm and communicate to practitioners, law enforcement and regulatory authorities throughout the country their strong commitment to a balanced national policy on diversion control that avoids interfering in legitimate medical practice and patient care, b) endorse the Federation of State Medical Board’s Model Policy, c) update its public information accordingly, and d) appoint an Advisory Committee to address how DEA can promote balanced approaches to the use and control of controlled substances.

Sincerely,

David E. Joranson
Senior Scientist, Director

Comment

This comment is in reference to the Interim Policy Statement (1) of November 16, 2004 (Docket No. DEA-258S) “Dispensing of Controlled Substances for the Treatment of Pain” and in response to the Solicitation of Comments (2) of January 18, 2005 (Docket No. DEA-261).

The Interim Policy Statement (IPS) questioned the legality of the situation where a practitioner who treats patients with chronic conditions issues more than one prescription on the same date with some marked for later dispensing at reasonable intervals. DEA stated that “For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance.”(p. 67171) (1)

Recommendation 1: The DEA should reaffirm its previous interpretations of law to permit practitioners to issue a series of prescriptions marked “do not fill” until a later date.

The federal Controlled Substances Act clearly bars refills of prescriptions for Schedule II controlled substances, but these are not refills; they are a series of original prescription orders by law-abiding practitioners trying to implement a medical treatment regimen for a period of months. Such a regimen has become part of standard medical practice because it has the advantages of reducing costs, increasing convenience, as well as limiting the potential for diversion.

Prior to November 16 2004, DEA had a longstanding, reasonable and unchallenged interpretation that specifically permitted this practice.¹ Some states enacted laws and regulations or adopted policies to be consistent with this interpretation and it has been widely disseminated in print and through educational programs.²

¹ DEA’s first interpretation of this matter was in 1995 in official correspondence from G. Thomas Gitchel who stated, “...the practitioner signs and dates as many as six prescriptions on the day of issuance. The prescriptions are noted that the pharmacist is not to dispense the prescription for 30, 60, 90, or 120 days...there appears to be no violation of current federal laws or regulations in the prescribing in the manner you have described.” (3)

In 2003, DEA’s Patricia Good stated in official DEA correspondence that “The DEA regulations do not prohibit a practitioner from issuing more than one prescription at a time. If, in keeping with the practitioner’s professional medical judgment, multiple prescriptions are issued at one time, each must bear the actual date that the prescriptions were issued and signed as well as directions for dispensing...the DEA does not consider multiple prescriptions in the scenario outlined above as refills, and has authorized this practice provided that it is not a violation of the laws of the state in which the practitioner is licensed.” (4)

More recently on February 14, 2005, DEA’s Patricia Good indicated that a practitioner may issue a *single* prescription signed and dated on the date of issue with a notation to the pharmacy to dispense at a later date. (5) While there is no question about the legality of issuing a single ‘do not fill’ prescription, now there is a situation where physicians and pharmacists must decide which ‘do not fill’ prescriptions are lawful and which are not.

² See, e.g., “Pharmacy Law for California Pharmacist”, Marcus & Cohen (5th ed., 2005), pg. 164, where the earlier advice was included in an update to the prior edition and had to be retracted for the 2005 edition. (6) See also the medical journal Pain Medicine which published five clinical vignettes in which DEA provided clinicians throughout the country with clarification on the legality of certain prescribing practices. In that issue, DEA stated that “DEA regulations do not prohibit a practitioner from issuing more than one prescription at a time...” [and if] “...multiple

DEA's interim interpretation interferes in legitimate medical practices and patient care and is harming the relationship DEA seeks to have with the healthcare community. The Controlled Substances Act was not intended to give authority to the Department of Justice to regulate medical practice. (8) Practitioners feel forced to see more patients more frequently than necessary in order to issue prescriptions; this may require increasing medical and office staff to accommodate the greater number of patient visits. Or, practitioners may write single prescriptions for large quantities of medication, or they may refer patients to other and sometimes less qualified practitioners.

The IPS interpretation is inconvenient and costly for sick patients as well as for the health care system. For patients who live a long distance from their practitioner or who have an insurance provider that limits them to a one-month supply it is a hardship to return to the office or clinic more frequently for prescriptions. The alternative of issuing single prescriptions for large quantities of controlled substances, although (appropriately) not illegal under federal law, could add to the risk of diversion. Some patients may not be able to afford a prescription for a large quantity of medication. Nor will prohibition of this practice address those who divert controlled substances. We can see no apparent benefits of DEA's interim interpretation with respect to diversion control.

Recommendation 2: Reassure practitioners that DEA uses appropriate indicators of diversion that cannot be confused with legitimate practice, and that its approach to investigation of practitioners is not a threat to law-abiding practitioners and patients.

The IPS said that "The August 2004 FAQ erroneously stated: 'The number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, and the duration of therapy with these drugs do not, by themselves, indicate a problem, and they should not be used as the sole basis for an investigation by regulators or law enforcement.' In fact each of these foregoing factors – though not necessarily determinative – may indeed be indicative of diversion Moreover, it 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 assurances 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 Controlled Substances Act (CSA)." (p. 67171) (1)

It is well-documented that prescribing patterns become more restrictive and that patient care suffers when practitioners are concerned about being investigated for prescribing controlled substances.³ Health professionals are already risk-averse and the vast majority are law-abiding.

prescriptions are issued at one time, each must bear the actual date that the prescriptions were issued and signed as well as directions for dispensing ...the DEA does not consider multiple prescriptions in the scenario outlined above as refills, and has authorized this practice, provided, that it is not in violation of the laws of the state in which the practitioner is licensed." (p. 304) (7)

³ See Appendix A "Recognition that practitioners fear unwarranted investigation"

DEA's recent statements about the factors indicative of diversion have been alarming to professionals who need clarity and reassurance rather than inconsistency and what appear to be threats that any practitioner can be investigated, instead of those where there is clear indication suggesting that laws have been violated.

DEA has indicated that it does not want practitioners to fear investigation⁴ and has also reiterated that in the IPS: "DEA recognizes that the overwhelming majority of physicians dispense controlled substances lawfully for legitimate medical reasons, including the treatment of pain." (p. 67170) (1) DEA has emphasized that only a very small number of practitioners are investigated, much less have actions taken against them. However, the messages the IPS sends, including its interpretation of the Rosen and Morton Salt cases, are intimidating. The factors cited in Rosen as indicative of diversion were used to show that Rosen knew what was going on, and it should be clear that when taken out of the context of the Rosen case, some of those factors are much less indicative of wrong-doing because they are found in legitimate pain practice (such as numerous prescriptions and large prescription quantities). In addition, DEA should realize that there could be some question about the relevance of the Morton Salt case since it involved investigation of an entity that had already been found guilty of violating federal law and addressed the question of what follow-up a federal agency could demand to ensure compliance with how prior charges had been resolved.

Recommendation 3: Clarify what constitutes unlawful conduct under the Controlled Substances Act and regulations.

State licensed and federally registered practitioners are obligated to comply with the laws and regulations governing the use of controlled substances, but practitioners need to be clear on what those laws are. Uncertainty about prescribing laws can lead to reluctance to prescribe. The present situation is an opportunity to clarify and communicate policy. DEA formerly had a Physicians Manual, but it seems to have been dropped. We ask that DEA confirm its understanding of the following statements, and any others it wishes to include, to clarify for practitioners what constitutes unlawful conduct under the Controlled Substances Act, as implemented by the DEA and DOJ with respect to the dispensing (including prescribing) of controlled substances.

Statement 3a) The knowing or intentional issue of controlled substance prescriptions for other than a legitimate medical purpose and outside the usual course of professional practice may be prosecuted as felony illegal distribution (United States vs. Moore). The prosecution must prove criminal charges beyond a reasonable doubt and show that the prescriptions were issued or dispensed not in good faith (i.e., the practitioner knew or intended, that a prescription was not for

⁴ On December 12, 2004 DEA Administrator, Karen Tandy, stated the following in a USA Today editorial: "Doctors and patients should not interpret DEA's action as cause for alarm or as a change in investigative practice. DEA continues to recognize that the overwhelming majority of doctors prescribe controlled substances lawfully for legitimate medical reasons." (9)

a legitimate medical purpose). “Knowing” includes where any reasonable practitioner would have known the prescriptions were not legitimate and should not have been issued or filled.

Statement 3b) It is unlawful for anyone other than a properly state-licensed and DEA-registered practitioner to issue prescriptions, to pre-sign prescriptions, and to date them other than on the date issued.

Statement 3c) It is unlawful for a practitioner to prescribe or dispense a narcotic drug for treatment of addiction without a separate registration; however, it is not unlawful under the CSA for a practitioner to issue a prescription for the treatment of pain for a patient with history of substance abuse, current addiction, including patients in Narcotic Treatment Programs.⁵ *Such prescribing may require special expertise, extra care and monitoring, but it is (appropriately) not illegal under federal law.*

Statement 3d) Continued prescribing to an individual whom the practitioner knows is illegally selling the drugs is not a legitimate medical purpose and the practitioner who continues to prescribe in this situation, and who does so knowingly, risks prosecution for unlawful distribution of a controlled substance. *We note that this situation requires further examination and discussion between practitioners and law enforcement, because although the vast majority of practitioners properly avoid such prescribing, we also must realize that any practitioner can be duped by a scam artist. Practitioners need reassurance that law enforcement is interested in situations where there is evidence of practitioner disregard for information, and that isolated*

⁵ July 12, 1993 *David H. Gillis, MD; Granting of Registration*: “The Drug Enforcement Administration initiated its investigation of the Respondent in April 1991 after receiving information from the...Sheriffs Department that Respondent was prescribing controlled substances to known drug abusers and drug traffickers... After reviewing these charts and the respondent’s testimony at the hearing, the administrative law judge concluded that Respondent issued controlled substances prescriptions to these individuals for legitimate medical purposes, such as relief of pain, muscle spasms, and anxiety...The [DEA] Administrator, having considered the entire record, adopts the administrative law judge’s findings of fact, conclusions of law, and recommended ruling in its entirety.”(10)

December 7, 1995 *William F. Skinner, MD, Continuation of Registration*: “The Drug Enforcement Administration (DEA) issued a show cause order...[because] the respondent had prescribed...excessive amounts of controlled substances...without a legitimate medical purpose and while not acting in the usual course of professional practice; and...prescribed narcotic drugs...for the purpose of maintenance treatment and engaged in detoxification treatment without holding a separate DEA registration to conduct a narcotic treatment program...The preponderance of the evidence supports a finding that the Respondent was tapering the drugs prescribed to [the patient] after acute pain resolved...Thus, the respondent was not maintaining [the patient’s] addiction nor detoxifying [the patient] without a prior registration...the Deputy Administrator concurs with Judge Tenney’s findings that the ‘overriding purpose of [the] Respondent’s prescribing practices was the treatment of [the patient’s] pain,’ a legitimate medical purpose. In the balance, the Deputy Administrator finds that it is in the public interest for the Respondent to retain his DEA certificate of Registration.” (11)

The DEA Pharmacist’s Manual from April 2004 states the following: “A practitioner may prescribe methadone or any other narcotic to a narcotic addict for analgesic purposes.” (12)

In 2004, the medical journal Pain Medicine published five clinical vignettes in which DEA provided clinicians throughout the country with clarification on the legality of certain prescribing practices. The response included the following, “Pain specialists may treat a chronic pain patient currently enrolled in a narcotic treatment program with narcotics...[although]...they may only treat the patient’s pain.” (p. 305) (7)

occurrences of patients re-selling drugs, absent knowledge or intent of the practitioner, would not result in charges against the practitioner, and that law enforcement would notify the practitioner of such occurrences.

Statement 3e) Prosecution for homicide involving a practitioner's prescriptions for controlled substances should be undertaken only in cases when there is clear recklessness with high probability of ensuing death or knowing misconduct with an ensuing death and where the causation is clear.⁶

Statement 3f) Good faith medical judgment (i.e., reasonable and good intentions in the honest exercise of a practitioner's profession), even if poor, should insulate practitioners from criminal action for acts done in good faith in the course of professional practice. See *United States v. Moore* in 1975 (423 U.S. 122), *State vs. Naramore* (1998, 965 P.2d 211) (Kansas), *People vs. Kwoh Cheng Sun* (1980, 290 N.W.2d 68) (Michigan), *People vs. Lonergan* case (1990, 219 Cal.App.3d. 82) (California), also *Stone*. (13)

Statement 3g) A practitioner's claim of good faith can be overcome by compelling evidence that the practitioner studiously avoided or deliberately ignored the information available (*United States vs. Kershman* (1977, 8th cir) 555 F.2d 198).

Statement 3h) Neither the CSA nor DEA regulations sets limits on the amount of a controlled substance prescription or the duration of therapy with controlled substances⁷ although some states still do. (14)

Statement 3i) Please explain the difference between an inquiry and investigation, and discuss the criteria DEA and DOJ ordinarily use to initiate these, and also to file criminal charges, as distinguished from a public interest revocation proceeding.

⁶ Highly publicized state homicide prosecutions have been brought against physicians only to fall apart at or before trial (*Fisher*, California) or on appeal (*Weitzel*, Utah; *Naramore*, Kansas) because causation could not be established or because lack of good faith medical practice could not be established, or both.

⁷ On March 17, 1998 Patricia Good, Chief of the Liaison Section of the DEA presented the following statement supporting the Federation of State Medical Board Model Guidelines, "The proposed Model Guidelines, [adopted by the Federation of State Medical Boards in 1998 and subsequently adopted by many state medical licensing boards] in setting out the required elements of legitimate pain practice, minimize the importance of historically suspicious factors such as prescribing quantity and frequency, and place them in the proper context of the other factors present in legitimate treatment." (15)

In March 2002, DEA Administrator Asa Hutchinson addressed the American Pain Society annual scientific conference, stating that "There's a misperception that we [the DEA] judge wrongdoing on the part of a doctor solely on whether he or she is prescribing high quantities of drugs. In reality, quantity alone is not an indicator of wrongdoing. We may look at numbers as a possible indicator of suspicious activity, but in the absence of other information about diversion, quantity alone is not an indication of violation." (16)

The most recent version of the DEA Pharmacists Manual from February 2003 stated the following "It is also important to understand that the quantity of drugs prescribed and frequency of prescriptions filled alone are not indicators of fraud or improper prescribing." (p. 57) (12)

Recommendation 4: Avoid sending messages of fear to the community of law-abiding practitioners.

Real perpetrators of prescription drug-related crime should not be sheltered; their activities lead to legal and public health consequences. Practitioners may be arrested and charged with crimes when there is probable cause they have distributed controlled substances unlawfully. However, we ask that DEA and the DOJ state that they recognize that restraint is necessary to avoid sensational headlines when a “pain doctor” is arrested for knowingly diverting drugs. Sensational media coverage leads to increased fear of investigation among the overwhelming majority of practitioners who prescribe and dispense controlled substances lawfully. We ask DEA to address the following questions and state how the Administration will work to reassure the vast majority of practitioners and patients that DEA’s policies and procedures will not interfere with legitimate pain management and patient care. Such an effort would strengthen the medical community’s support for law enforcement thus adding to its effectiveness of law enforcement.

Recommendation 4a) DEA should work with other law enforcement agencies with whom it cooperates to ensure that arrests are not made with show of force in medical offices and patient waiting rooms including when patients are present. DEA, the DOJ and their law enforcement partners should limit the use of force in the health care arena to situations where it is necessary to secure premises and evidence and protect safety of officers and others. Compliance and criminal investigations and arrests should be conducted in a professional law enforcement manner that does not spawn sensational coverage and spread fear of law enforcement among practitioners.

Recommendation 4b) Prior to arresting a physician who also treats legitimate pain patients, DEA and its partners should consider ways to ensure that those patients are not abandoned (a violation of state law) and that they have access to medical records that may have been seized and that will be needed immediately by the patient’s next physician. This is an area where state licensing boards and selected experts could be of assistance. In this way, both sides of the public health problems of pain and drug abuse and diversion are addressed.

Recommendation 4c) DEA’s criteria for selecting experts should include a background in the subject doctor’s area of practice, experience with pain management and current experience prescribing opioids to treat pain.⁸

5. Reaffirm DEA’s commitment to a balanced approach to diversion control

Recommendation 5: Following clarification of the above policies and procedures, the DEA and the Department of Justice should a) affirm and communicate to practitioners, law enforcement and regulatory authorities throughout the country their strong commitment to a balanced national policy on diversion control that avoids interfering in legitimate medical practice and patient care, b) endorse the Federation of State Medical Board’s

⁸ See e.g. Medical Board of California, Investigating Prescribing of Controlled Substances for pain. August, 2003. and Medical Board of California, Expert Reviewer Program, July, 1994.

Model Policy, c) update its public information accordingly, and d) appoint an Advisory Committee.

DEA has stated a number of times its support for achieving a balanced approach so that diversion control does not interfere in legitimate medical practice and pain management.⁹ However, following DEA's interim statements, practitioners are growing more rather than less concerned about being investigated, and patients are having more rather than less difficulty gaining access to pain medications. The need to reassure legitimate practitioners and patients has never been greater. Implementation of the previous recommendations will contribute to the clarity that is needed to reassure physicians that they have nothing to fear if they practice professionally.

DEA should reaffirm that it respects practitioners' exercise of professional judgment in the treatment of patients and that its focus regarding criminal charges is on cases where a practitioner has not acted in good faith, and that cases where the practitioner exercised medical judgment, even if poor, are generally left to state medical boards.

DEA endorsed the Federation of State Medical Boards Model Guidelines for the Use of Controlled Substances for the Treatment of Pain in 1998. (14) The guidelines have been adopted all or in part in 25 states, and have recently been updated. DEA should endorse publicly the

⁹ On October 23, 2001 DEA released *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act – A joint statement from 21 health organizations and the Drug Enforcement Administration*, which stated that “Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, healthcare practitioners, and patient advocates alike, that it should not hinder patients’ ability to receive the care they need and deserve.” (17)

On October 23, 2001 DEA issued a press release titled *Drug Enforcement Administration, 21 Health Groups call for Balanced policy on prescription pain medications like OxyContin* in which DEA Administrator Asa Hutchinson urged a policy that protects the appropriate use of opioid pain relievers for patients who need them, while also preventing abuse and diversion of drugs. He said “We don’t want to cause patients who have legitimate needs for these medications, to be discouraged or afraid to use them. And we don’t want to restrict doctors or pharmacists from providing these medications when appropriate. At the same time, we must take all reasonable steps to ensure that these powerful medications don’t end up in the wrong hands and lead to abuse. We want a balanced approach that addresses the abuse problem without keeping patients from getting the care they need and deserve.” (18)

On March 14, 2002 DEA Administrator, Asa Hutchinson spoke to the American Pain Society annual scientific conference. In a presentation titled “*DEA and Doctors: Cooperation for the Public Good*,” he said “It was critical that we let the public know [that] law enforcement and the health community are working together. We are not at odds. We have a shared goal of making sure that controlled substances are used only for the health and welfare of the American public. We made a commitment at that press conference to achieving a balanced approach to the prescribing and regulating of opioids. My message to you tonight is that we stand by that commitment.” (16)

On January 27, 2005 William Walker, Deputy Assistant Administrator for DEA wrote to William Winsley, Executive Director of Ohio State Board of Pharmacy and said “DEA believes it is essential to strike an appropriate balance between providing guidance and reassurance to the overwhelming majority of physicians who engage in legitimate pain treatment while deterring the unlawful conduct of a very small number of physicians who exploit the term “pain treatment” as a pretext to engage in prescription drug diversion.” (19)

2004 Model Policy for the Use of Controlled Substances for the Treatment of Pain and its stated purposes.

Further, we ask that DEA update its informational and educational vehicles to reflect its stance on these issues, for example its website and the practitioner manuals.

The DEA should establish before the end of 2005 an advisory committee for the purpose of ongoing communications with organizations involved in the use of controlled substances for pain management, palliative care and other recognized uses to promote communication, education and understanding of a balanced approach to the use and control of controlled substances.

Recognition that practitioners fear unwarranted investigation

A. United States

1. National Association of Attorneys General. Improving End-of-Life Care: The Role of Attorneys General. Edmondson WAD, ed. Washington, DC: National Association of Attorneys General, 2003.

- “According to numerous studies, physicians also avoid prescribing opioids because of a prevailing fear that they will be scrutinized by state medical boards and narcotics regulators”(p.28).

2. New York State Public Health Council. Breaking down the barriers to effective pain management: recommendations to improve the assessment and treatment of pain in New York State. Albany, NY: New York State Department of Health, 1998.

- In 1998, a survey was administered by the New York State Public Health Council to assess the barriers to effective pain management. Survey results indicate that, “Health care practitioners may underprescribe pain medication due to fear of unwarranted legal consequences.” More specifically, survey results indicate that (22% response rate): 66% of those surveyed were moderately to very concerned about regulatory investigation when treating acute pain in a patient with a known history of substance abuse. 78% moderately to very concerned about the development of drug abuse during opioid treatment of a noncancer patient. 71% utilize drugs not requiring a triplicate form, even when an alternative drug requiring a triplicate form is otherwise indicated, b/c of concern about regulatory scrutiny, when treating cancer patients with opioids. 82% utilize nontriplicate drugs, even when a triplicate drug is otherwise indicated, b/c of concern about regulatory scrutiny, when treating noncancer patients with opioids. 77% believe that NY overregulates opioid drugs.

3. State Intractable Pain Treatment Statutes

- The main goal of Intractable Pain Treatment Acts (IPTAs) is to address physician reluctance to prescribe opioids for the treatment of chronic pain, due to concern about regulatory scrutiny, by providing immunity from discipline by state medical boards. Twelve state legislatures have adopted IPTAs, these include: Arkansas, California, Colorado, Minnesota, Missouri, North Dakota, Ohio, Oregon, Rhode Island, Tennessee, Texas, and West Virginia.

4. Institute of Medicine Committee on Care at the End of Life. Approaching death: improving care at the end of life. Washington, DC: National Academy Press, 1997.

- In 1997, the Institute of Medicine Committee on Care at the End of Life published this book which includes statements about the need to address physicians' fears of regulatory scrutiny. This book can be accessed at:
<http://www.nap.edu/catalog/5801.html>

5. Federation of State Medical Boards of the United States Inc.

(a) Model guidelines for the use of controlled substances for the treatment of pain. Euless, TX: Federation of State Medical Boards of the United States Inc, 1998.

(b) Federation of State Medical Boards of the United States Inc. Model policy for the use of controlled substances for the treatment of pain. Dallas, TX: Federation of State Medical Boards of the United States Inc., 2004.

- In 1998 and 2003 the FSMB issued model policies which said that physicians' "...fears of investigation or sanction by federal, state, and local agencies may also result in inappropriate or inadequate treatment of chronic pain patients." The Model Guidelines clearly state that, "...these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage pain management... Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice" (p. 1-2).

6. California Health & Safety Code §11159.2 Prescriptions for terminally ill patients

- This statute states that, "The Appropriate Prescribing Task Force of the Medical Board of California has recognized that pain is undertreated in California in part due to physicians' concern about undergoing investigation for overprescribing."

7. Cancer Pain Management Policy Review Group. American Cancer Society position statement on regulatory barriers to quality cancer pain management. National Government Relations Department, American Cancer Society, 2001.

- In 2001, the American Cancer Society issued a position statement recognizing that physician fear of regulatory scrutiny is contributing to the inadequate treatment of pain and needless suffering of cancer patients.

8. Pain & Policy Studies Group. Achieving balance in federal and state pain policy: A guide to evaluation, second edition. Madison, WI: University of Wisconsin Comprehensive Cancer Center, 2003.

- This policy evaluation found that 34 states have policy language that recognize and addresses practitioners' concerns about regulatory scrutiny: Alabama, Arizona, California, Colorado, Florida, Iowa, Kansas, Kentucky, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Montana, North Carolina, North Dakota, Nebraska, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Washington, West Virginia, and Wyoming. This document can also be accessed at: http://www.medsch.wisc.edu/painpolicy/2003_balance/

B. International

1. International Narcotics Control Board

(a) International Narcotics Control Board. Report of the International Narcotics Control Board for 1995: Availability of opiates for medical needs. New York, NY: United Nations, 1996.

- An INCB survey (1996) of impediments to opioid availability for pain relief reports that: "...*reluctance to prescribe or stock opiates owing to concerns about legal sanctions ranked third (47%)*" (p. 4).

(b) International Narcotics Control Board. Report of the International Narcotics Control Board for 1989: Demand for and supply of opiates for medical and scientific needs. Vienna, Austria: United Nations, 1989.

- The INCB (1989) determined that there were a number of reasons for inadequate availability, including that: "*the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented*" (p.1).
- The INCB (1989) further suggests that: "*Health professionals... should be able to...[provide opiates]...without unnecessary fear of sanctions for unintended violations...[including]...legal action for technical violations of the law...[that]...may tend to inhibit the prescribing or dispensing of opiates*" (p. 15).
- As a result, the INCB (1996) requested that all governments in the world: "*determine whether there are undue restrictions in national narcotics*

laws, regulations or administrative policies that impede prescribing, dispensing or needed medical treatment...[and]... communicate with health professionals about the legal requirements for prescribing and dispensing narcotic drugs and...provide an opportunity to discuss mutual concerns” (p. 15-16).

2. World Health Organization. Cancer pain relief and palliative care (technical report series 804). Geneva, Switzerland: World Health Organization, 1990.

- The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (1990) states that: *“Health care workers may be reluctant to prescribe, stock or dispense opioids if they feel that there is a possibility of their professional licenses being suspended or revoked by the governing authority in cases where large quantities of opioids are provided to an individual, even though the medical need for such drugs can be proved” (p. 39).*

End Notes

- (1) Federal Register. 69 FR 67170. 2004
- (2) Federal Register. 70 FR 2883. 2005.
- (3) Gitchel GT. DEA policy concerning the legality of a practitioner issuing several Schedule II prescriptions on the same date and not to be dispensed until the date indicated. Washington, DC. Letter from Chief of the Liaison and Policy Section, DEA Office of Diversion Control to Patrick Gavin; June 8, 1995.
http://pharmacy.ohio.gov/DEA_to_Meijer_060895.pdf
- (4) Good PM. DEA policy concerning the legality of a practitioner issuing several Schedule II prescriptions on the same date for the same medication for a stable patient. Washington, DC. Letter from Chief of the Liaison and Policy Section, DEA Office of Diversion Control to Dr. Howard Heit; January 31, 2003.
http://www.asam.org/pain/federal_regulations_for_prescrib.htm
- (5) Good PM. DEA policy concerning the legality of a practitioner issuing a single prescription signed and dated on the date of issue with a notation to the pharmacy to dispense at a later date. Washington, DC. E-mail communication from Chief of the Liaison and Policy Section, DEA Office of Diversion Control to David Joranson; February 14, 2005.
- (6) Marcus WL, & Cohen MN. Pharmacy Law for California Pharmacists. (Fifth edition). William L. Marcus & Marsha N. Cohen: Los Angeles, CA, 2005.
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