STATE ATTORNEYS GENERAL

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March 21, 2005

Deputy Administrator
Drug Enforcement Administration
Washington, DC 20537
Attention: DEA Federal Register Representative/CCD

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

Dear Ms. Leonhart,

We, the undersigned Attorneys General, write to comment on “Dispensing of Controlled Substances for the Treatment of Pain”, pursuant to the Solicitation of Comments published on January 18, 2005. As the chief legal officers of our respective states, many Attorneys General investigate and prosecute drug-related offenses ranging from diversion and trafficking of prescription drugs to Medicaid fraud and abuse. In our consumer protection role, working to remove barriers to quality care for citizens of our states at the end of life, we have learned that adequate pain management is often difficult to obtain. One key contributor to this problem is that many physicians fear investigations and enforcement actions if they prescribe adequate levels of opioids or have many patients with prescriptions for pain medications. We are working to address these concerns while ensuring that individuals who do divert or abuse drugs are prosecuted. There are many nuances of the interactions of medical practice, end of life concerns, definitions of abuse and addiction, policy-making and enforcement considerations that make balance difficult in practice. However, we believe this balance is very important to our citizens, who deserve the best pain relief available to alleviate suffering, particularly at the end of life.

This comment acknowledges the past efforts of the Drug Enforcement Administration (DEA) to support the dual goals of preventing drug abuse and diversion and ensuring the availability of prescription pain medications to those who are legitimately in need of them. The undersigned have strived to maintain the delicate balance between these two goals in carrying out our own legal mandates. We are concerned that recent DEA actions send mixed messages to the medical community and are likely to discourage appropriate prescribing for the management of pain. Those actions also put DEA at odds with advances in state policies.
regarding prescription pain medication. The undersigned are committed to working with the DEA to develop a balanced policy that supports both goals and hope that the following comments will assist in the realization of such policy.

This comment also addresses several specific issues raised in the November 16 Interim Policy Statement on Dispensing of Controlled Substances for the Treatment of Pain. These include commencement of investigations, preparation of multiple prescriptions on the same day with instructions to fill on different dates, concerns of family members, and the issue of how to treat pain in former or current addicts. Finally, we address changes in the realities of health care and prevalence of pain over the past 80 years that suggest a reconsideration of how law from 80 years ago should be applied today.

Our recommendations include the following:

1. We urge DEA to clearly restate its commitment to the balance policy released in 2001 and commit to balance in all public communications. We also recommend that DEA consider appointing an Advisory Committee both to reassure all major groups (health care professionals, consumers, state and federal law enforcement officers) that are affected by DEA’s actions and to assist DEA in translating balance policy into practice;
2. In commencing investigations, focus on factors that distinguish the criminal trafficking and diversion of pain medications from the legitimate and responsible practice of medicine and other health professions;
3. Develop a clear statement of policy that the preparation of multiple prescriptions on the same day with instructions to fill on different dates can be a legitimate practice;
4. Allow health care professionals to determine how to interpret communications by family members consistent with the requirements of their professions and licensing boards;
5. Develop an Advisory Committee or commission an Institute of Medicine study to consider in depth the medical, ethical, law enforcement and policy issues involved in prescribing pain medications to former and current addicts for the treatment of pain and to report recommendations;
6. Consider the changing realities of health care and the patient population in the United States, in addition to changes in the nature of drug abuse, as policy regarding prescription pain medication is developed.

1. **DEA’s Commitment to Balancing the Importance of Ensuring Patient Access to Prescription Pain Medications with Preventing Abuse of Those Medications.**

Subsequent to DEA endorsement of the 2001 Joint Statement from the DEA and 42 Health Organizations supporting balance between the treatment of pain and enforcement against diversion and abuse of prescription pain medications, the National Association of Attorneys General (NAAG) in 2003 adopted a Resolution Calling for a Balanced Approach to Promoting

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Pain Relief and Preventing Abuse of Pain Medications. Both these documents reflected a consensus among law enforcement agencies, health care practitioners, and patient advocates that the prevention of drug abuse is an important societal goal that can and should be pursued without hindering proper patient care.

In an October 23, 2001 press release, 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. “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,” Hutchinson said. “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.”

On March 14, 2002, DEA Administrator Asa Hutchinson presented a speech to the annual scientific conference of the American Pain Society entitled “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 of the 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.” (emphasis added).

More recent DEA Statements.

The Frequently Asked Questions (FAQ) document, which we understand to be an effort to educate law enforcement and health care personnel about advances in knowledge concerning the medical treatment of pain and the meaning of “balance,” was released on August 11, 2004 following development with DEA involvement. In an August 11 Frequently Asked Questions (FAQ) Press Release by DEA, Administrator Karen Tandy said, “The medical and law enforcement communities continue to work together to carefully balance the needs of legitimate patients for pain medications against the equally compelling need to protect the public from the risk of addiction and even possible death from these medications.”

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3 Resolution Calling for a Balanced Approach to Promoting Pain Relief and Preventing Abuse of Pain Medications, National Association of Attorneys General (March 17-20, 2003).
5 Id.
7 Id.
There was a period of over a month between the October withdrawal of the FAQ from the DEA and other websites\textsuperscript{10} and the November 16, 2004 publication in the Federal Register of the DEA Interim Policy Statement.\textsuperscript{11} During and after that time, we and the health organizations originally involved in the 2001 Joint Statement with DEA wondered what this withdrawal meant about current DEA policy with respect to dispensing pain medications and the practice of medicine. The Interim Policy Statement addressed “a few of the significant misstatements” contained in the FAQ, leaving the interested community wondering what other aspects of the FAQ were likely to be considered “misstatements” later. This type of uncertainty alone is detrimental to the practice of medicine because physicians tend to practice conservatively to avoid even the possibility of legal involvement. Such practice is not primarily concerned with the best interests of patients, but is instead concerned with protecting physicians from liability. Whenever possible, physicians and other health care providers should not be put in the position of having to choose between protecting themselves and providing the best possible care for the patients who need their services.

The November 16 Interim Policy Statement did state that “It is crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified. DEA recognizes that the overwhelming majority of physicians dispense controlled substances lawfully for legitimate medical reasons, including the treatment of pain.”\textsuperscript{12} However, physicians and others did not find this document reassuring. It is likely that this is in part because the document, citing \textit{U.S. v. Morton Salt Co.}\textsuperscript{13}, also stated that “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.’”\textsuperscript{14} While the FAQ was an effort to provide explanations of how to implement balance policy in practice, to provide some guidance on how to practice pain management responsibly and to avoid investigation and prosecution of legitimate and responsible practitioners, the Interim Policy Statement made it clear that DEA now felt it necessary to state that any physician (or other health care provider) could be investigated at any time for any reason.

If DEA is serious about promoting a balanced approach to enforcement without hindering the availability and use of prescription pain medications for those who need them for legitimate medical purposes, we recommend that the DEA begin by clearly restating its commitment to the balance policy released in 2001 and also commit to balance in every public communication. That would mean describing what constitutes legitimate use and what advantages accrue to such use in addition to identifying the dangers associated with abuse, rather than focusing solely on the dangers. Our understanding is that the FAQ were intended in part to make such communication easier, but in view of the uncertainty since the withdrawal of the FAQ, this should be a consideration in all public DEA communications. We also recommend that DEA consider developing an Advisory Committee comprised of physicians, pain experts, consumers

\begin{footnotesize}
\textsuperscript{10} Letter from William J. Walker, Deputy Assistant Administrator, Office of Diversion Control, DEA, to David E. Joranson, Director, Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, \url{http://www.medsch.wisc.edu/painpolicy/DEA/Mr.%20David%20Joranson.PDF}.

\textsuperscript{11} Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67, 170.

\textsuperscript{12} \textit{Id.} at 67, 170.


\textsuperscript{14} Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. at 67, 171.
\end{footnotesize}
(pain patients), and state and federal prosecutors to evaluate potential consequences of DEA actions on the various communities and to reassure prescribing professionals, law enforcement officials and consumers of prescription pain medications that their needs are being taken seriously.

2. **Commencement of Investigations.**

The November 16 Interim Policy Statement identified the following statement from the FAQ as a “misstatement”:

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.\(^{15}\)

DEA stated, “In fact, each of the foregoing factors – though not necessarily determinative – may indeed be indicative of diversion.” The Interim Policy Statement goes on to cite factors from *United States v. Rosen*\(^ {16}\) as support for that position.

While we do not question the legal authority for such an investigation, this position presents a problem for consumers, particularly at the end of life. It discourages physicians from treating those with severe pain or those who might need high doses, multiple medications, or long term palliative care with opioids. Those physicians who are willing to treat such vulnerable patients are likely to see many because their colleagues are often afraid to do so\(^ {17}\) (or treat the patients, but treat the pain inadequately, resulting in many cases of unrelieved pain and concomitant suffering). The undertreatment of pain is a significant problem and led the Federation of State Medical Boards (FSMB), in 2004, to promulgate new model policy to emphasize that undertreatment of pain, like overtreatment, constitutes poor practice.\(^ {18}\) Several states have already adopted all or part of the FSMB Model Policy.\(^ {19}\) Because good practice may involve precisely the factors that DEA believes might be indicative of diversion, DEA is creating a climate that puts legitimate medical practitioners in danger of investigation and discourages good practice.

We do not believe that either the Controlled Substances Act or *Rosen* must be read to require this result. A number of previous communications from DEA have stated that quantity of

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\(^{15}\) Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. at 67, 171.

\(^{16}\) *United States v. Rosen*, 582 F.2d 1032, 1035-1036 (5th Cir. 1978).


\(^{19}\) According to the FSMB, as of March 8, 2005, Colorado, Nevada, Massachusetts, Missouri, Minnesota, Virginia, West Virginia, and Wisconsin have all adopted or endorsed the 2004 FSMB Model Policy.
drugs prescribed and frequency of prescriptions filled alone are not indicators of fraud or improper prescribing. The facts of Rosen itself make clear that it was not a single factor, but a host of factors inconsistent with good medical practice that resulted in the affirmation of Dr. Rosen’s conviction. The Rosen court derived the list of behaviors presented in the Interim Policy Statement from a number of cases, most if not all of which involved multiple behaviors. At least some of those behaviors were more indicative of acting outside a legitimate medical purpose than are the number of patients, number of tablets or duration of treatment. In addition, the population of patients and practice of medicine have changed considerably since Rosen was decided in 1978 (and since some of the cases cited therein, which date back as far as 1919 and 1922). This is reflected in the updating of the FSMB policies and should also be reflected in DEA policy.

Diversion is a serious problem and we must be serious about stopping it. As law enforcement agents, we should concentrate on drugs that are illegally on the streets and work back to see how they got there. An undue focus on potentially misleading factors like the number of prescriptions written or number of patients seen in a practice would serve neither the goals of law enforcement nor the needs of suffering patients. We need indicators that distinguish the small number of physicians and other DEA registrants engaging in criminal behavior from responsible practitioners of legitimate health professions. Perhaps research is needed to better identify those indicators. In the meantime, we cannot cast a broad net over all health care practitioners hoping that a few criminals will be caught while the other cases are thrown out. It is precisely this approach that leads to the problem of inadequate availability of prescription pain medications to consumers who need them.

DEA could assist in ensuring the responsible practice of medicine and pain management. Physicians need to be confident that good practices will not be investigated by DEA. Good patient workups, good record-keeping, following practice guidelines, seeking and documenting consultations for necessary departures from such guidelines, and other aspects of the responsible practice of medicine as required by state medical boards should be sufficient.

3. Preparation of Multiple Prescriptions on the Same Day with Instructions to Fill on Different Dates.

The Interim Policy Statement states:

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. To do so conflicts with one of the fundamental purposes of section 829(a). [W]riting multiple prescriptions on the same day with instructions to fill on different dates is a recurring tactic


21 This will be described further in section six infra.
among physicians who seek to avoid detection when dispensing controlled substances for unlawful (nonmedical) purposes.\textsuperscript{22}

This appears to be a change of DEA position\textsuperscript{23} and is already causing hardships for physicians, pharmacists and consumers in the states.\textsuperscript{24} The preparation of multiple prescriptions on the same day with instructions to fill on different dates is a way of making it unnecessary for patients with chronic conditions to have to schedule, travel to, and pay for physician appointments for the sole purpose of renewing prescriptions. This is particularly important for patients in severe pain or near the end of life, for whom travel may be very difficult, and for patients in rural areas who may live hours away from an appropriate physician.

The preparation of multiple prescriptions on the same day with instructions to fill on different days is an area in which DEA's current position, as expressed in the Interim Policy statement, is at odds with practices permitted by state licensing boards.\textsuperscript{25} As described above, we do not believe that single aspects of the responsible practice of medicine or pharmacy should be used to commence investigations and do not believe that Rosen is dispositive on this issue. The current DEA position is not consistent with the responsible practice of medicine and does not seem to be a necessary or useful position with respect to drug abuse and diversion control. We believe the risk of drug abuse and diversion is greater if physicians are forced to prescribe more medication at one time in order to balance DEA's new requirement with the needs of their patients than if they are allowed to write multiple prescriptions with instructions to pharmacists to fill on different dates.

If DEA now intends to prohibit writing predated prescriptions, it should promulgate new regulations, allowing for appropriate public comment. However, we urge DEA to communicate a balanced policy on this issue by clearly stating a position consistent with DEA's communications prior to the Interim Policy Statement.

\section*{4. Potential Significance of Concerns of a Family Member or Friend.}

Question #11 of the August, 2005 FAQ document was "What kinds of problems might patients encounter when obtaining opioid prescriptions, in having them filled, or in taking the medications properly?" The last bulleted item under that heading was:

Family and friends, or health care providers who are not directly involved in the therapy, may express concerns about the use of opioids. These concerns may result from a poor understanding of the role of this therapy in pain management or from an unfounded

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\item[\textsuperscript{22}] Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. at 67, 171.
\item[\textsuperscript{23}] See Howard A. Heit, Edward Covington & Patricia M. Good, Dear DEA, Pain Medicine, Sept. 2004 at 303; Letter from G. Thomas Gitchel, Chief Liaison and Policy Section, Office of Diversion Control, DEA to Patrick Gavin, R. PhD., Vice President, Pharmacy Operations, Meijer, Inc. (June 8, 1995), http://pharmacy.ohio.gov/DEA_to_Meijer_060895.pdf.
\item[\textsuperscript{24}] See e.g. Letter from William T. Winsley, Executive Director, Ohio State Board of Pharmacy to Karen P. Tandy, Administrative Director, Drug Enforcement Administration (Dec. 16, 2004), http://pharmacy.ohio.gov/BOP_to_DEA_121604.pdf.
\item[\textsuperscript{25}] See id.
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fear of addiction; they may be exacerbated by widespread, sometimes inaccurate, media coverage of opioid pain medications.

DEA, in the Interim Policy Statement, states that the FAQ “incorrectly minimized the potential significance of a family member or friend expressing concern to the physician that the patient may be abusing the medication” and went on to say that the FAQ “statement is incorrect to the extent that it implies that physicians may simply disregard such concerns expressed to them by family members or friends.”

This appears to us to be a misunderstanding by DEA of what was stated in the FAQ. It is true that many potential patients, families and practitioners are afraid of opioids because they have heard largely about the abuse potential and less about the medical use and benefits of such drugs. If not addressed, this can result in non-compliance problems – patients trying not to use the opioids or to use less of them. Such deviation from physicians’ or pharmacists’ instructions can lead to undertreated pain or even to opioid abuse as the pain continues when the drugs are taken improperly.

A later section of the FAQ, Question #20 is “What behaviors are potential indicators of problems for patients on long-term opioid therapy?” “Deterioration in functioning at work, in the family, or socially” is listed as the first point in a list of behaviors that are “egregious” and are more probably indicators of abuse, addiction, or diversion than a list of other possibly problematic behaviors listed on an earlier page.

Health care professionals are often called upon to make judgments about the extent to which family involvement is beneficial or detrimental to patient care – this is an important aspect of professional practice. It would be difficult for DEA to direct appropriate doctor/patient/family communication without unintended consequences because so many variables are involved. We do not believe the Interim Policy Statement strikes the correct balance on this issue.

5. **Prescribing Pain Medications to Former or Current Addicts for the Treatment of Pain.**

This is perhaps the most difficult area in which to balance law enforcement and medical considerations because the stakes are high and perhaps not enough is known.

We agree with the Interim Policy Statement that if a physician is aware that a pain patient is a drug addict or has re-sold prescription narcotics, the physician has a responsibility to exercise a much greater degree of oversight than with other patients in order to protect society and to take appropriate precautions with respect to care of the patient.

In practice, prescribing pain medications to former or current addicts for the treatment of pain is a very difficult area. An important perspective is reflected in the following statement, which is paraphrased from testimony to the Health, Education, Labor and Pensions Committee by Maine Attorney General G. Steven Rowe.

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People with chronic pain are no different from the general population. Some are more susceptible than others to addiction and substance abuse. When pain patients become dependent upon prescribed drugs, sometimes their doctors don’t react appropriately. Some physicians suddenly cut patients from narcotic medications without appropriate referral to substance abuse treatment or to medical detoxification and without an adequate pain management plan. These patients may try to secure drugs illegally. These patients are different from those who abuse narcotic drugs because they are seeking to get high. They are patients whose dependency is the product of an area of medical treatment that is still, in many ways, in its infancy. Such addictions are preventable, but not in an environment where doctors are scared to treat pain because of fear and threat of prosecution. The answer to preventing this type of addiction is an environment where doctors are comfortable and knowledgeable treating pain and have adequate resources for referrals to substance abuse prevention and treatment programs. When doctors are confident in their knowledge and ability to actively manage their patient’s pain, we will see fewer medical problems transformed into law enforcement problems.\(^{27}\)

It is essential that we seek to develop workable guidelines and policy in this area, which is where the most difficult questions reside. Drug-addicted people in pain represent the toughest case in which to put the general principles of balance into practice. How will we, as law enforcement officers, regulators and policy-makers, balance the need for alleviation of the suffering of people in severe pain with the need to protect individuals and society from the devastating effects of drug abuse and trafficking? How can we simultaneously respect the important ethical and professional decisions health care professionals must make on behalf of individual patients?

We recommend that DEA convene an advisory committee or ask the Institute of Medicine to develop a study committee to consider these issues in depth and to develop recommendations for policy and for the practice of law enforcement, medicine, pharmacy and other health care professions. We would be happy to participate in such an endeavor.

6. **Changes in the realities of health care and the prevalence of pain.**

The Interim Policy Statement concludes that none of the principles summarized in it are new, but that they have been incorporated for more than 80 years into federal laws and regulations governing drugs of abuse. Whether or not we agree with that characterization, what has changed during the past century and is expected to continue to change in the future, is that improvements in health sciences and health care have not only allowed people to live longer, but have also prolonged the process of dying for most people in the United States.\(^{28}\)

\(^{27}\) Paraphrased from Testimony of Attorney General G. Steven Rowe before the Health, Education, Labor & Pensions Committee, United States Senate, September 20, 2001.

more people suffering from chronic diseases than in the past, when death was earlier and quicker, but many are dying following prolonged suffering in pain. Medical practice and pain management have changed and will probably continue to change as a result. These realities make it imperative that DEA consider the impact of its policies on the legitimate treatment of pain.

CONCLUSION

The undersigned Attorneys General respectfully submit these comments and offer our assistance in analyzing and resolving these issues. We urge the Drug Enforcement Administration to (1) clearly restate its commitment to the balance policy released in 2001, commit to balance in all public communications, and to consider creation of an Advisory Committee composed of state and federal law enforcement officers, health professionals (including specialists in pain management) and legitimate consumers of prescription pain medications; (2) in commencing investigations, focus on factors that distinguish the criminal trafficking and diversion of pain medications from the legitimate and responsible practice of medicine and other health professions; (3) develop a clear statement of policy that the preparation of multiple prescriptions on the same day with instructions to fill on different dates can be a legitimate practice; (4) allow health care professionals to determine how to interpret communications by family members consistent with the requirements of their professions and licensing boards; (5) develop an Advisory Committee or commission an Institute of Medicine study to consider in depth the medical, ethical, law enforcement and policy issues involved in prescribing pain medications to former and current addicts for the treatment of pain and to report recommendations; (6) consider the changing realities of health care and the patient population in the United States, in addition to changes in the nature of drug abuse, as policy regarding prescription pain medications is developed.

Thank you for considering our views.

Sincerely,

W.A. Edmondson  
Attorney General W.A. Drew Edmondson  
Attorney General of Oklahoma

G. Rowe  
Attorney General G. Steven Rowe  
Attorney General of Maine

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Docket Number DEA 261  
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Docket Number DEA 261
March 21, 2005

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