

PAIN & POLICY STUDIES GROUP



WHO Collaborating Center
for Policy and Communications
in Cancer Care

November 24, 2004

Michelle Leonhart
Deputy Administrator
Office of Diversion Control
Drug Enforcement Administration
Washington DC 20537

Dear Ms. Leonhart,

This is to respond to the Interim Policy Statement (IPS) in the November 16 2004 Federal Register, titled “Dispensing of Controlled Substances for the Treatment of Pain.” The stated purpose of the IPS was to explain how some of the statements in DEA’s withdrawn “Prescription Pain Medications” FAQ were erroneous and how DEA plans to address the issue of dispensing controlled substances for the treatment of pain.

Unfortunately, we are compelled to tell you that the IPS misrepresented the FAQ and made suggestions that are likely to interfere in medical practice and pain management, while contributing little if anything to addressing prescription drug abuse and illegal activities that result in diversion. The IPS criticized selected language out of context and did not acknowledge that some of DEA’s concerns were in fact addressed elsewhere in the document. Some interpretations of law governing prescribing and dispensing contradict DEA’s own earlier official statements and have already started to cause confusion and concern among pain practitioners. Presently, a number of newsletters and journals (including the Journal of the American Medical Association) are no doubt trying to decide how to deal with the fact that they published stories about the FAQ, prior to DEA’s withdrawal and before the IPS was issued in the Federal Register. We are also providing background on the development of the FAQ so as to set the record straight.

We conclude that there is an urgent need for DEA to re-examine these matters and to establish a meaningful consultative relationship with the community of medical and law enforcement organizations and experts that are committed to pain management, palliative and end-of-life care, as well as to rational efforts to address prescription drug abuse and diversion.

There are some parts of the IPS with which we agree, such as that prescription drug abuse and diversion are serious public health problems needing further discussion and systematic attention; that chronic pain is a serious problem for many Americans; that it is crucial that practitioners who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients; that the overwhelming majority of physicians and other health professionals including pharmacists, nurses and physicians assistants dispense controlled

substances lawfully. Indeed, these themes were clearly stated in the FAQ. We further agree that it is important for practitioners to consider the concerns of family members and friends.

However, the IPS did not recognize the well-established principle in federal law that enforcement of the Controlled Substances Act is not intended to interfere with ethical medical practice and patient care. While there are many safe and effective drug and non-drug ways to treat pain, practitioners must be able to use their professional judgment in treating their patients, including whether opioid analgesics are needed for relieving moderate to severe pain, while also taking steps to avoid contributing to diversion.

DEA has in the past endorsed this principle. In 2000, DEA initiated a discussion with the University of Wisconsin Pain and Policy Studies Group (PPSG) about the need for a more balanced approach to pain management and prescription drug abuse. This discussion led to the development of the 2001 Joint Statement from 21 Health Organizations and the Drug Enforcement Administration titled “Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act.” This statement was released in October of 2001 by Asa Hutchinson, then Administrator of DEA. Since then, many more organizations have endorsed the Joint Statement, which can be found at http://www.deadiversion.usdoj.gov/pubs/pressrel/newsrel_102301.pdf.

Subsequently, DEA, PPSG and several other major organizations and national experts in pain and addiction began developing an educational effort about pain management and prescription drug abuse--the FAQ. The aim was to address a compelling need for a clear and concise educational product for health care practitioners and the law enforcement and regulatory communities.

We were impressed with the high degree of professionalism of the DEA staff with whom we worked. There was frequent consultation with DEA on approximately 20 drafts before the FAQ was released by DEA on August 11, 2004. This was a good example of cooperation between medicine and law enforcement, while at the same time the drafting process observed the necessary distinction between the different realms of expertise and authority of law enforcement and medicine. The FAQ stated that “...practitioners must try to relieve pain, but must obey laws and regulations, and avoid contributing to diversion, while law enforcement personnel and regulators must address the sources of diversion, but do so in a manner that never interferes in clinical pain management.”

The IPS said the FAQ had not been an official statement of DEA policy. Indeed, to avoid such a misperception, the FAQ clearly stated that it was “...not intended to be used as medical practice guidelines or standards or as legal advice with regard to specific practices or cases for which clarification should be obtained by consulting the relevant practice guidelines, laws, and regulations...”

The IPS criticized the FAQ statement that the number of tablets prescribed does not by itself indicate a problem and should not be used as the sole basis for investigation. However, the

FAQ was consistent with Model Guidelines published by the Federation of State Medical Boards of the US, as well as DEA's written testimony endorsing the Federation policy:

“The proposed model guidelines, 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 other factors present in legitimate treatment.” (See <http://www.medsch.wisc.edu/painpolicy/domestic/dea98.htm>).

Former Administrator Hutchinson repeated DEA's position in prepared remarks to the 2002 American Pain Society annual scientific meeting: “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.” Furthermore, PPSG studies show that approximately 24 states have medical regulatory policies recognizing that prescription amount alone is insufficient to determine legitimacy of prescribing, and that most states have removed arbitrary quantity limits on prescriptions.

We recognize DEA's authority to properly apply and enforce the statutes and regulations under which it operates. However, DEA's insistence that it will exercise the right to investigate practitioners for the merest suspicion of wrongdoing will profoundly affect the regulatory climate for pain management. The IPS cite to the *Morton Salt* case law appears to be of questionable relevance to investigating practitioners since this case involved enforcement actions against a company that had already been found guilty of violations of federal law. It is exactly this attitude that will exacerbate practitioner fears of investigation, even though they could ultimately show, after a costly and demoralizing process, that the prescribing was medically appropriate. Furthermore, PPSG studies show that 34 states have adopted policies to address practitioners concerns about undue regulatory scrutiny. Indeed, addressing these concerns was one reason why the FAQ was necessary.

The IPS criticized the FAQ for understating the degree of caution that must be exercised by physicians who treat pain in individuals who are “known or suspected addicts.” The FAQ recognized the need for practitioners to be on the lookout for “red flags” in treating patients with a history of substance abuse, and said that a physician's knowledge of a patient's criminal activity such as diversion (i.e., “re-selling controlled substances”) is grounds for terminating the doctor-patient relationship. Does DEA consider this an understatement?

The IPS did not recognize that it is within the scope of federal law to prescribe opioids for the purpose of treating pain in patients with addictive disease or a history of substance abuse, as did the FAQ. Some individuals with addictive disease also have severe pain due to cancer and other diseases. While other treatment options should be explored, is DEA suggesting that it objects to the use of opioids in the treatment of pain in this population of medical patients?

The intersection of law and medicine is an extremely important issue for clinicians and law enforcement; it is especially important in the situation where practitioners treat pain in patients with addictive disease or a history of substance abuse. If DEA has an interpretation

about the legality of such treatment, it is critically important for clinicians and the agencies that regulate them to know what that view is and to have the opportunity to comment.

The IPS questioned the legality of a practitioner issuing more than one prescription on the same date and marked for later dispensing. However, DEA endorsed this practice in official correspondence dated January 31, 2003:

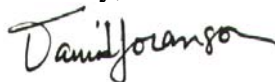
“DEA regulations do not prohibit a practitioner from issuing more than one prescription at a time...” [and if] “...multiple prescriptions are issued at one time, each must bear the actual date that the prescriptions were issued and signed as well as directions for dispensing...the DEA does not consider multiple prescriptions in the scenario outlined above as refills, and has authorized this practice, **provided**, that it is not in violation of the laws of the state in which the practitioner is licensed.” (see http://www.medsch.wisc.edu/painpolicy/domestic/DEA_Rx.htm).

This interpretation of DEA regulations has now appeared in peer-reviewed journals, text books, and websites, and has been the subject of many educational presentations by experts in pain management and law enforcement. Clarity, consistency and reasonableness of federal controlled substances policy is crucially important to prescribers and dispensers who want to deliver effective and efficient pain care while avoiding unnecessary costs. If DEA is going to reverse a previous interpretation of law and regulations, there should be an opportunity to comment on the change in policy.

Clearly, DEA’s statements in the IPS have raised issues relating to the interpretation of federal and state controlled substances policy. In addition, DEA’s abrupt withdrawal of support for the FAQ, without any consultation with co-authors about its concerns, raises questions about what communication the pain management community can expect to have with DEA.

Looking to the future, we urge DEA to consult with organizations and experts in the health and legal experts, with providers of pain management, palliative and end-of-life care, and with state law enforcement and regulatory organizations. We encourage DEA to take positive steps quickly to re-examine the approach proposed in the IPS relating to the medical use of controlled substances for the treatment of pain.

Sincerely,



David E. Joranson
Senior Scientist, Director