

Commentaries

Healthcare Professionals and the DEA: Trying to Get Back in Balance

It was with cautious optimism that I and my colleagues accepted an invitation to participate in a meeting on August 10 at the offices of the Drug Enforcement Administration (DEA) in Arlington, Virginia, whose purpose was to bring together leaders outside the government in the field of pain and addiction medicine with officials of the DEA. Among those present were representatives of practicing healthcare professionals, the Pain and Policy Studies Group, University of Wisconsin–Madison Medical School, National Association of Boards of Pharmacy, National Association of Chain Drug Stores, and the Federation of State Medical Boards. The DEA was represented by Michele Leonhart, Deputy Administrator, and eight of her high-ranking staff members.

The purpose of the meeting was for officials at the DEA to listen to those in the frontlines of the “pain community” voice concerns about the interim policy statement (IPS) on “Dispensing of Controlled Substances for the Treatment of Pain” that was published in the Federal Register on November 16, 2004. This IPS followed the unilateral withdrawal by the DEA of *Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel* (FAQ), a document originally published on the Office of Diversion Control’s Website in August 2004. The IPS addressed several alleged “misstatements” in FAQ, but failed to affirm the educational value of the overwhelming majority of the 30 questions-and-answers statements in the FAQ.

The DEA, Last Acts Partnership, and the Pain and Policy Studies Group at the University of Wisconsin joined forces in 2001 to produce FAQ. The authors consisted of a principal working group (6), which included the experts who developed the framework of FAQ, and a review committee (12), which included experts from the fields of nursing, neurology, psychiatry, pharmacology, pharmacy, and addiction medicine, whose charge was to produce a highly readable FAQ that would cover the clinical and regulatory issues surrounding prescribing of controlled substances (CS). The material, developed over 2 years with over 20 drafts, represented a consensus supported by the

available literature and by the laws and regulations that govern the use of controlled prescription drugs.

FAQ was an educational document that endorsed the principle of “balance” [1] with the use of CS for the treatment of pain. Balance is defined as the dual imperative of governments to establish a system of controls to prevent abuse and diversion of CS and to ensure availability of CS for medical and scientific purposes and accessibility to all patients who need them for the relief of pain. There was a compelling need for a clear and concise educational document, which would be targeted to both healthcare professionals and professionals in the law enforcement and regulatory communities.

After the DEA announcement of FAQ at the National Press Club in Washington, D.C., in August 2004, it was reviewed favorably by newspapers across the country and also received a positive review in JAMA [2]. FAQ was viewed as a major step forward toward cooperation between the DEA and healthcare professionals in providing education about the appropriate treatment of pain and regulatory requirements for prescribing CS.

After reaction to the November 16, 2004, IPS, in January 2005, again in the Federal Register, the DEA invited comments on the subject of dispensing CS for the treatment of pain. Responses were received from all stakeholders in the pain community—physicians, patients, pharmacists, professional organizations, etc. One issue in particular raised concern from almost all, that is, the section of the November Federal Register headed “Refills of schedule II prescriptions.”

The FAQ stated that “Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates.” This principle was affirmed by the DEA in an article that was published in *Pain Medicine* [3]. Yet, the IPS stated that “for a physician to prepare multiple prescriptions [for a schedule II controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescrip-

tion authorizing refills of a schedule II controlled substance.” It goes on to state that “. . . writing multiple prescriptions on the same day with instructions to fill on different dates is a recurring tactic among physicians who seek to avoid detection when dispensing controlled substances for unlawful (nonmedical) purposes.”

Those of us prescribing and dispensing schedule II CS to our patients for pain control disagreed strongly with the DEA, and the comments sent reflected this. We pointed out that writing more than one prescription on the same date with directions to fill on another date (Do Not Fill Until . . . [DNF]) should be and usually is done for legitimate medical reasons. It is often used for the benefit of the patient who is stable and compliant and therefore can be seen less frequently. It is also used when a pain and/or addiction specialist may have a concern about misuse or diversion of CS. He or she may want to give just 1 or 2 weeks’ worth of medication at a time, but does not need to see the patient that frequently. The majority of insurance companies and/or managed care companies set a 30-day limit on the amount of medication covered. If the physician has determined that the patient is stable and does not need to be seen that often, writing two prescriptions with DNF instructions is a way to comply with that requirement and to control costs by preventing the need for another office visit. In addition, many pain specialists will not write a prescription for a 3-month supply of a schedule II medication to be ordered by mail. This is due to fear that, if the prescription and/or medication is lost, there is the potential for a large amount of medication unaccounted for that can be abused or diverted.

In every instance, writing DNF prescriptions is not done as a way to *refill* a prescription; rather it is a way to issue a *new* prescription. The prescription cannot be filled until the date indicated on it; moreover, the patient has the responsibility to take each prescription to the pharmacy personally on or after the appropriate date in order to receive the medication. He or she cannot call the pharmacy to request a refill, nor can the healthcare professionals call the pharmacy and authorize a “refill.” Moreover, there are no published data that I am aware of to support the DEA’s position that writing a DNF prescription contributes to diversion.

What the DEA’s position prohibiting the use of DNF prescriptions does is penalize our patients, make more administrative work and costs for healthcare professionals, and ironically, may in-

crease the risk of diversion. Most pain specialists have chosen two options to comply with the IPS: they either see patients who are stable more often, causing increased costs to the patient and the healthcare system; or they continue to see those patients less frequently and mail their prescriptions to them, causing much more work for the physician and his staff and increasing the risk of diversion if the prescriptions get into the wrong hands.

So when I received notice that the DEA, in response to all the comments it had received, was inviting pain specialists and others involved in the delivery of care to pain patients to a meeting to listen to our concerns, I was hopeful that a face-to-face encounter would be more persuasive than written comments. Unfortunately, after reading the posting on the DEA’s Office of Diversion Control Website dated August 26, 2005, under “Rules—2005,” I realized I was wrong. Even though the DEA officials at the meeting listened as we reiterated our concerns with their position on multiple prescriptions for CS, the clarification posted on the Website made no change at all to the original position stated in the IPS of November.

It now is apparent to me that the spirit of cooperation that existed between the DEA and the pain community to achieve the goal of balance has broken down. The DEA seems to have ignored the input and needs of the healthcare professionals and pain patients who actually prescribe, dispense, and use CS.

The DEA did not take into consideration the inordinate amount of time and effort that went into FAQ when they unilaterally withdrew support because of several alleged “misstatements” without any consultation with the other parties involved. Did not the FAQ workgroup deserve to be consulted before the final decision was made? Most likely edits, if necessary, could have been made that would have made this educational document acceptable to all stakeholders. Is not this the original intent of FAQ?

The result of this unilateral action by the DEA is that healthcare providers are even more reluctant than ever to prescribe CS for pain. Those of us prescribing CS are fearful of being investigated, and those healthcare professionals perhaps considering prescribing CS will think twice. By focusing on the very small minority of patients and healthcare professionals who abuse the system, the DEA makes it harder for patients with a legitimate medical need for CS for pain to find a healthcare pro-

fessional to treat them. Who suffers the most from this situation? Of course, the patients are the ones who suffer, as does the greater society [4].

It is essential that we resume dialogue between the DEA and healthcare professions for the benefit of our patients and society. The DEA and the healthcare professionals treating pain both have an important job to do in ensuring those who need CS for pain receive them while preventing misuse and diversion. Only through dialogue based on mutual trust and respect can this balance be restored.

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References

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