



American Alliance of Cancer Pain Initiatives

March 17, 2005

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

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

Dear Ms. Leonhart:

We are responding on behalf of the American Alliance of Cancer Pain Initiatives (AACPI) to the Drug Enforcement Administration's (DEA) solicitation for comments on the Interim Policy Statement (IPS) published in the Federal Register on November 16, 2004 (Docket No. DEA-2588).

The AACPI is a national network of health care professionals and patient advocates dedicated to improving the management of cancer pain. It was one of 21 health organizations that joined the DEA in drafting a joint statement, *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*, released in September 2001. That statement provided critical reassurance to health care professionals that the appropriate medical use of controlled substances for pain control would not subject them to inappropriate regulatory scrutiny.

The Federal Register statement and the abrupt withdrawal of the document entitled *Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel (FAQ)* in October have created much concern among members of the pain community. 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. We endorse the Comment provided to you on March 11, 2005 by the Pain and Policy Studies Group (PPSG) at the University of Wisconsin Comprehensive Cancer Center.

We specifically request the DEA to:

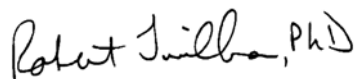
1. reaffirm its previous interpretation of the Controlled Substances Act (CSA) that permitted clinicians to issue more than one prescription for a Schedule II controlled substance at a time with instructions to fill on different dates. The IPS asserts that “No prescription for a controlled substance in Schedule II may be refilled 21 U.S.C. 829(a). 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).” The DEA had a long-standing interpretation of 21 U.S.C. 829(a) that permitted a practitioner to issue a series of prescriptions marked “do not fill” until a later date. A reversal of that interpretation would have major implications for many persons with chronic pain. We agree with the PPSG that “the issuance of a series of original prescription orders 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. Prohibition of this practice will not affect those who divert controlled substances; indeed the standard for determining lawful prescriptions should be whether they are issued for legitimate medical purposes and in the course of professional practice.”
2. reassert its position that the number of tablets prescribed for each patient and the duration of therapy will not by themselves indicate a problem and should not be used as the sole basis for an investigation by regulators or law enforcement. Neither the CSA nor DEA regulations set limits on the amount of a controlled substance that can be prescribed or on the duration of therapy with controlled substances.
3. confirm that the weight a practitioner should give to information provided by family and friends about the possibility that a patient may be abusing pain medications should be a matter of his/her professional judgment. Information from family and friends may be valuable, but their concerns about abuse could be based on a misunderstanding of the role of opioids in the management of pain and on unfounded fears and confusion about the meaning and incidence of addiction.
4. affirm that it is lawful and may be medically appropriate to prescribe controlled substances for treatment of pain in a person with a past or current history of addiction. Such prescribing may require special expertise, extra care and monitoring but it is not illegal under federal law.

We believe that the DEA could address these issues in a subsequent policy statement in the Federal Register, by endorsement of the Model Policy on the Use of Controlled Substances for Pain Control from the Federation of State Medical Boards and reinstatement of the FAQ.

We strongly concur with the recommendation from the Pain and Policy Studies Group that the DEA “immediately establish an advisory committee for the purpose of maintaining ongoing communication with organizations involved in pain management and palliative care.” The AACPI also requests the DEA to join with health organizations to affirm its commitment to the principle of balance by reissuing the September 2001 policy statement and implementing a strategy to assure its widespread dissemination to health care professionals, law enforcement and state regulatory authorities.

We applaud Administrator Tandy’s assertion that “the myth that the DEA is out to get doctors needs to be put to rest. Doctors acting in good faith and in accordance with established medical norms should remain confident in their ability to prescribe appropriate pain medications.” The recommendations we have made would do much to reestablish our confidence in the DEA’s commitment to assuring that it does not interfere in the legitimate practice of medicine and impede patient access to appropriate pain medications.

Sincerely,



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