
COMMENTS

of the

**WASHINGTON LEGAL FOUNDATION,
ABIGAIL ALLIANCE FOR BETTER ACCESS
TO DEVELOPMENTAL DRUGS, AND
LORENZEN CANCER FOUNDATION**

to the

**DRUG ENFORCEMENT ADMINISTRATION,
U.S. DEPARTMENT OF JUSTICE**

Concerning

DISPENSING OF PAIN MEDICATIONS
(Docket No. DEA-261)

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March 21, 2005

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Michelle Leonhart
Deputy Administrator
Drug Enforcement Administration
2401 Jefferson Davis Hwy.
Alexandria, VA 22301

**Re: Dispensing of Controlled Substances for the Treatment of Pain
(Docket No. DEA-261)**

Dear Ms. Leonhart:

We appreciate the opportunity to comment on the policy guidance that DEA is contemplating with regard to the dispensing of controlled substances for the treatment of pain. We submit these comments on our own behalf and on behalf of the Abigail Alliance for Better Access to Developmental Drugs and the Lorenzen Cancer Foundation.

The Washington Legal Foundation (WLF) is a nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. Since its founding in 1977, WLF has engaged in litigation and advocacy to defend and promote individual rights and a limited and accountable government, including in the area of patients' rights. For example, WLF successfully challenged the constitutionality of Food and Drug Administration restrictions on the ability of doctors and patients to receive truthful information about off-label uses of FDA-approved medicines. See *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D. D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000).

Commenter Abigail Alliance for Better Access to Developmental Drugs is a nonprofit organization based in Arlington, Virginia, dedicated to helping terminally ill patients obtain access to the medicines they need. Abigail Alliance was founded in 2001 by Frank Burroughs, who is now its president. The group is named for Burroughs's daughter, Abigail, an honors student at the University of Virginia. Abigail died of cancer on June 9, 2001, after she was stymied in her efforts to obtain new cancer drugs that her oncologist believed could save her life, but which were still in clinical trials. Abigail Alliance has numerous members and supporters who are suffering from terminal illness or who have lost family members to terminal illness.

Commenter Lorenzen Cancer Foundation is a nonprofit organization based in Monterey, California, providing assistance to patients fighting pancreatic cancer. The Foundation maintains a large database of clinical trials of pancreatic cancer therapies, as well as current medical news, to aid these patients and their physicians in keeping up to date on the range of available

treatment options for pancreatic cancer. The chairman of the Foundation is Lee Lorenzen, who founded it in response to the diagnosis and subsequent passing of his brother Gary Lorenzen due to metastatic adenocarcinoma of the pancreas.

It is clear that this area of policy presents particularly difficult ethical and legal issues for physicians and for law enforcement. On one hand, misuse of controlled substances and trafficking in those substances is a critical societal problem – one that requires energetic efforts on the part of both physicians and law enforcement to prevent. On the other hand, patients suffering from chronic pain have a legitimate need (and sometimes even a desperate need) for treatment with prescription pain medications. Cancer patients and other terminally ill patients frequently fall into this category.

Federal law enforcement policies that consider only the first half of this dilemma can chill the availability of pain treatments to patients with a *bona fide* need for them. DEA's August 2004 guidance document, *Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel* – the product of a collaborative effort between the medical community and federal law enforcement – sought a middle ground to address the need to prevent drug diversion and to serve patients in need. We are concerned that the DEA's November 16, 2004, withdrawal of that guidance may signal a broader policy shift away from the balanced approach taken there.

In its January 18, 2005, solicitation of comments, DEA indicated that it intends to issue a new guidance document that will offer “reassurance to the overwhelming majority of physicians who engage in legitimate pain treatment while deterring unlawful prescribing and dispensing of pharmaceutical controlled substances.” 70 Fed. Reg. 2883 (Jan. 18, 2005). This is heartening. Yet the solicitation also seems to imply that the guidance will primarily “reiterate legal concepts that have been incorporated in the federal laws and regulations for many years.” If this means the guidance is to reiterate legal concepts in isolation from day-to-day issues in medical practice, it will have little value to the medical community. The boundaries of lawful conduct in this area are defined in large measure by the boundaries of legitimate medical practice. Thus, it is important for the medical community to have a clear view of DEA's view of legitimate medical practice – a view that should, in turn, reflect what physicians are actually doing to meet the *bona fide* needs of patients.

To achieve the salutary end of providing “reassurance to the overwhelming majority of physicians who engage in legitimate pain treatment,” we believe DEA's guidance should, at a minimum, reaffirm the following observations and principles set out in its 2004 guidance:

- “[T]he arrest and indictment of a physician cannot occur unless he or she can be shown to have knowingly and intentionally distributed or prescribed controlled substances to a person outside the scope of legitimate practice.” (P. 8)

- “Opioid therapy is accepted around the world as the most important approach to managing severe, acute pain (such as pain after surgery), moderate to severe chronic cancer pain, and moderate to severe pain caused by other life-threatening diseases (such as AIDS). The use of opioid therapy to treat chronic nonmalignant pain has been more controversial and is still being actively discussed by medical experts. The consensus now is that some patients with chronic pain should be considered as candidates for long-term opioid therapy, and some will gain great benefit from this approach.” (P. 15)
- “Tapering of a patient being treated for pain is legally distinct from ‘detoxification’ of a patient being treated for addiction. Physicians who are directing the taper of a therapy do not need a separate DEA registration as do those who are directing detoxification programs. . . . There are no federal or state regulations governing the tapering from opioids of a patient being treated for pain.”

More generally, we submit that when setting out the responsibilities of physicians, the agency should take care to avoid overly-broad statements that may deter physicians from meeting patients’ needs for fear of prosecution, administrative action, or investigation.

Respectfully submitted,

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