

Pain and Politics: DEA, Congress, and the Courts, Oh My!

In this issue, Howard Heit describes a pressing problem that faces two public health crises that are seemingly at odds with each other. Although few would question that combating drug abuse as well as resolving the under treatment of pain justify our attention and resources, helping one need not harm the other. The perfect storm in which these issues are now colliding stems from real public needs and agencies and professionals who are focused, perhaps too narrowly, on each of their individual causes. There are no real bad guys here even though some in law enforcement may see some well-intended physicians as drug dealers and some from the pain community may see the Drug Enforcement Administration (DEA) leadership as disingenuous and lacking in respect or concern for the collateral victims of their antidrug abuse activities. The reality here is that healthcare workers focus on improving health and, in large part, are not primarily invested in the enforcement of laws to prevent drug abuse. Law enforcement is just the opposite, with primary responsibility in fighting abuse as set forth by the law, with friendly fire being the price of doing business. No wonder we hear the DEA present themselves in the best public light, as the same old physician-friendly agency, while almost simultaneously, their behavior suggests a diametrically different position. It is as though their words and their music go with two different songs.

In light of several other governmental initiatives that have challenged the line between health policy and law enforcement, the current state of affairs with the DEA is just one of several examples of a subtle shift in governmental oversight of medicine from agencies responsible for public health to law enforcement. For instance, just last year, Congress gave the DEA increased authority for reviewing new drugs, a role that has always been held solely with the Food and Drug Administration (FDA). The new authority came through an almost secret process as it was not legislated through the normal process of making law, but legislated directly through appropriation of funding to the DEA, a process known as legislation through appropriation. This process occurred with no public review or commentary. The new authority was vague and exactly how it could impact patients is not clear. It is clear however, that a real line was crossed as prior to this new law,

approving new drugs was the sole function of the government agency that focused on health and drugs, the FDA. Through this legislative shell game, the FDA's oversight for new medicines became shared with a government agency that is solely focused on drug abuse (DEA). Law enforcement and healthcare policy have often been intentionally separated so that one does not interfere with the other. In light of the detrimental effects that this change could have on the development of new analgesics, members of the pain care community raised concerns, attracted media attention, and recruited political support. On November 4, 2005, Congress reversed itself and removed the new authority as well as the 50 million dollars it had granted to the DEA just 1 year earlier. Nonetheless, the message here was clear, that many in positions of power believe that policies to decrease drug abuse take precedent over other public health concerns.

The potential role of the DEA in FDA activities is just one example of a disturbing trend of regulatory authority over healthcare shifting *away* from health agencies and *to* law enforcement agencies. The DEA and federal prosecutors have increased scrutiny of physicians' practices by using the courts to bypass state medical boards to bring criminal charges against doctors. Although the practice of Dr. William Hurwitz was arguably at an extreme or even beneath the standard of care, review of the court proceeding of his prosecution for drug trafficking reflects a breach of an important separation between medicine and criminal activity. This line has traditionally protected society from the potential of law enforcement to degrade the quality of the public's health care—in essence, the effect of paralyzing legitimate clinicians who would otherwise be fearful of wrongful prosecution. In the federal trial of Dr. Hurwitz, the jury was never given adequate instructions on the difference between an individual prescribing abusable substances within the bounds of medicine and those dealing drugs outside these bounds. Hurwitz was convicted on 50 counts (and sentenced to 25 years in federal prison) by a jury who was given woefully inadequate guidance on the law that specifically seeks to protect physicians, even those who practice substandard medicine, from criminal prosecution when they are acting in good faith. Whether Hurwitz was or

was not acting in good faith as a treating physician was therefore not even allowed to be a consideration for this jury. The precedent set in this case has dire implications for any legitimate physician who may need to appropriately treat a patient with aggressive dosages of a potentially abusable medication. If this is drug trafficking, who among the legions of physicians who treat pain every day are not drug traffickers? At the time of this writing, the 4th District Court of Appeals is poised to hear these arguments. Nonetheless, in its service to adjudicate and enforce the law, the willingness of the original federal court to potentially change the practice of medicine through this precedent setting action again reflects the zeal to combat drug abuse, even at the expense of public health.

Another example of shifting oversight of medicine in general and pain care in particular, is the recently passed law instituting a national prescription monitor program called the National All Schedules Prescription Electronic Reporting Act (NASPER.) This new program is specifically intended to encourage states to develop their own prescription monitoring programs (PMPs) for schedule II and other abusable drugs. PMPs have become a necessary part of pharmacovigilance at a time when prescription drug abuse is alarmingly on the rise. However, while it is well known that such PMPs can be used as helpful tools for enhancing safe prescribing, when administered with the appearance of law enforcement, they can impede optimal prescribing and even perpetuate aberrant prescribing that may facilitate abuse. Unfortunately, NASPER is suspiciously vague, leaving it up to each state to decide whether they will even participate. Moreover, the law neither mandates that the authority to monitor prescribing would come under state agencies responsible for health rather than law enforcement, nor does it ensure that the collected information would be available to physicians at the time that they treat their patients. These profound inadequacies suggest that this law may be intended less as a clinical tool than as a physician mouse trap.

Drug abuse and under treated pain are both public health crises, but there is no evidence to suggest that the solution to one must impact the other. In fact, new evidence by Joransen et al. [1] suggests that the growing problem of prescription drug abuse may be much less related to prescribers than to theft of the drugs at points along the sup-

ply chain that do not include clinicians (REF). Therefore, targeting physicians may make good press for government agencies that have little good news to report on the war on drugs, but these efforts are unlikely to significantly curb drug abuse in America.

The regulation of medicine has traditionally been held with government agencies responsible for health and not law enforcement because this separation offers the greatest public benefit and least risk of incidental harm. The scenario described in the preceding essay by Heit of the DEA intruding into the practice of medicine by reinterpreting the Controlled Substances Act has its own incidental harm that may ironically reduce safe prescribing and increase abuse risk. But this incidental harm is not the primary concern of the DEA. Neither is it the concern of courts that zealously criminalize physicians who practice within the bounds of medicine nor politically minded legislators that pass laws with the appearance of strong antidrug programs.

Healthcare decisions, including those involving legitimate use of analgesics, must remain in the hands of healthcare professionals. The DEA should be required to work with health agencies and healthcare professionals in finding common ground and reaching the rational position of balance that is in the public's best interest. Fortunately, Congress, who ultimately gives the DEA its funding, may be seeing the writing on the wall. Healthcare oversight must remain within agencies whose primary responsibility is to improve public health. Contrary to recent events in Washington, we must continue to insist that drug abuse can be curbed without undermining patients in pain and striving for such policies is in the best interest of society. The least we can do is to make sure that the casualties of the war on drugs are not suffering patients who legitimately deserve relief.

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Reference

- 1 Joransen DE, Gilson AM. Drug crime is a source of abused pain medications in the United States. *J Pain Symptom Manage* 2005;30(4):299–301.