

Policy Brief

Balance, Uniformity and Fairness:

Effective Strategies for Law Enforcement
for Investigating and Prosecuting the Diversion
of Prescription Pain Medications While
Protecting Appropriate Medical Practice

February 2009



© Copyright 2009 by the Center for Practical Bioethics
Harzfeld Building
1111 Main Street, Suite 500
Kansas City, MO 64105-2116

Phone: 816-221-1100
Fax: 816-221-2002
www.PracticalBioethics.org

Balance, Uniformity and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice - A Policy Brief

Preamble

Diversion of prescription pain medicine from legitimate healthcare channels is a serious, and a growing, healthcare problem in this country. When that diversion and abuse affects teen-agers, it is particularly troubling. Under-treatment of pain is likewise a serious national healthcare problem. This under-treatment includes patients with chronic conditions as well as those who are critically ill or near death.

The Balanced Pain Policy Initiative Law Enforcement Roundtable (the “Law Enforcement Roundtable”) was formed by people from both law enforcement and health care communities, focused on finding common ground – to ensure that patients who need pain medications have access, and to prevent these drugs from becoming a source of harm and abuse. The roles of both law enforcement and the medical community are critical to reach the vital balance between prevention of drug diversion and good patient care.

Most in the public understand the scourge of drug abuse in modern day society. They also understand that law enforcement is filled with dedicated public servants standing on society’s battlements, protecting the public from a variety of associated dangers. Fewer are aware of the massive healthcare problem of under-treatment of pain. For example, a study in the *Journal of the American Medical Association* concluded that 40% of the 2.2 million nursing home residents in this country live with “moderate” to “excruciating” pain daily,¹ which is not treated for as long as six months after being reported. Many studies corroborate such under-treatment across society, for young and old alike, and the negative impact on society of under-treatment of pain on quality of life, work productivity, general health status and health care costs.

The under-treatment of pain is due in part to a kind of undesirable “chilling effect.” The concept of a chilling effect, generally, is a useful law enforcement tool. When publicity surrounding a righteous prosecution “chills” related criminal conduct, that chilling effect is intended, appropriate, and a public good. A chilling effect on the appropriate use of pain medicine, however, is not a public good. Recent research by members of the Law Enforcement Roundtable confirms that prosecutions of doctors for diversion of prescription drugs are rare.² But, on occasion, overly-sensationalized stories of investigation of doctors have hit the nightly news. When that happens, the resulting chilling effect reaches far beyond a “good” chilling effect on bad actors, and directly affects appropriate medical practice. The consequence is extreme, and not what law enforcement would ever seek – our parents and other loved ones who are in pain simply cannot get the medicines they need.

The Law Enforcement Roundtable came together to address the societal challenge of reaching an appropriate balance in our approaches to diversion and pain management. In meetings marked by the frank, respectful, thoughtful exchange of views, people on all sides searched for ideas – looking for strategies to focus law enforcement directly on the many sources of illegal drug diversion, while at the same time avoiding any effect on appropriate medical practice and patient care. At the end of the last meeting, the participants reached consensus on a number of issues, including ideas for several effective strategies that law enforcement can consider when confronted with the potential prosecution of a doctor suspected of or known to be illegally prescribing these medications.

Effective Strategies

Summary

Strategy 1. Distinguishing between criminal behavior and medical negligence. The Roundtable developed a simple, five-step Procedural Template, explained below, to assist enforcement in assessing a doctor's behavior and determining when to refer investigations to medical licensure boards for evaluation and when to pursue criminal charges. Use of such a Template in investigations involving the prescribing of pain medications should aid in achieving balanced pain policy.

Strategy 2. Balancing publicity. The undesirable chilling affect from a tiny number of sensationalized media cases on doctors' prescribing practices has been damaging. The Roundtable recommends that law enforcement officers follow the guidelines of the Department of Justice Media Relations rules³ and the American Bar Association. To the extent these rules counsel against speaking publicly, that advice is particularly appropriate in the investigating of doctors, given the far-reaching consequences of under-treatment of pain.

Strategy 3. Access to experts. Appropriate treatment of patients suffering from chronic pain as well as critically ill patients is complex. Law enforcement, particularly at the local and state level, often does not have a well-qualified pain medicine expert to consult. Leading pain societies plan to develop a roster of national experts who agree to be available to law enforcement for informal, "curbside consultation."

Strategy 4. Technological aids. Electronic prescription monitoring programs (PMPs) can be useful as a quality improvement tool, and can provide important information for doctors in identifying drug-seeking behavior. PMPs are preferable to now-outdated triplicate prescription forms. PMPs are not a law enforcement tool, however, and should only be available to enforcement as part of the investigation of an active case and only with appropriate procedural safeguards.

Strategy 5. Interagency collaboration. Where legally possible and ethically appropriate, law enforcement, state, local and federal investigators, medical boards, and third-party payers, should share information regarding investigation of a suspect physician. Physician behavior that arguably falls into a "gray area" between criminal and regulatory, should be deferred to state medical boards for evaluation and corrective action.

Strategy 6. Education. Education on all sides is critical. State medical boards that have not yet done so should study, adopt and promote the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* developed by the Federation of State Medical Boards. State medical societies and medical-specialty societies should do likewise. Law enforcement should seek to learn the basics of good pain management for chronic pain sufferers and critically ill patients. And all interested in a balanced pain policy should work to educate the consumer that opioids and other pain medicine are a part of quality medical practice. Finally, it is critical to educate consumers to make certain that their medicines are secured against diversion that may occur in the home.

Effective Strategies

Background

Members of the law enforcement and healthcare community have been working toward a balanced pain policy for many years. On October 23, 2001, then-DEA Administrator Asa Hutchinson announced "A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration – Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act."⁴ Roughly two years later, Oklahoma Attorney General Drew Edmondson framed high-quality end-of-life care as a consumer protection issue for his chosen 2002-03 initiative as President of NAAG, the National Association of Attorneys General. Part of that initiative included seeking a balanced pain policy. NAAG joined in this effort with the U.S. Drug Enforcement Administration and many other organizations representing healthcare policy, ethics, law enforcement, pain advocates, consumers, and others. Unfortunately, in 2004, this collaborative effort largely stalled with the highly-publicized federal prosecution of a Virginia doctor and distrust replaced dialogue.

In 2006, in an effort to renew the earlier spirit of collaboration, the Center for Practical Bioethics in Kansas City, NAAG, and the Federation of State Medical Boards formed a group they named the Balanced Pain Policy Initiative (BPPI). The BPPI group met in Oklahoma City in June of 2006. One result of that meeting was the agreement that solid data was needed, and a research project was commissioned. The results of this research were published in the peer-reviewed journal, *Pain Medicine*, on September 9, 2008.⁵ The key finding of the study: "The study identified 725 doctors, representing an estimated 0.1% of practicing patient care physicians, who were charged between 1998 and 2006 with criminal and/or administrative offenses related to prescribing opioid analgesics." Many found the bottom-line of study authors somewhat startling. The authors concluded: "Criminal or administrative charges and sanctions for prescribing opioid analgesics are rare."

The study results were presented at a DEA meeting in June of 2007; at the first Law Enforcement Roundtable meeting in Dallas in November of 2007; and to the U.S. Attorney General Controlled Substances Abuse committee in San Diego in September of 2008. These results were also part of the discussion at the second meeting of the Roundtable, held in Washington, D.C. in September of 2008. Attendees at that meeting, with their affiliations are listed on page 15.

The product of that second Law Enforcement Roundtable meeting in 2008 is this Policy Brief. The Roundtable attendees, in a significant spirit of collaboration, openness, and candor, developed these *Effective Strategies*, aimed at balanced pain policy, with one true consumer in mind – the patient in need of good medical care. The Law Enforcement Roundtable also agreed to work to disseminate this Policy Brief widely.

Effective Strategies In Detail

Strategy 1. Distinguishing between criminal behavior and medical negligence. The Roundtable developed a simple, five-step Procedural Template, set out on the next page, to assist enforcement in assessing a doctor's behavior and determining when to refer investigations to medical licensure boards for evaluation and when to pursue criminal charges. Use of such a Template in investigations involving the prescribing of pain medications should aid in achieving balanced pain policy.

Law enforcement personnel, at all levels, are committed public servants with, unfortunately, plenty of bad conduct to investigate. They have no interest in interfering with appropriate medical practice or patient care. In an area as complex as pain medicine, however, investigation can prove complicated. To address that issue, the Roundtable developed this Procedural Template. Use of the Template in investigations should aid in achieving balanced pain policy.

Strategy 2. Balancing publicity. The undesirable chilling effect from a tiny number of sensationalized media cases on doctors' prescribing practices has been damaging. The Roundtable recommends that law enforcement officers follow the guidelines of the Department of Justice Media Relations rules⁶ and the American Bar Association. To the extent these rules counsel against speaking publicly, that advice is particularly appropriate in the investigating of doctors, given the far-reaching consequences of under-treatment of pain.

Members of the BPPI from law enforcement and medicine met in Oklahoma City in June 2006. All parties present agreed that to develop policy, the group needed better facts. A task force began an extensive research project, which culminated with the article published in the journal *Pain Medicine* in September of 2008. Studying the eight-year period from 1998 to 2006, the researchers reported this dramatic result: only 725 doctors, about one-tenth of one percent of all doctors in the U.S., had been charged with criminal and/or administrative offenses related to prescribing opioid analgesics. The article concluded: "Criminal or administrative charges and sanctions for prescribing opioid analgesics are rare." It is important that the medical world learn these results, and part of the education described in *Strategy 6* below will include such education. Such education will also help doctors learn that with careful record-keeping and attention to related, legally-required procedures for acquiring, storing, and handling controlled substances, this minimal 0.1% risk described in the article can be even further reduced.

Nonetheless, it is vital that those in law enforcement understand that even when doctors are well educated in this area, the undesirable chilling effect on good medical practice will persist, and it will have very real effects on the quality of medical care. Controlled substances to treat pain are unique medicines for doctors. No other medicines in the doctor's prescribing arsenal have the "shadowy side" of controlled substances – clever "patients" seeking to mislead doctors in order to obtain prescriptions they later sell to abusers on the street; a small percentage of pain patients who already are, or who become, genuinely addicted; public service ads on television about the risks of teens stealing opioids from their parents' medicine cabinets; stories told and retold of blue-coated

Procedural Template* for Achieving the Policy of Balance

1. Assess the medical-needs aspect of the suspect behavior. Is the doctor knowingly prescribing controlled substances in the absence of or grossly in excess of medical needs? How do you know this fact?

At this point, unless there is a total absence of evidence of medical need, a consult with medical experts may be in order. Has the case been handled by the State Medical Board? Should it be reviewed by the Board prior to proceeding? Do you have a pain specialist to consult? Consultation with a doctor familiar and comfortable with pain management is important; not every doctor is an expert in this field (in fact, competency of physicians in pain management is quite variable).

2. Assess the medical-practice aspect of the suspect behavior. Does the suspect doctor take any of the steps required by normal practice standards (history, examination, record keeping, tests, lab work)?

As a law enforcement officer you must be familiar with medical standards of practice or have professionals with whom you can consult regarding those standards. If the patient presents with pain, and the suspect doctor complies with even minimal practice standards, the prescribing of controlled substances is probably NOT a criminal matter.

Issues of poor record keeping, inadequate history-taking or skipped examinations are more properly considered by a state medical board.

If the doctor is reckless and re-prescribes when prescriptions are "lost" or "stolen," even if the patient is selling on the street, the doctor's actions will be criminal only if there is legal knowledge on his part.

Moreover, prescribing controlled substances to a patient with an addiction disorder or with known substance abuse is not *per se* illegal. For example, though such medical treatment would be complicated, a doctor could prescribe opioids to a drug dependent person with cancer or AIDS for the purpose of treating the pain. That doctor would not be prescribing for a non-medical purpose.

3. Assess the compensation aspect of the suspect behavior. Aside from and in addition to the normal fees and reimbursements associated with the practice of medicine, like office visit charges, fees for tests and time, does the suspect doctor receive anything of value in exchange for his prescription of controlled substances? For example, are his office visit charges inflated for a "pain" patient? Does he take cash? Is he trading drugs for personal favors? Is he splitting drugs with patients?

4. Carefully assess any negative medical outcomes. Even when a patient dies from an overdose involving prescription controlled drugs, the matter may be more appropriate for the state medical board, and steps 1, 2 and 3 above should receive primary emphasis. Medical outcomes, good or bad, are best evaluated and judged by medical experts, particularly in a field as complicated as pain medicine, and where patient behavior can play a significant role in such an outcome.

5. Decide whether to file criminal charges. Given answers to steps 1-4 above, if the doctor is prescribing for other than a medical reason, does not perform examinations or take medical histories (or if the exams and histories do not indicate medical need), and if the doctor has also been receiving extra financial or personal benefit from prescribing controlled drugs, criminal prosecution is appropriate. Law Enforcement personnel should take steps necessary to protect patients at this stage.†

†One of the consequences of the investigation and prosecution of physicians for prescription drug violations is that, often, patient records are seized for review or to use as evidence. In those cases, genuine pain patients are unable to immediately retrieve their records so that they can receive treatment from another physician. For this reason, it is suggested that law enforcement agencies establish a procedure to copy seized records and make them available to patients as soon as possible, and to post notices or otherwise advise patients how to retrieve their medical records.

*The original template was developed by Drew Edmondson, Attorney General of Oklahoma.

federal agents swooping in on allegedly innocent doctors; and medicines which can help patients greatly, but which are also being abused at increasingly higher levels, in part because there are greater quantities dispensed for patient care and subject to theft from pharmacies and medicine cabinets.

Controlled substance medications also pose unique issues for law enforcement. No other targets of law enforcement, when properly used, have such a huge upside benefit for the public. Unlike problems such as guns on the street, child abusers, crack cocaine – all problems with no social value – opioids and controlled substances can, dramatically and appropriately, improve the lives of millions of Americans in chronic pain, allowing them to participate more fully in life. Opioid medicines are basically a societal good, with a potential for diversion and harm to the public health.

A sensible balanced pain policy should not and cannot counsel law enforcement to in any way stand down from efforts to stop the criminal diversion and trafficking of prescription drugs. But such a policy should counsel discretion. That discretion can come in the form of the Template in *Strategy 1*, which steers law enforcement towards state medical boards in cases that are clearly not criminal in nature.

And that discretion is of particular importance in dealing with the media. Simply put – the stakes from unbalanced media coverage of a doctor being targeted for improper prescribing of pain medicine are too high. Some patients in pain are likely to experience lost or diminished access to needed medicine every time a sensational story about doctor prescribing is aired.

The Department of Justice Media Relations rules state: “In cases in which a search warrant or arrest warrant is to be executed, no advance information will be provided to the news media about actions to be taken by law enforcement personnel, nor shall media representatives be solicited or invited to be present.”⁷ These DOJ rules also counsel prudence and discretion in many other areas for media relations. Such rules, important in all law enforcement activity, are vital in any investigation of a doctor. These rules should set a baseline for media relations in cases involving prescription of controlled medicines.

The goal of law enforcement is to protect the public. In the area of pain medicine, perhaps unique in all of the issues facing law enforcement, the path to protecting the public can grow complicated. The federal Controlled Substances Act acknowledges the need for balance – the Act recognizes that opioids have a potential for abuse, but also that they are necessary for maintaining the public health. Without question, discretion with the media concerning the investigation of prescribing-related cases is critical, because the consequences of the undesirable chilling effect on pain medicine and the public are simply too high. Moreover, in cases in which law enforcement eventually does communicate with media, those officials can potentially minimize the undesirable chilling effect by making clear the criminal nature of the conduct involved, conduct well outside the boundaries of appropriate medical practice.

Strategy 3. Access to experts. Appropriate treatment of patients suffering from chronic pain as well as critically ill patients is complex. Law enforcement, particularly at the local and state level, often does not have a well-qualified pain medicine expert to consult. Leading pain societies plan to develop a roster of national experts who agree to be available to law enforcement for informal, “curbside consultation.”

A prosecutor for a state medical enforcement agency for nearly 20 years, who worked as a police officer and district attorney before that, told the Law Enforcement Roundtable in Washington about a complaint he investigated involving a pharmacist, a doctor, and a patient who was receiving 16,000 milligrams of morphine a day.⁸ His initial reaction to that high dosage, even as a seasoned, talented investigator, was one of alarm. Yet when his office conducted a thorough study of the doctor's medical records and other information, guided by knowledge of modern medical practices in treating severe pain, they found the medical chart impeccable, the treatment decisions sound, and the seemingly-high dosage exactly right for this patient. (Morphine has no dosage ceiling, which is why it is so valuable in treating severe and escalating pain and why some patients develop tolerance, which requires medicine in high doses in order to reduce pain so that they can continue to function.)

Treating pain is complicated, and law enforcement personnel often need expert help to evaluate cases. Law enforcement attendees at the Washington Roundtable meeting believed that having access to national experts for "curbside consultation" to evaluate cases could prove a very useful tool. Accordingly, leaders of the main pain advocacy organizations in the country, like the American Academy of Pain Medicine, the American Pain Society, the American Pain Foundation, have agreed to help establish a roster/registry of knowledgeable board certified physicians who would be available to law enforcement for such consultations. The Law Enforcement Roundtable will distribute this list widely.

Strategy 4. Technological aids. Electronic prescription monitoring programs (PMPs) can be useful as a quality improvement tool, and can provide important information for doctors in identifying drug-seeking behavior. PMPs are preferable to now-outdated triplicate prescription forms. PMPs are not a law enforcement tool, however, and should only be available to enforcement as part of the investigation of an active case and only with appropriate procedural safeguards.

Like much of medicine, the field of pain management is relatively new, the product of rapid advances in medical science. Pain management emerged as a separate science in the mid-1980s as doctors were working to do a better job treating cancer pain. Increased use of pain medicines led to state legislative efforts to regulate the use of those medicines. Most visible were "triplicate" laws in some states. These laws required doctors to use large, cumbersome state-issued pads, with multi-copy forms in triplicate, for prescribing controlled substances. The laws created a feeling for doctors that they were "being watched." Dr. Richard Payne, a nationally-respected expert in pain medicine, has called such laws "the number one barrier to better pain management."⁹

Today, triplicate laws have evolved into less intrusive, and more effective, electronic prescription monitoring, or PMPs (prescription monitoring programs). To date, thirty-eight states have adopted laws establishing PMPs, and eleven additional states are in the process of proposing, preparing, or considering legislation.¹⁰ Under most programs, pharmacies or doctors send records or their opioid prescriptions to a state-based, centralized regulatory agency, which monitors whether individuals are receiving opioid prescriptions from multiple doctors. Such electronic programs are less expensive than the ineffective triplicate programs. More importantly, they are less intrusive on medical practice. In addition, some PMPs allow the prescriber to check on whether a particular patient is receiving prescriptions from other physicians, a phenomenon called "doctor shopping," which leads to diversion.

PMPs are not a law enforcement tool, however, and should only be available to enforcement as part of the investigation of an active case and only with appropriate procedural safeguards. There are a number of other sources of information that can be used by law enforcement to identify sources of diversion, such as Medicaid drug utilization data, third party payer data bases, data on retail distribution of controlled substances, and pharmacy theft reports.

The goal of PMPs, ultimately, is a balanced pain policy. To that end, regulatory agencies should work to educate providers about the nature, goals, and access to PMPs. They should also conduct research to determine the effect PMPs have on both access to medicine for legitimate medical purposes as well as their effect on diversion and abuse.

Strategy 5. Interagency collaboration. Where legally possible and ethically appropriate, law enforcement, state, local and federal investigators, medical boards, and third-party payers, should share information regarding investigation of a suspect physician. Physician behavior that arguably falls into a “gray area” between criminal and regulatory, should be deferred to state medical boards for evaluation and corrective action.

Investigations involving the possible diversion of controlled substances can cross many organizational lines. Most state medical boards are required to investigate all complaints; state law enforcement authorities can refer cases to federal authorities and vice versa; medical boards can send cases to law enforcement and law enforcement can refer to the boards. Often investigations of a single physician have been conducted in parallel by separate agencies.

In such a line-crossing world, principles to guide interagency collaboration are hard to define. Nonetheless, two general principles can aid agencies in the effort to reach a balanced pain policy. First, all parties involved should work aggressively to communicate with one another. Such communication should include sharing information and analysis to the fullest extent possible within the investigatory rules of the agency and the ethical rules of prosecutors. The goal of all sides should be the protection of the public. (The Uniform Controlled Substances Act contains a section titled “Diversion Prevention and Control,” part of which aims at interagency cooperation.)¹¹

Second, applying the Procedural Template from *Strategy 1*, law enforcement should whenever possible work closely with state medical boards and, absent clear cut criminal conduct, refer “gray-area” cases to the appropriate medical board. To enhance the confidence of law enforcement in making such referrals, state medical boards should not only rigorously enforce their rules, but should significantly expand their education as outlined below. Moreover, whenever possible state medical boards should communicate directly to law enforcement the outcome of all matters referred to the board.

To the extent enforcement and regulatory agencies have confidence in and communicate well with one another, a balanced pain policy will be more readily achieved.

Strategy 6. Education. Education on all sides is critical. State medical boards that have not yet done so should study, adopt and promote the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* developed by the Federation of State Medical Boards. State medical societies and medical-specialty societies should do likewise. Law enforcement should seek to learn the basics of good pain management for chronic pain sufferers and critically ill patients. And all interested in a balanced pain policy should work to educate the consumer that opioids and other pain medicine are a part of quality medical practice. Finally, it is critical to educate consumers to make certain that their medicines are secured against diversion that may occur in the home.

Education on many fronts is critical to the success of a balanced pain policy – for law enforcement, medical boards, doctors, consumers and legislators.

Law enforcement. The *Strategies* set out above, particularly *Strategies 1-3*, form the foundation for education in the law community. If law enforcement 1) learns and applies the Procedural Template; 2) is guided by careful publicity rules of the DOJ and ABA; and 3) and knows about and uses available expert consultants to screen appropriate cases, the goal of a balanced pain policy will be advanced immeasurably. Moreover, though law enforcement personnel will not become trained experts in pain medicine, in order to develop an effective prosecution there should be a general understanding of clinical principles of good pain management and the complexity of caring for chronic pain patients. This includes understanding terms in the Glossary, like “tolerance,” “chronic pain,” and the distinction between “physical dependence” and “addiction,” and reviewing the FSMB *Model Policy for the Use of Controlled Substances for the Treatment of Pain*¹² to understand the components of appropriate medical practice in the treatment of pain patients.

State Medical Boards. The FSMB *Model Policy* forms the foundation for education of state medical boards. State boards in all states should learn, study, adopt and promote this *Model Policy*. The *Policy* begins with this guiding Preamble: “The (board) recognizes that principles of quality medical practice dictate that the people of the State have access to appropriate and effective pain relief.” The *Policy* then outlines procedures for doctors to follow in assessing patients with pain, patients the doctor may potentially treat with controlled substances. These procedures include careful evaluation of the patient; a written treatment plan; informed consent and a potential written agreement with high risk patients; periodic review; consultation with experts; careful and detailed record-keeping; and compliance with controlled substances laws. In addition to educating themselves, state boards should actively promote the *Policy* to physicians in their states, and should work together with state medical societies, medical schools, and other groups to promote education about a balanced pain policy. Lastly, state boards should seek to include board-certified pain specialists in their membership.

All of these steps will help provide law enforcement sufficient confidence in the capacity and professionalism of the state medical boards to handle complex opioid-prescription cases referred to them by law enforcement.

Physicians. The FSMB *Model Policy* provides an excellent starting point for physicians to appropriately treat pain with opioid analgesics in the course of legitimate medical practice. Physicians would also benefit from learning the limited risks outlined in the *Pain Medicine* article. In particular, that article counsels that even a 0.1% risk can be reduced dramatically through appropriate record keeping. The short primer on record keeping and other aspects of pain medicine in Scott Fishman’s book, *Responsible Opioid Prescribing: A Physician’s Guide*, is another excellent resource for doctors.¹³

Moreover, physicians should not only seek to educate themselves, but should educate their patients and others in the community to convey the importance of a balanced pain policy.

Consumers. All involved in this effort need to help educate consumers that appropriate treatment of chronic and acute pain with opioid analgesics is an important part of good medical care. Consumers also need education on their duty to safeguard their prescription medicines against diversion.

Legislators/policy makers. Those involved in the balanced pain policy effort should likewise seek to educate state law makers about basic pain medicine, and the importance of balanced pain policy. State laws not informed by sensible policy can erect barriers to good care of patients. Balanced pain policy advocates should work to steer legislators to useful resources – model laws like the “Uniform Controlled Substances Act” drafted by the National Conference of Commissioners on Uniform State Laws, or resources developed expressly for state legislatures like “Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation 2008,”¹⁴ produced by the University of Wisconsin Pain & Policy Studies Group, and others.

Effective Strategies

Conclusion

This Policy Brief is not intended to be inconsistent with the laws regulating controlled substances, nor is it intended to be prescriptive. Instead, the *Effective Strategies* are intended to assist law enforcement in successfully prosecuting rogue doctors while minimizing the undesirable chilling effect on responsible medical practice. All involved seek the same goal – patients receiving needed pain medications that do not become a source of harm and abuse in the community. This goal is the essence of a balanced pain policy.

Effective Strategies

Glossary of Medical Terms*

Addiction – a sociologic term which refers to compulsive drug use, psychological dependence, and continued use despite harm. “Physical dependence” and “tolerance” (defined below) are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Tolerance – a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Physical dependence – also describes the physical adaptation of the body to the presence of an opioid. Physical dependence is characterized by signs of withdrawal when use of an opioid is stopped abruptly, or when an opioid antagonist is administered to an individual who has been on chronic opioid therapy. Physical dependence, by itself, does not equate with addiction.

Pain – an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute pain – the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain is generally time-limited.

Chronic pain – a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Opiate – refers to drugs whose origin is the opium poppy, including codeine and morphine.

Opioid – a scientific term denoting both natural (codeine, morphine) and synthetic (methadone, fentanyl) drugs, and whose pharmacological effects are mediated by specific receptors in the nervous system. Opioid also applies to agonists and antagonist with morphine-like activity.

* These definitions were adapted from definitions in the Federation of State Medical Boards *Model Policy* and on the website of the University of Wisconsin Pain & Policy Studies Group (references in endnotes).

Effective Strategies Endnotes and Acknowledgement

- ¹ Teno, JM, et al., "Persistent Pain in Nursing Home Residents." *JAMA*. 2001; 285(16): 2081.
- ² Goldenbaum, D., Christopher, M., et al., "Physicians Charged with Opioid Analgesic-Prescribing Offenses," *Pain Medicine*, Vol. 9, No. 6, pp. 737-47 (Sept. 9, 2008).
- ³ 28 U.S.C. 509 (USAM 1-7.000 – 1-7.700); ABA Model Rules of Professional Conduct, 3.6.
- ⁴ "A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration – Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act," Oct. 23, 2001, available online at www.medsch.wisc.edu/painpolicy/dea01.htm (accessed Jan. 8, 2009).
- ⁵ Goldenbaum, D., Christopher, M., et al.
- ⁶ 28 U.S.C. 509 (USAM 1-7.000 – 1-7.700); ABA Model Rules of Professional Conduct, 3.6.
- ⁷ Department of Justice Media Relations rules, 28 U.S.C. 509 (USAM 1-7.600(D), available online at http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title1/7mdoj.htm (accessed Jan. 8, 2008).
- ⁸ Transcript, "Prescriptions, Doctors & Law Enforcement Meeting," September 22, 2008, National Ass'n of Attorneys General, Washington, D.C., p. 44.
- ⁹ "Advances in State Pain Policy and Medical Practice," State Initiatives in End-of-Life Care.
- ¹⁰ University of Wisconsin Pain & Policy Studies Group, U.S. Pain Policy Resources, available online at <http://www.painpolicy.wisc.edu/domestic/pmp.htm> (accessed Jan. 8, 2009); U.S. Dep't of Justice, Drug Enforcement Administration, Office of Diversion Control, "Questions & Answers," available online at http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm (accessed Jan. 8, 2009).
- ¹¹ Uniform Controlled Substances Act (1994), Nat'l Conference of Commissioners on Uniform State Laws, sec.309, available online at www.NCCUSL.org (accessed Jan. 8, 2009)
- ¹² A Policy Document of the Federation of State Medical Boards of the United States, Inc., *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (Dallas: 2004).
- ¹³ Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide*, Waterford Life Sciences Press (Washington, D.C.: 2007).
- ¹⁴ University of Wisconsin Pain & Policy Studies Group, U.S. Pain Policy Resources, available online at http://www.painpolicy.wisc.edu/Achieving_Balance/EG2008.pdf (accessed Jan. 8, 2009).

Funding Acknowledgement

The Balanced Pain Policy Initiative (BPPI) is a program of the Center for Practical Bioethics in Kansas City in partnership with the Federation of State Medical Boards and the National Association of Attorneys General. The Dallas and Washington, D.C. meetings of the BPPI were funded in part by grants from the United Health Foundation and the National Association of Attorneys General Foundation. The Center for Practical Bioethics is a 501(c)(3) organization that receives funding from a variety of sources. The corporate gift policy is available at www.PracticalBioethics.org. The primary author of the Policy Brief is William Colby, JD, of the Center for Practical Bioethics.

For inquiries, contact Mr. Colby at bcolby@PracticalBioethics.org. Electronic copies of the Policy Brief are available online at www.PracticalBioethics.org.

Law Enforcement Roundtable, Meeting Attendees – Washington, DC – September 22, 2008

Mark W. Caverly

Chief, Liaison & Policy Section
U.S. Drug Enforcement Administration
Springfield, Virginia

Myra J. Christopher

President and CEO
Center for Practical Bioethics
Kansas City, Missouri

Adam Clark, PhD

Director of Health Policy
Lance Armstrong Foundation
Austin, Texas

William H. Colby

Senior Fellow, Law and Patient Rights
Center for Practical Bioethics
Kansas City, Missouri

Daniel S. Connolly

Managing Director
Giuliani Partners
New York, New York

Frankie Sue Del Papa

Former Attorney General, Nevada
Reno, Nevada

Drew Edmondson

Attorney General, State of Oklahoma
Oklahoma City, Oklahoma

Linda Edmondson

Co-Chair, Oklahoma Attorney General's
Task Force on End-of-Life Care
Oklahoma City, Oklahoma

Cathy Gallagher

Associate Section Chief
Liaison & Policy Section
U.S. Drug Enforcement Administration
Springfield, Virginia

Rollin "Mac" Gallagher, MD, MPH

President Elect
American Academy of Pain Medicine
Philadelphia, Pennsylvania

William L. Harp, MD

Executive Director
Virginia Board of Medicine
Richmond, Virginia

Susan Hildebrandt

Assistant Director, Government Relations
American Academy of Family Physicians
Washington, DC

David E. Joranson

University of Wisconsin Pain & Policy
Studies Group
Madison, Wisconsin

Mark Leenay, MD

Vice President, Clinical Affairs
UnitedHealth Group/Ovations
Minnetonka, Minnesota

Judy McKee

EOL Counsel
National Association of Attorneys
General
Washington, DC

Heather McLaughlin

Corresponding Secretary
National Association of Drug Diversion
Investigators
Manchester, Maryland

James E. McPherson

Executive Director
National Association of Attorneys
General
Washington, DC

Sebastian J. Mollo

(for Asa Hutchinson)
Venable LLP
Washington, DC

Richard Payne, MD

Director, Professor of Divinity
Duke Institute on Care at the
End of Life
Durham, North Carolina

Lisa Robin

Senior Vice President
Federation of State Medical Boards
Euless, Texas

Richard B. Roper

U.S. Attorney, Northern District of Texas
Dallas, Texas

Charles P. Sabatino

Director, American Bar Association
Commission on Law & Aging
Washington, DC

Jack Schwartz

University of Maryland School of Law
Baltimore, Maryland

William Sorrell

Attorney General, State of Vermont
Montpelier, Vermont

Arthur Thexton

Prosecuting Attorney
Wisconsin Dept. of Regulation
& Licensing
Madison, Wisconsin

Reed Tuckson, MD, FACP

Executive Vice President
and Chief of Medical Affairs
UnitedHealth Group
Minnetonka, Minnesota

Penelope P. Ziegler, MD

Medical Director Emeritus
The William J. Farley Center
Williamsburg, Virginia

[Additional Attendees
at November 19, 2007
Dallas Meeting](#)

Jennifer Bolen, JD

Legal Side of Pain
Lenoir, Tennessee

Thomas Charron

Executive Director
National District Attorneys Ass'n
Alexandria, Virginia

Charles Cichon

Executive Director
National Association of Drug
Diversion Investigators
Manchester, Maryland

Robert Fine, MD

Baylor University Medical Center
Dallas, Texas

Don Goldenbaum, PhD

Center for Practical Bioethics
Kansas City, Missouri

Mary Beth Kean, MSN

Baylor University Medical Center
Dallas, Texas

Chris Toth

Acting Executive Director
National Association of Attorneys General
Washington, DC

Craig Watkins

District Attorney
Dallas, Texas

