

**Out of Control: The Flawed Regulation of Schedule II Drugs and its Impact on Pain and Addiction**

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## ABSTRACT:

This paper explores the current state of regulation of controlled substances at the federal and state level and analyzes how such regulations impact the undertreatment of pain and prescription drug abuse. Taking a historical view of the pain treatment movement and using the recent OxyContin crisis as a case study, the future of controlled substance policy as it relates to painkillers is analyzed. It argues that any successful policy will have to do a better job of balancing law enforcement and health care goals.

## I. Introduction

The undertreatment of pain in America has become a crippling problem. The American Pain Society estimates that 44 million households have at least one member suffering from chronic pain.<sup>1</sup> The American Medical Association estimates the total number of Americans with chronic pain at 75 million.<sup>2</sup> The problem is even worse for those aged 65 or older, of whom 20-40% suffer from long-term pain – pain that is only properly treated in a fraction of cases.<sup>3</sup> Overall it is estimated that only one out of every four persons suffering from chronic pain receives adequate pain treatment.<sup>4</sup> The financial cost, over and above the personal costs, is enormous as well, with estimates placing the cost of lost productivity and treatment at as much as \$100 billion a year in the United States.<sup>5</sup>

Beyond chronic pain, many have found their final days marred by the presence of uncontrolled and unnecessary pain as well. A groundbreaking 1995 study involving more than 9000 patients in five large hospitals across the country found, among other lapses, that half of patients experienced moderate to severe pain in

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<sup>1</sup>See Rita Rubin, *Powerful Painkillers: A Reprieve for Patients, but a Conflict for Doctors*, USA TODAY, Aug. 9, 2001.

<sup>2</sup>See Dr. Donald Palmisano, *Chronic Pain Remains Relevant Issue*, USA TODAY, November 13, 2003. (Dr. Palmisano is the President of the American Medical Association).

<sup>3</sup>See Kelly Greene, *Geriatrics Group to Release New Recommendations On Management of Pain*, WALL ST. J., May 9, 2002.

<sup>4</sup>See Carolyn Kleiner, *A Curse and a Cure*, U.S. NEWS & WORLD REPORT, Aug. 6, 2001.

<sup>5</sup>See Patrick J. Michaels, *A DEA Crackdown That's Going to Hurt Those in Pain*, WASH. POST, Feb. 29, 2004; See also Melanie Thernstrom, *Pain, The Disease*, N.Y. TIMES, Dec. 16, 2001; Michael J. Reynolds, Note, *Morphine or Malpractice: Should Court Recognize a Legal Duty to Prescribe Opiates for Treating Chronic Pain*, 15 ST. JOHN'S L. COMMENT 79, 79 (2000) (estimating the cost of undertreated chronic pain at \$70 billion).

the three days prior to death.<sup>6</sup> A 1998 study of nursing home patients with cancer found similar results, concluding that daily pain is common in almost 40% of patients and that such pain is often undertreated.<sup>7</sup> Even more disturbing, studies have also shown that undertreatment is often far more prevalent among non-white patients.<sup>8</sup>

The tragedy of such findings is that many experts agree that such pain is completely unnecessary and avoidable.<sup>9</sup> Unfortunately, unlike other medical challenges faced over the past century, the primary obstacle in the quest to provide adequate pain treatment for all who require it is not the lack of adequate medication or technology. Rather, the largest roadblocks come from the unique characteristics of pain itself and the drugs required to treat it. These obstacles will be discussed at length in the next sections, but it is useful to touch on some briefly at this point.

Pain<sup>10</sup>, first of all, is largely a subjective condition – there are generally no objective tests to confirm its existence.<sup>11</sup> As Barry Meier describes it:

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<sup>6</sup>Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (“Support”) Principal Investigators, *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients*, 274 JAMA 1591, 1594 (1995).

<sup>7</sup>See Roberto Bernabei et al., *Management of Pain in Elderly Patients with Cancer*, 279 JAMA 1877, 1877 (1998).

<sup>8</sup>See Vence L. Bonham, *Race, Ethnicity, and Pain Treatment: Striving to Understand the Causes and Solutions to Disparities in Pain Treatment*, 29 J.L. MED. & ETHICS 52 (2001).

<sup>9</sup>See James Cleary, *Treatment of Pain at the End of Life: A Position Statement from the American Pain Society* (90% of dying cancer patients can have their pain adequately treated by well-trained physicians); See also Kathryn L. Tucker, *A New Risk Emerges: Provider Accountability For Inadequate Treatment of Pain*, 9 ANNALS OF LONG-TERM CARE 52, 52 (2002).

<sup>10</sup>One often-referenced definition of “pain” is as follows: “An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. . . . Pain is always subjective. . . . Each individual learns the application of the word through experiences related to injury in early life. . . . Experiences which resemble pain, e.g., pricking, but are not unpleasant, should not be called pain. Unpleasant abnormal experiences may also be pain but are not necessarily so because, subjectively, they may not have the usual sensory qualities of pain. Many people report pain in the absence of tissue damage or any likely pathological cause; usually this happens for psychological reasons. There is no way to distinguish their experience from that due to tissue damage if we take the subjective report. If they regard their experience as pain and if they report it in the same ways as pain caused by tissue damage, it should be accepted as pain. This definition avoids tying pain to the stimulus.” International Association for the Study of Pain, *Pain Terms: A List with Definitions and Notes on Usage*, 6 PAIN 249 (1979).

<sup>11</sup>See, DAVID B. MORRIS, *ILLNESS AND CULTURE IN THE POSTMODERN AGE*, 119 (1998); See also Ben A. Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 WM. MITCHELL L. REV. 1, 21 (2000) (“Chronic pain syndromes are almost by definition conditions in which the degree of objectively verifiable pathology does not explain (or justify) the patient’s complaints of pain and/or claims of functional disability.”).

There is no pain thermometer, no pain gauge, no pain meter. A doctor can't send a patient's blood out hoping to find clues about his or her pain and its intensity. Technology. . . is sometimes helpful but notoriously unreliable. For instance, while 80 percent of those people who complain of back pain have X rays that show evidence of spinal disc degeneration, about 70 percent of all adults who exhibit similar problems on X rays have no pain. The science of measuring pain had made such little progress by the end of the twentieth century that one of its key tools was a scale of crude cartoonlike faces that ranged from smiling to grimacing, to which patients pointed to indicate their pain's intensity.<sup>12</sup>

This, on its own, may be an explanation for a good part of the undertreatment problem – as the treatment of chronic pain as a condition independent from an underlying disease runs contrary to the curative model of medicine that many physicians have been taught to practice.<sup>13</sup> If that was the only obstacle to effective pain treatment, the problem could perhaps be solved with an effective educational campaign. Unfortunately for those suffering from pain, it is not.

A more difficult problem to overcome in resolving the policy challenges around the relief of pain is that, in many cases, the most effective treatment for chronic and end of life pain is the use of opiate<sup>14</sup> analgesics.<sup>15</sup> These same narcotics, however, also have a high potential for non-medical abuse and addiction when administered improperly.<sup>16</sup> As a result, they are highly regulated at both the federal<sup>17</sup> and state levels.<sup>18</sup>

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<sup>13</sup>See Ben A. Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 WM. MITCHELL L. REV. 1, 23-24 (2000) (“The curative model devalues or discounts anything that is subjective and, hence, not objectively verifiable and quantifiable. Since pain and suffering, understood as sensation and emotion, are quintessentially subjective human experiences, they lie outside of the acceptable parameters of the curative model.”); See also Ellen Fox, *Predominance of the Curative Model of Medical Care: A Residual Problem*, 278 JAMA 761 (1997).

<sup>14</sup>Opioids include codeine, morphine, hydrocodone, oxycodone and fentanyl. The word itself refers to the “natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system.” DAVID E. JORANSON ET AL., *ACHIEVING BALANCE IN STATE PAIN POLICY: A PROGRESS REPORT CARD* (2004) (available at <http://www.medsch.wisc.edu/painpolicy>).

<sup>15</sup>See interview with Russell Portenoy, Chairman of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York City (Apr. 23, 2004) (estimating that 30-50% of patients with serious pain problems could benefit from some form of opioid therapy); See also Kathy Foley, *Opioids and Chronic Neuropathic Pain*, 348 NEW ENGL. J. MED. 1279, 1279-81; Russell Portenoy, *Current Pharmacotherapy of Chronic Pain*, 19 J. PAIN SYMPTOM MANAGE. S16, S16-S20 (2000); WORLD HEALTH ORGANIZATION, *CANCER PAIN RELIEF: WITH A GUIDE TO OPIOID AVAILABILITY* (1996) (available at <http://whqlibdoc.who.int/publications/9241544821.pdf>).

<sup>16</sup>See 21 U.S.C. §812(b)(2).

<sup>17</sup>See 21 U.S.C. §811.

<sup>18</sup>See DAVID E. JORANSON ET AL., *ACHIEVING BALANCE IN STATE PAIN POLICY: A PROGRESS REPORT CARD* (2004) (available at: <http://www.medsch.wisc.edu/painpolicy>).

Despite the regulation, however, prescription drug abuse continues to grow as a major public health problem.<sup>19</sup> Though these regulations aim only to prevent drug abuse and diversion<sup>20</sup>, they often have the effect of chilling legitimate medical treatment as physicians often fear that prescribing such drugs will attract regulatory and criminal scrutiny, even when such treatment is well within the scope of accepted medical practice.<sup>21</sup> This fear has only increased in recent years with the high-profile crackdowns by federal and state law enforcement officials on physicians who have been accused of illegally diverting the controversial painkiller OxyContin.<sup>22</sup> Many also believe that the recent threat by Attorney General John Ashcroft to use the Controlled Substances Act to target Oregon physicians using federally controlled substances and acting under the state's Death with Dignity Act has added to the regulatory fears of all physicians treating patients in pain at the end of life – regardless of whether they were engaged in physician-assisted suicide.<sup>23</sup>

This confusion is only augmented by the subjective nature of pain discussed above. As Dr. James Mickle, a family doctor in Pennsylvania put it, the dilemma for doctors when confronted with a pain patient is complex: “Is it objective or subjective? How do you know you’re not being tricked or taken advantage of to get narcotics? And chronic-pain patients are, generally, well – a pain. Most doctors’ reaction to a patient

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<sup>19</sup> See Michael Janofsky, *Drug-Fighters Turn to Rising Tide of Prescription Abuse*, N.Y. TIMES, Mar. 18, 2004 (reporting that prescription drugs have overtaken amphetamines as the second most abused drug in the country).

<sup>20</sup> See Asa Hutchinson, Statement to House Committee on Appropriations, Subcommittee on Commerce, Justice, State, and Judiciary (Dec. 11, 2001) (available at: <http://www.health.org/govpubs/dea/0112oxytestimony.aspx>).

<sup>21</sup> See David Joranson et al., *Controlled Substances, Medical Practice, and the Law*, in PSYCHIATRIC PRACTICE UNDER FIRE: THE INFLUENCE OF GOVERNMENT, THE MEDIA, AND SPECIAL INTERESTS ON SOMATIC THERAPIES 173-194 (H. Schwartz ed., 1994).

<sup>22</sup> See Barry Meier, *OxyContin Prescribers Face Charges in Fatal Overdoses*, N.Y. TIMES, Jan. 19, 2002; see also Barry Meier, *A Small-Town Clinic Looms Large as a Top Source of Disputed Painkillers*, N.Y. TIMES, Feb. 10, 2002; Bill Kaczor, *Panhandle Doctor's OxyContin Conviction to Send Message*, DENVER ROCKY MOUNTAIN NEWS, Feb. 20, 2002; *Doctor Given Long Prison Term for 4 Deaths Tied to OxyContin*, NEW YORK TIMES, Mar. 23, 2002; Josh White, *Citing U.S. Probe, Va. Doctor Says He'll Close Practice*, WASH. POST, Aug. 31, 2002; Catherine Saillant, *Ventura County Doctor Focus of Painkiller Inquiry*, L.A. TIMES, Mar. 7, 2003; Marc Kaufman, *Worried Pain Doctors Decry Prosecutions*, WASH. POST, Dec. 29, 2003.

<sup>23</sup> Interview with Barbara Coombs-Lee, President of Compassion in Dying in Portland, Oregon (Apr. 5, 2004) (“Creating the crime of ‘intending death’ with a controlled substance would jeopardize pain and symptom management for terminal patients. Hospice physicians and palliative care specialists understand this well. Doctors should not have to justify their intentions whenever death occurs soon after administration of strong medication to a dying patient. The threat of such justification prompts doctors to withhold pain car and causes unnecessary suffering on a grand scale.”).

with chronic pain is to try to pass them off to someone who's sympathetic."<sup>24</sup>

This paper seeks to explore this increasingly complex intersection of pain relief, opioid abuse and government regulation. It will demonstrate why the current response by both government and the medical profession has been woefully inadequate and will propose a change of policy that will return the country back toward progress in the war against pain while still taking seriously the threat of prescription drug diversion and abuse.

The first section will examine the history and dimensions of the undertreatment of pain problem in the United States over the past 25 years. The second section will briefly explore the history of opioid use and abuse, with a focus on the recent surge in OxyContin diversion. The third section will outline and evaluate the existing regulatory structure governing the use of opiates both at the federal and state level as well as the recent response by the government, the medical profession and the law to both pain and opiate abuse. The final section will propose a series of policy changes for the medical, regulatory and legal community to advance goals of pain relief while minimizing suffering from both undertreatment and prescription abuse

## **II. The Problem – The Epidemic of Undertreatment**

### **a. The Nature of Pain**

As the numbers above indicate, the problem of undertreatment of pain is vast. As Dr. Russell Portenoy,

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<sup>24</sup>See Melanie Thernstrom, *Pain, The Disease*, N.Y. TIMES, Dec. 16, 2001.

the chairman of pain medicine and palliative care at Beth Israel Medical Center, describes it, “there is an epidemic of chronic pain in the United States.”<sup>25</sup> But before the potential causes of the “epidemic” are explored, it is perhaps best to begin by explaining what is meant by “pain.”

The word “pain” itself is a broad term and can usefully be divided into three subcategories: acute, intractable, and cancer (or chronic non-malignant).<sup>26</sup> Acute pain is best thought of as the normal sensation that is triggered by the nervous system when one is injured.<sup>27</sup> The pain often is proportional to the level of damage to the body and it disappears when the underlying problem is cured or repaired.<sup>28</sup>

Chronic pain is fundamentally different – it is persistent and feeds back onto itself. The pain itself can actually create more pain in what doctors call “chronic-pain windup.”<sup>29</sup> Though it may be triggered by an initial injury such as a back injury, it can occur without any evidence of past physical damage. It often manifests itself in the form of migraine headaches, cluster headaches, lower back pain, and other sensations.<sup>30</sup> Tragically, those with chronic pain also often develop anxiety and depression, as both chronic pain and depression stem from similar serotonin and endorphin imbalances.<sup>31</sup> In the case of chronic pain sufferers, the imbalances are triggered by extended stress responses produced by the body in dealing with the pain. Often, depression and anxiety not only stem from the pain, but also enhance the pain.<sup>32</sup> The cycle of pain and depression often leaves its victims incapable of sustained work, a normal family life and other

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<sup>25</sup> See Josh White, *DEA Backs Medical Use of OxyContin*, WASH. POST, Oct. 24, 2001.

<sup>26</sup> See RONALD MELZACK & PATRICK D. WALL, *THE CHALLENGE OF PAIN* 52-56 (1982); See also Ben Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 WM. MITCHELL L. REV. 1, n. 8 (2000).

<sup>27</sup> See NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, NINDS CHRONIC PAIN INFORMATION PAGE ([http://www.ninds.nih.gov/health\\_and\\_medical/disorders/chronic\\_pain.htm](http://www.ninds.nih.gov/health_and_medical/disorders/chronic_pain.htm)).

<sup>28</sup> See Thernstrom *supra* note 24.

<sup>29</sup> *Id.*

<sup>30</sup> See *supra* note 25.

<sup>31</sup> See *supra* note 24.

<sup>32</sup> *Id.*

supportive social interactions.<sup>33</sup>

Ongoing and severe pain also often accompanies cancer as malignant tumors put pressure on sensitive nerves or destroy bones.<sup>34</sup> Though similar to chronic pain, cancer pain differs fundamentally in that the trajectory of the pain often culminates in death, while the chronic pain patient must manage their pain throughout their lifetime.<sup>35</sup>

## **b. The Reasons for Undertreatment**

With so many millions of Americans in pain, often debilitating pain, that is very often treatable, how is it that the problem has been able to persist so long? The answer to that question is one that has consumed the energies of a dedicated core of pain physicians across the country for more than two decades. Identifying the answer to this question is critical to formulating policies that address the problems underlying the undertreatment of pain.

### *1. Fear of regulatory scrutiny:*

Though many different reasons have been offered to explain the undertreatment of pain, nearly all agree that physician fear of regulatory scrutiny by state medical boards, prosecutors or the Drug Enforcement

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<sup>33</sup> See Jane Brody, *Misunderstood Opioids and Needless Pain*, N.Y. TIMES, Jan. 22, 2002.

<sup>34</sup> See BARRY MEIER, PAIN KILLER, 50 (2003).

<sup>35</sup> See Ben Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 WM. MITCHELL L. REV. 1, 13 (2000).

Administration is at, or near, the top, of the list of explanatory factors.<sup>36</sup>

The state and federal law surrounding the prescription of controlled substances by physicians will be discussed later in this paper, but it is worth noting at this point that a large number of the most effective medications for treating chronic and end-of-life pain are highly regulated by the federal and state governments because of their high potential for addiction and abuse. Being disciplined by a state medical board, or even just being investigated, can result in professional embarrassment among ones peers, the loss of institutional privileges, the loss of access to insurance or the loss of one's license.<sup>37</sup>

As a result of a number of high profile cases and law enforcement efforts (that are discussed later in the paper) that targeted physicians for the illegal distribution of such drugs, many physicians fear, regardless of whether they are prescribing for an accepted and legitimate medical purpose, that they will be investigated for possible illegal diversion or physician-assisted suicide if they prescribe large amounts regulated drugs. The subjective nature of pain and the difficulty of providing objective proof of the actual existence of legitimate pain reinforce the fear that physicians could expose themselves to disciplinary or criminal actions even if their course of treatment seemed appropriate and medically reasonable at the time pain medication was prescribed. Jacob Sullum perhaps put the dilemma faced by physicians best:

How do you prove the existence of migraine headaches or back pain, not to mention poorly understood conditions such as fibromyalgia and chronic fatigue syndrome? A doctor can take a patient's history, inquire about symptoms, and perform an exam. He can consider the patient's character and reputation. But in the end, he is only surmising that the pain is real. Ultimately, he has to take the patients at his word, knowing that misplaced trust could mean professional ruin. <sup>38</sup>

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<sup>36</sup>See S. Johnson, *Disciplinary Actions and Pain Relief: Analysis of the Pain Relief Act*, 24 J.L. MED. & ETHICS, 320 (1996); Ann Alpers, *Criminal Act or Palliative Care? Prosecutions Involving the Care of the Dying*, 26 J.L. MED & ETHICS 308 (1998); Ann M. Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?*, 26 J.L. MED. & ETHICS, 332, 332 (1998); Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective*, 24 J.L. MED. & ETHICS 296, (1996); C.S. Hill, *The Negative Influence of Licensing and Disciplinary Boards and Drug Enforcement Agencies in Pain with Opioid Analgesics*, 1 J. OF PHARM. CARE IN PAIN AND SYMPTOM CONTROL, 43 (1993)

<sup>37</sup>See Ann M. Martino, *In Search of a New Ethic for Treating Patients With Chronic Pain: What Can Medical Boards Do?*, 26 J.L. MED. & ETHICS, 332, 334 (1998).

Recent studies confirm physician fears. A survey of physicians in Texas found that more than 26% of respondents believed that prescribing narcotics for patients in pain would trigger an investigation by a drug enforcement agency.<sup>39</sup> A 1991 study of Wisconsin physicians indicated that 54% of respondents prescribed a different schedule of drug, lowered the dose, decreased the quantity or limited refills of opioid prescriptions when concerned about a possible regulatory investigation.<sup>40</sup> When treating patients at the end of life, physicians also fear that investigators may misperceive the aggressive treatment of pain as physician-assisted suicide.<sup>41</sup> One physician described their perspective as follows:

Chronic pain patients are difficult enough to treat without having to worry about ‘big brother’ looking over your shoulder. The DEA, the boards... [they] don’t trust doctors to be able to distinguish between a patient who needs medication for pain and a patient who is seeking drugs. I resent it and I’m not about to jeopardize my livelihood because of it. I refer almost all of my pain patients these days.<sup>42</sup>

Some argue that these regulatory fears are reinforced by requirements in some states that physicians use triplicate prescription forms<sup>43</sup> for any prescription of a controlled substance.<sup>44</sup> Opponents of such requirements argue that they deter the adequate treatment of pain because physician fears that large prescriptions for pain relieving medication – even if well within medically appropriate levels – will trigger scrutiny from officials.<sup>45</sup> Furthermore, many doctors may simply avoid the trouble of navigating the paperwork and risking scrutiny for their use.<sup>46</sup> A study conducted of California doctors – a state that has required triplicate prescriptions –

<sup>39</sup> See Sharon M. Weinstein et al., *Physicians’ Attitudes Toward Pain and the Use of Opioid Analgesics: Results from a Survey from the Texas Cancer Pain Initiative*, 93 SOUTH MED. J. 479, 479-87 (2000).

<sup>40</sup> See David E. Joranson et al., *Wisconsin Physicians’ Knowledge and Attitudes About Opioid Analgesic Regulations*, 90 WIS. MED. J. 671, 675 (1991). (available at <http://www.medsch.wisc.edu/painpolicy/publicat/91wmj.htm>).

<sup>41</sup> See Nicholas P. Lovrich, Jr. & Stephen J. Ziegler, *Pain Relief, Prescription Drugs, and Prosecution: A Four-State Survey of Chief Prosecutors*, 31 J.L. MED. & ETHICS 75, 76 (2003); See also Arthur Caplan & David Orentlicher, *The Pain Relief Promotion Act of 1999: A Serious Threat to Palliative Care*, 283 JAMA, 255, 255-58 (2000).

<sup>43</sup> Such regulations require prescriptions for Schedule II drugs to be written on multiple copy forms with one copy going to the doctor, one to the patient (who brings it to the pharmacy, and the final copy going to the state). See Sullum *supra* 36.

<sup>44</sup> See Kathryn L. Tucker, *A New Risk Emerges: Provider Accountability for Inadequate Treatment of Pain*, 9 ANNALS OF LONG-TERM CARE 52, 52 (2001).

<sup>45</sup> *Id.*

<sup>46</sup> See David E. Weissman, *Pain Management and the Bogeyman*, HEALTHLINK (2001) (available at: <http://healthlink.mcw.edu/article/1007067408.html> (explaining how physicians in California taught residents in training to avoid registering for triplicate prescription pads to avoid regulatory scrutiny)).

found that only 60% of physicians were authorized to write triplicate prescriptions, and of those, only 40% actually did.<sup>47</sup> Many states are now considering moving, or have moved, to electronic prescription monitoring programs in response to the recent rise in prescription drug abuse.<sup>48</sup> Some believe this will alleviate many of the problems of deterrence while others remain skeptical of the improvement they will bring.<sup>49</sup> The value of electronic monitoring to curb prescription drug abuse will be discussed in the final section of this paper.

2.

*Failure of Medical Education – The Dominance of the Curative Approach*

Perhaps more troubling than the fear of regulatory scrutiny – a cause that could, at least theoretically, be rectified with a change in governmental policy – are the problems within the culture of medicine itself that contribute to epidemic of undertreatment. More troubling because even if many of the various proposals for regulatory and legal reform were adopted, it is still possible that real change for patients would not be forthcoming.

At the root of the critique of the medical profession's contribution to the undertreatment is an attack on the dominance of the curative, rather than palliative, approach to patient care, even in situations where a curative approach is not appropriate.<sup>50</sup> For patients suffering from chronic pain—pain that does not necessarily have an underlying curable disease as its cause—or terminal illness, this difference in priorities can have severe consequences.<sup>51</sup> Ben Rich explains the problem facing patients with chronic or end-of-life

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<sup>47</sup> See Damien Cave, *No Relief*, SALON.COM, Apr. 4, 2002 (available at [http://www.salon.com/mwt/feature/2002/04/04/no\\_relief/](http://www.salon.com/mwt/feature/2002/04/04/no_relief/)).

<sup>48</sup> See Michael Janofsky, *Drug-Fighters Turn to Rising Tide of Prescription Abuse*, N.Y. TIMES, Mar. 18 2004.

<sup>49</sup> See Tucker supra note 41.

<sup>50</sup> See Rich supra note 11 at 21-25.

<sup>51</sup> See Martino supra note 36.

pain when they encounter a curative-based medical culture:

The all-too-common response of caregivers to the patients is to label such patient's requests for more effective medications as "drug-seeking" or addictive behaviors, and their protestations of physically disabling pain as "malingering." The haste with which some caregivers dismiss or diminish patient complaints about pain suggests not only an ambivalence toward the pain experience of others, but a more fundamental quandary about the place of pain in human experience. The prevailing curative model of medicine is not only hostile to effective care of chronic pain patients, but to patients with terminal illness as well.<sup>52</sup>

The SUPPORT study, discussed briefly earlier, also provides insight into the dominance of the curative approach, at least among some physicians.<sup>53</sup> In that study, nearly 40% of advance directives were ignored and more than 50% of patients were left in pain in their final days of life. In that stage of life, one would hope that the focus would be on the relief of suffering and respect for the wishes of the patient rather than an attempt to conquer an underlying disease, but that is too often not the case. Unfortunately, such care requires a humanistic, empathetic and interpersonal approach toward medicine that is tailored to the individual patient as much as it does any scientific or technological skill – a skill far too often lacking in physicians entrusted with the care of those in pain.<sup>54</sup> A quarter of recent medical school graduates said that the primary goal of medicine was to cure disease rather than relief of suffering was the primary pursuit of medicine.<sup>55</sup> In 1997, the Institute of Medicine published a report that concluded: "deficiencies in undergraduate, graduate, and continuing education for end-of-life care reflect a medical culture that defines death as failure and ignores care for dying people as a source of professional accomplishment and personal meaning."<sup>56</sup>

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<sup>53</sup> See supra note 6.

<sup>54</sup> See Rich supra 11 at 24; See also Melanie Thernstrom, *The Writing Cure*, N.Y. TIMES, Apr. 18, 2004. (explaining the importance of narrative in medical care).

<sup>55</sup> See ASSOCIATION OF AMERICAN MEDICAL COLLEGES, 2003 MEDICAL SCHOOL GRADUATION QUESTIONNAIRE, ALL SCHOOLS REPORT (2003).

<sup>56</sup> COMMITTEE ON CARE AT THE END OF LIFE, INSTITUTE OF MEDICINE, APPROACHING DEATH: IMPROVING CARE AT THE END OF LIFE (1997); See also Beth P. Weinman, *Freedom From Pain: Establishing a Constitutional Right to Pain Relief*, 24 J. LEGAL MED. 495, 517-18 (2003).

Explanations for such an approach can be found in medical school curriculums – curriculums that still do not seem to take pain relief and palliative care seriously. Only four out of a surveyed 125 medical schools required a pain management course for graduation in 2001, and only 40 offered a separate elective course on the subject.<sup>57</sup> Tufts University is currently in the only medical school in the country that offers a multidisciplinary postgraduate pain management program of study in pain medicine.<sup>58</sup>

Not surprisingly, the result of the lack of formal training has been that new doctors often feel as if they lack adequate training for treating pain. A recent study found that almost 48% of 14,000 recent medical school graduates believed that their pain management training was inadequate.<sup>59</sup> Another survey found that fewer than 18% of medical students indicated that they received some sort of formal end-of-life training at all in medical school.<sup>60</sup> Studies also indicate that graduating medical students are “eager for more training” in care for the dying.<sup>61</sup> As will be discussed in the final parts of this paper, this failure of our nation’s educational institutions has had devastating ramifications not only for pain patients who are unable to find physicians to provide adequate care, but also for society as a whole who must cope with a prescription drug abuse problem that is partially fostered by physicians who are inadequately trained at administering opioid painkillers and identifying potential abusers.<sup>62</sup>

### *3. Failure of Medical Education – Opiophobia*

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<sup>57</sup>See ASSOCIATION OF AMERICAN MEDICAL COLLEGES, 2003 MEDICAL SCHOOL GRADUATION QUESTIONNAIRE, ALL SCHOOLS REPORT (2003).

<sup>58</sup>See <http://www.tufts.edu/med/prep/index.html>

<sup>59</sup>See ASSOCIATION OF AMERICAN MEDICAL COLLEGES, 2003 MEDICAL SCHOOL GRADUATION QUESTIONNAIRE, ALL SCHOOLS REPORT (2003). The good news is that progress is being made – the same study found that 56.1% of surveyed students believed that their pain education management training was inadequate just two years earlier in 2001.

<sup>60</sup>See *Dana-Farber Cancer Institute Press Release*, Oct. 29, 2003 (available at: <http://www.dana-farber.org/abo/news/press/102903.asp>).

<sup>61</sup>See J. Andrew Billings & Susan Block, *Palliative Care in Undergraduate Medical Education: Status Report and Future Directions*, 278 JAMA 733, 734 (1997).

<sup>62</sup>See *infra* Section IV & V.

Tied to the attack on the dominance of the curative model is the charge that a majority of the medical profession significantly overestimates opiates' potential for addiction and serious side-effects, while at the same time underestimating their potential for positive good for patients in chronic pain and pain at the end of life. For those in the pain relief community, the preferred term for this phenomenon is "opiophobia."<sup>63</sup> The result, it is argued, is that patients who could benefit greatly from opioids are denied valuable treatment simply because of mistaken assumptions.<sup>64</sup>

For advocates of the use of opioids for chronic pain, at heart of opiophobia is the deeply held, yet mistaken, fear that long-term exposure to opioids creates an addiction risk that outweighs any potential gains that result from using opioid analgesics.<sup>65</sup> The roots of such fear stretch back more than a hundred years when large numbers of Civil War veterans became addicted to morphine.<sup>66</sup> It started to become a major issue in American medicine starting in the 1890's.<sup>67</sup> At that time, still unregulated, opiates were prescribed for a wide range of problems, ranging from menstrual cramps to anxiety – heroin was marketed as a cough remedy.<sup>68</sup> As addiction spread among working class young men and middle-class housewives<sup>69</sup>, physicians quickly became the target of blame.<sup>70</sup> In 1919, doctors began to be prosecuted by the federal government for creating and treating opiate addicts.<sup>71</sup> By the mid-1920's physicians became increasingly wary of using opiates or treating patients who had previously become addicted and many were forced into an underground

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<sup>63</sup> See Beth P. Weinman, *Freedom From Pain: Establishing a Constitutional Right to Pain Relief*, 24 J. LEGAL MED. 495, 515-16 (2003) ("Opiophobia is the fear of prescribing or taking opioids due to an overestimation of the potential for addiction");

<sup>64</sup> See Damien Cave, *No Relief*, SALON.COM, Apr. 4, 2002 (quoting Barbara Coombs-Lee, President of Compassion in Dying: "We are an opiophobic nation. . . . We have a craziness about this issue and the effect is that it harms patients in pain and those at the end of their life).

<sup>65</sup> See Rich *supra* at 20.

<sup>66</sup> See Jacob Sullum, *No Relief in Sight*, REASON (1997).

<sup>67</sup> See CAROLINE JEAN ACKER, CREATING THE AMERICAN JUNKIE, 1 (2002).

<sup>68</sup> *Id.* at 1-2.

<sup>69</sup> See Meier *supra* note 13 at 57 ("Around 1900 there were an estimated three hundred thousand morphine addicts in the United States").

<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 35-36.

drug culture to find relief.<sup>72</sup> The emphasis on the “War on Drugs” over the last twenty years and the rise of prescription drug abuse has only contributed to this general sense that all uses of potentially addictive drugs are “dangerous.”<sup>73</sup>

Rather than being a source of addiction and destruction, advocates argue that the risk of addiction with properly administered opiate analgesics is actually minimal.<sup>74</sup> As Dr. Sidney Schnoll, the Chairman of the Division of Substance Abuse Medicine at the Medical College of Virginia puts it:

We will go to great lengths to stop addiction—which, though certainly a problem, is dwarfed by the number of people who do not get adequate pain relief. So we will cause countless people to suffer in an effort to stop a few cases of addiction. I find that appalling.<sup>75</sup>

Even institutions such as the National Institute on Drug Abuse, an organization particularly attuned to the risk of drug abuse, acknowledge that fears of addiction tied to opiates in the pain context have had dangerous consequences.<sup>76</sup> Further, some argue that the effect of substituting supposedly “safer” drugs such as anti-inflammatory drugs like aspirin can have even more severe health consequences.<sup>77</sup> Others contend that, in many cases, opiates can be administered safely to even to patients with a history of drug abuse.<sup>78</sup> For people with severe chronic pain, opiophobia produces the difficult obstacle of finding physicians who are willing to prescribe what is sometimes the only drug that will adequately treat their pain because under-trained doctors and pharmacists often mistake a pain patient’s desperate search for pain relief as illegitimate

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<sup>72</sup> *Id.* at 62-63.

<sup>73</sup> *See* Weinman *supra* note 55 at 514-515.

<sup>74</sup> *See id.*; *See also* Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 *PROG. PAIN RES. & MGMT.* 247, 263 (1994); Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 *NEW ENG. J. MED.*, 123, 123 (1999).

<sup>76</sup> *Id.* (quote from NIDA Director Charles Schuster in 1989: “We have been so effective in warning the medical establishment and the public in general about the inappropriate use of opiates that we have endowed these drugs with a mysterious power to enslave that is overrated.”).

<sup>77</sup> *See supra* note 5 (“According to the Federal Drug Abuse Warning Network, anti-inflammatory drugs (including aspirin and Aleve) were implicated in the deaths of 16,000 people in 2000 because of bleeding ulcers and related complications.”); *See also* Jane Spencer, *Crackdown on Drugs Hits Chronic-Pain Patients*, *WALL ST. J.*, Mar. 16, 2004 (citing physician concerns about the health impact of shifting pain patients to over-the-counter drugs).

<sup>78</sup> *See* Martino *supra* 36 at 333.

or illegal drug-seeking behavior.<sup>79</sup> The result is that many patients find themselves both in pain and with the stigma of being a “druggie” once they finally do find a doctor willing to prescribe.<sup>80</sup> The stigma often extends to all aspects of an opiate users life. As one patient described her experience with opioids that were prescribed to treat chronic back pain:

When I realized that without the medication I could not function, I felt like a “druggie” . . . no better than a crack-head. My husband pleaded with me to stop [taking the prescribed medication] for the sake of our family. . . .He harassed me and the doctor. I was forbidden to mention that I took the drugs even to my closest friends. After a while, I started to act like a drug addict. I hid my medications from him and from everyone else. I drove miles to have my prescriptions filled at drugstores where no one knew me. NO one ever explained to me that it was ‘okay’ to need my medications. . . that needing drugs to take away pain is different [from] being a druggie. So I stopped and the pain nearly killed me. I wanted to start up again, but the doctor who treated me before said no, not after all the trouble, even though I got divorced. . . .He [the doctor] was afraid I’d lose him his prescribing [privileges].<sup>81</sup>

The tragic result of such stigma is that legitimate pain patients themselves and their families often become significant obstacles to their own effective treatment.

#### 4. *Societal Attitudes Toward Pain*

The West’s, and specifically the American, cultural view toward pain and suffering also certainly plays some role in the undertreatment of pain – though it is a topic that could likely make an entire paper in itself.<sup>82</sup>

For the purposes of this venture it is necessary to only outline some of the major cultural factors to consider as one seeks to evaluate and form policy. One such factor is the role of suffering in major religions, including,

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<sup>79</sup> See id. at 336.

<sup>80</sup> See Josh White, *Painkiller a Headache for Police*, WASH. POST, May 2, 2001 (tells patient story who indicates that pharmacists treat him like an “illicit drug user” when he fills his OxyContin prescription); Linda Mars, *OxyContin Abuse May Curb Progress in Pain Field*, L.A. TIMES, Aug. 31, 2001 (patient who was received treatment in the ER because she used opiate pain killers prescribed by her doctor); Carolyn Kleiner, *A Curse and a Cure*, U.S. NEWS & WORLD REPORT, Aug. 6, 2001 (patient who had prescription refused by doctor even when confirmed that it was legitimate and who had to visit 10 pharmacies before finding one that would finally fill it).

<sup>82</sup> See Rich supra note 11 (laying out an extensive overview of the intersection of pain tolerance and western religious and cultural influences).

most notably, Christianity.<sup>83</sup> Another is the role of toughness in America’s concept of “manhood” – from sports to war, there have always been examples of the linkage between the ability to withstand pain without complaint and virtue.<sup>84</sup> To the extent such cultural factors play a role in the undertreatment, they act through both patients who do not notify their physician to pain or through a concept of medicine that sees pain as more of a complaint than a legitimate medical disease. Because these factors are so deep rooted where they are present, they are likely the least likely to be substantially affected by policy change, at least in the short term.

#### *5. Insurance Pressure*

As is the case with almost every issue in health care today, money also plays a role in the provision of adequate pain relief. First and foremost, the lack of insurance for millions of Americans is a major obstacle to treatment of any sort of pain, let alone chronic or end-of-life pain – as effective pain treatment requires not only doctor’s visits, but also sometimes expensive medication.<sup>85</sup> Even with insurance, the subjective nature of pain combined with the time and cost involved in treatment make it an easy target for cost-saving measures.<sup>86</sup> Additional complications arise when the bureaucratic requirements of Medicare and Medicaid are brought into play.<sup>87</sup>

#### *c. The Pain Relief Movement*

To understand the current policy challenges of undertreatment it is necessary to understand the history of

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<sup>83</sup>See *id.*; See also Weinman supra note 55 at 519.

<sup>84</sup>See Weinman supra note 55 at 519.

<sup>85</sup>See *id.* at 519-520; See also Martino supra 36 at 335.

<sup>86</sup>See Cave supra note 62. (quoting Daniel Carr, founding medical director of the pain management program at Tufts: “Anything that looks like it will take more time is a tremendous disincentive”).

<sup>87</sup>See Weinman supra note 55 at 520.

the pain relief movement. For the future policy maker it serves a number of valuable purposes. First, it provides an account of how past policy and regulation failed, and how a small group of physicians were able to move the medical community toward today's emerging pain relief consensus. Second, it provides a foundation to understand how that consensus both partially contributed to the current policy crisis and how it also provides an essential foundation for any policy regime of the future.

The problem of chronic pain and pain at the end of life is not a novel phenomenon – it has existed as long as humankind itself. It is only recently, however, that policy makers and doctors have recognized it as a major policy challenge that can no longer be ignored. A large share of the credit for this shift goes to the efforts of a small group of dedicated physicians who have worked tirelessly for the last quarter-century to both advance pain treatment methods and to raise the profile of those suffering from treatable pain.<sup>88</sup>

Many consider the first major modern article to be published on the problem of undertreatment of pain to be a 1973 article by psychiatrists Richard Marks and Edward Sachar.<sup>89</sup> Assigned to study “difficult” patients in a number of New York hospitals, they concluded that the primary reason for continued pain complaints among patients being treated with narcotics was not psychological, but rather because the physicians in charge of caring for them were unaware of proper dosage amounts and overestimated risks of addiction.<sup>90</sup>

Marks and Sachar came to the following conclusion with regard to the use of opioids to treat pain: “For

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<sup>88</sup>Though certainly not meant to be exhaustive, three of the most prominent leaders in this movement have been Dr. Kathleen Foley (Memorial Sloan-Kettering Cancer Center), Dr. Russell Portenoy (Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center), and Dr. Daniel Carr (Tufts School of Medicine).

<sup>89</sup>See Richard M. Marks & Edward J. Sachar, *Undertreatment of Medical Inpatients with Narcotic Analgesics*, 78 ANNALS INTERNAL MED. 173, 173-81 (1973); see also Rich supra note 11 at 8.

<sup>90</sup>See Marks at 174-80.

many physicians these drugs may have a special emotional significance that interferes with their rational use.”<sup>91</sup> Such a refrain would become standard among pain relief experts in the decades to follow.<sup>92</sup>

It was not until the early 1980’s, however, that real progress started to be made at the level of the patient. In 1981 the Sloan-Kettering Cancer Center in New York City became the first hospital in the United States to open a unit specifically dedicated to the treatment of pain.<sup>93</sup> Among the most important contributions to come of this new effort at Sloan-Kettering was the discovery that cancer patients in pain could be given constant doses of morphine rather than waiting for patients to request it – thus stabilizing its pain relief effects and avoiding the roller-coaster effect on the patient.<sup>94</sup> To most expert’s surprise at the time, the new method improved pain treatment and did not create any additional risk of addiction or euphoric high.<sup>95</sup>

Though the efforts at Sloan-Kettering were making progress in the use of opioids to treat cancer pain, the question of opioids being used for the treatment of chronic pain was still very much an open question. Many in the medical establishment were against their use with chronic pain patients, fearing the narcotics could lead to abuse, addiction, rebound pain and loss of awareness.<sup>96</sup> For the overwhelming of chronic pain patients, the only options for treatment were pain clinics that taught them how to “live with the pain.”<sup>97</sup> Treatments included hypnosis, physical therapy, counseling, expensive diagnostic tests, and surgery.<sup>98</sup> Though the surgery, often a last resort, was intended to relieve pain, in far too many cases it ended up making their pain worse.<sup>99</sup> In general, a large portion of the population suffering from chronic pain did not find relief that

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<sup>91</sup> See *id.* at 180; See also Sullum *supra* note 38 (for further discussion of the Marks and Sachar article).

<sup>92</sup> See Brody *supra* note 33 (quoting Dr. Henry McQuay, professor of pain relief at Oxford University: “Opioids are our most powerful analgesics, but politics, prejudice and our continuing ignorance still impede optimum prescribing. What happens when opioids are given to someone in pain is different from what happens when they are given to someone not in pain. The medical use of opioids does not create drug addicts, and restrictions on this medical use hurt patients.”).

<sup>93</sup> See Meier *supra* note 13 at 63.

<sup>94</sup> See *id.* at 59.

<sup>95</sup> See *id.* at 60.

<sup>96</sup> See *id.* at 61.

<sup>97</sup> See Jane M. Orient, Testimony at House Office Building (Dec. 16, 2003) (available at <http://www.aapsonline.org/painman/paindocs.htm>).

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

allowed them to return to their previous quality of life.<sup>100</sup>

In 1986, however, Russell Portenoy and Kathleen Foley published a groundbreaking study in the journal *Pain* in which they argued that the long-term use of opioids was effective in treating intractable pain and safe for those with no history of drug abuse.<sup>101</sup> This article sparked a debate about the dangers of opioid addiction that would later become central to federal and state policies directed at the regulation of prescription pain relief medication such as OxyContin.

Though the Portenoy and Foley piece was focused directly on the question of opioid use for chronic pain patients, there were other articles that were written in the same time period that would also become the focus of the OxyContin and surrounding policy debates. The first was a 1977 study of headache sufferers that found only three patients out of 2,369 developed addiction problems after being treated with opioids.<sup>102</sup> Another study, issued in 1980, found similar results in a study looking at hospital patients – in that survey, only four out of 11,882 patients developed an addiction problem.<sup>103</sup> Together, these studies would form the basis of a claim, later challenged by some, that the threat of addiction was minor for opiate treatment for chronic pain patients who had no history of abuse.<sup>104</sup>

By 1989, the message of opioid treatment for chronic pain began to gain traction, and Texas became the first

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<sup>100</sup>*Id.*

<sup>101</sup>See Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain*, 25 PAIN 171, 171-186 (1986).

<sup>102</sup>See Seymour Diamond & Jose L. Medina, *Drug Dependency in Patients with Chronic Headaches*, 17 HEADACHE 12, 12-14 (1977).

<sup>103</sup>See Herschel Jick & Jane Porter, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENGL. J. MED. 123 (1980).

<sup>104</sup>See Meier *supra* note 13 at 67.

state to pass an Intractable Pain Treatment Act.<sup>105</sup> For the first time, medical board guidelines specifically recognized the role of opioids in treating chronic pain. At the same time, critics of the undertreatment of pain continued to sound the alarm that the medical profession itself was continuing to provide inadequate relief. In an article written the same year that Texas passed its Intractable Pain Act, Kathleen Foley, the founding director of Sloan-Kettering’s pain treatment unit, declared that “most physicians lack sufficient knowledge of the clinical pharmacological approaches” necessary to treat chronic pain effectively.<sup>106</sup> This combination of an undereducated medical community and an increasingly liberalized view toward the routine use of opioid analgesics in the treatment of chronic pain is at the root of the policy problem surrounding the explosion of prescription drug abuse that is currently ravaging much of the country (and that will be discussed in the following sections of the paper).

## II.

### **The Other Problem – The Epidemic of Prescription Drug Abuse**

As was alluded to earlier, finding a solution to the “epidemic”<sup>107</sup> of the undertreatment of pain is made infinitely more difficult by the worsening crisis of the related “epidemic”<sup>108</sup> of prescription drug abuse.

Though the specter of abuse and diversion has always clouded the expansion in the use of opiates to treat pain, the growth in prescription drug abuse over the last five years, led by the explosion in OxyContin use, has

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<sup>105</sup> See Tex. Rev. Civ. Stat. Ann. Art. 4495c (Vernon 2001) (adopted by Acts 1989, 71<sup>st</sup> leg., 1<sup>st</sup> C.S., ch. 5, §1, eff. Nov. 1, 1989) (§5 reads as follows: “No physician may be subject to disciplinary action by the board for prescribing or administering dangerous drugs or controlled substances in the course of treatment of a person for intractable pain.”); See also Meier *supra* note 13 at 69.

<sup>106</sup> See Kathleen M. Foley, *The “Decriminalization” of Cancer Pain*, 11 ADV. PAIN RES. & THERAPY 5, 15 (1989); See also Rich *supra* note 20 (discussing the Foley article in the context of other writing on pain at the time).

<sup>107</sup> See White *supra* note 25 (quoting Russell Portenoy: “There is an epidemic of chronic pain in the United States.”).

<sup>108</sup> See Sandra Blakeslee, *Drug Makers Hope to Kill the Kick in Pain Relief*, N.Y. TIMES, Apr. 20, 2004 (quoting Dr. Clifford Woolf of Massachusetts General Hospital and Harvard Medical School on the rise of prescription drug abuse: “No other drug type in the last 20 years had been so abused in such a short period of time. . . .It’s an epidemic.”)

changed the issue dramatically.<sup>109</sup> If further progress is to be made in the battle against the undertreatment of pain, advocates of opiate availability must confront head on the problems presented by OxyContin abuse and diversion.

***a. Prescription Drug Abuse Overall***

Surging numbers of abuse, combined with increased media coverage and a number of high profile celebrity bouts of addiction<sup>110</sup> have made prescription drug abuse a major national policy issue. Just this year, prescription drugs overtook amphetamines as the second most abused drug in the country.<sup>111</sup> According to the National Survey on Drug Use and Health, 6.2 million people, or 2.6% of the U.S. population over the age of 12, abused prescription drugs in 2001.<sup>112</sup> Of those, 4.4 million abused pain relievers.<sup>113</sup> By comparison, 2 million Americans were found to abuse cocaine and 14.6 million to abuse marijuana.<sup>114</sup> Emergency room visits that can be tied to the non-medical use of prescription painkillers doubled between 1994 and 2001.<sup>115</sup> Hydrocodone-related visits—a painkiller prescribed more than 100 million times in 2003—nearly doubled on its own between 1998 and 2001.<sup>116</sup>

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<sup>109</sup> See Barry Meier, *The Delicate Balance of Pain and Addiction*, N.Y. TIMES, Nov. 25, 2003.

<sup>110</sup> See Jill Barton, *Doctor Shopping, Drug Use Reported in Limbaugh Raid*, HOUSTON CHRONICLE, Dec. 5, 2003 (detailing charges against radio talk show superstar Rush Limbaugh for alleged illegal drug use); See also Rebekah Denn, *Love's Antics Cost Her Custody of Daughter*, SEATTLE POST-INTELLIGENCER, Oct. 18, 2003 (discussing rock star Courtney Love's problems with OxyContin); Michael Starr, *Jack Hooked on OxyContin*, N.Y. POST, Jul. 3, 2003 (profiling television star's (and son of Ozzy Osbourne) battle with OxyContin addiction).

<sup>111</sup> See Michael Janofsky, *Drug-Fighters Turn to Rising Tide of Prescription Abuse*, N.Y. TIMES, Mar. 18, 2004.

<sup>112</sup> See 2002 NATIONAL SURVEY ON DRUG USE AND HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES (2002) (overview available at: <http://www.oas.samhsa.gov/nhsda/2k2nsduh/Overview/2k2Overview.htm#toc>)

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> See Marc Kaufman, *U.S. is Working to Make Painkillers Harder to Obtain*, WASH. POST, Feb. 15, 2004. (DEA officials are currently pushing to have hydrocodone re-classified as Schedule II, the same regulatory category as OxyContin).

Of particular concern, abuse of painkillers is on the rise amongst teens. In 2002, 11.2% of teenagers reported using prescription pain relievers for non-medical reasons at least once.<sup>117</sup> This is up from 9.6% in just 2001 and 1.2% in 1989.<sup>118</sup> This rise in abuse among teens comes at the same time that use of other illicit drugs by 8<sup>th</sup>, 10<sup>th</sup> and 12<sup>th</sup> graders has dropped by 11%.<sup>119</sup>

The spread among teens and others is facilitated by the wide availability of such prescription drugs through illegal websites.<sup>120</sup> A recent study by the National Center on Addiction and Substance Abuse at Columbia University found 157 Internet sites selling prescription drugs.<sup>121</sup> Of those sites, 90% did not require a prescription.<sup>122</sup> Drugs available on these sites included OxyContin, Valium, Ritalin and Adderall.<sup>123</sup>

This spring, in response to the growing problem the Bush administration, for the first time, announced the formation of a coordinated drug strategy to confront prescription drug abuse.<sup>124</sup>

### ***b. The Rise of OxyContin***

Though prescription drug abuse broadly defined is a major policy challenge, there is one drug in particular – OxyContin – that deserves special attention, as its unique qualities both pose substantial risks and substantial potential for benefits to millions of Americans. It is a drug that both offers the hope of significant progress in the battle against undertreatment of pain and creates incredible concern as its abuse carries the potential of destroying lives and communities all over the country. Because it lies at the intersection

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<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> See Janofsky supra note 111.

<sup>120</sup> See Marc Kaufman, *Crackdown on Prescription Abuse*, WASH. POST, Mar. 2, 2004.

<sup>121</sup> See NATIONAL CENTER ON ADDICTION AND SUBSTANCE ABUSE AT COLUMBIA UNIVERSITY, ‘YOU’VE GOT DRUGS!’: PRESCRIPTION DRUG PUSHERS ON THE INTERNET, A CASA WHITE PAPER (2004) (available at: <http://www.casacolumbia.org/pdshopprov/shop/item.asp?itemid=61>).

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> See OFFICE OF NATIONAL DRUG CONTROL POLICY, U.S. DRUG PREVENTION, TREATMENT, ENFORCEMENT AGENCIES TAKE ON “DOCTOR SHOPPERS,” “PILL MILLS,” Mar. 1, 2004 (available at: <http://www.whitehousedrugpolicy.gov/news/press04/030104.html>).

of the national debate over drug abuse and pain relief, the resolution of the policy challenges surrounding OxyContin will determine the course of progress in pain relief for the decade to come. To properly evaluate the policy options that the OxyContin debate offers, however, it is first necessary to outline the framework of the dilemma that it presents.

1.

*The Benefits of OxyContin*

OxyContin's primary active ingredient is oxycodone—a synthetic opiate developed in a Germany laboratory in 1916<sup>125</sup>—and it has been used extensively in the United States for more than fifty years.<sup>126</sup> When used in a medical context, oxycodone is considered an effective treatment for mild to moderate pain control, chronic pain syndromes, and the treatment of cancer pain.<sup>127</sup> Over the years, a number of oxycodone-based painkillers have been approved by the FDA, including Percodan, Percocet, MS Contin and Tylox.<sup>128</sup> It is estimated that oxycodone is twice as potent as morphine, another frequently prescribed pain relief drug.<sup>129</sup> When approved by the FDA in 1995, OxyContin was thought to be a breakthrough drug for three primary reasons. First, like previous oxycodone painkillers, OxyContin also had the advantage of not containing acetaminophen or aspirin – thus avoiding their potentially damaging effects on the liver.<sup>130</sup>

Second, unlike its oxycodone predecessors, OxyContin offered 12 hours of constant relief with one pill, as opposed to four hours with previous options.<sup>131</sup> In order to deliver enough drugs for a full 12-hour period,

<sup>125</sup> See Paul Tough, *The Alchemy of OxyContin*, N.Y. TIMES MAGAZINE, Jul. 29, 2001.

<sup>126</sup> See Meier supra note 12 at 81-82 (the first drug sold using oxycodone was Percodan, a combination of oxycodone and aspirin, introduced around 1950).

<sup>127</sup> See Laura M. Nagel & Patricia M. Good, OXYCODONE, DEA-INDUSTRY COMMUNICATOR, OXYCONTIN SPECIAL (2001) (available at: [http://www.dea diversion.usdoj.gov/pubs/nwsltr/spec2001/oxy\\_spec.pdf](http://www.dea diversion.usdoj.gov/pubs/nwsltr/spec2001/oxy_spec.pdf)).

<sup>128</sup> See *id.* at 12.

<sup>129</sup> See G.B. Curtis, et al., Relative Potency of Controlled-Release Oxycodone and Morphine in a Postoperative Pain Model, *European Journal of Clinical Pharmacology*, vol. 55, no. 6 (1999): 55:425-429.

<sup>130</sup> See Claudia Kalb, *Playing with Pain Killers*, NEWSWEEK, Apr. 9, 2001.

<sup>131</sup> See Weinman supra note 56 at 498; See also Debra E. Heidrich, *Controlled-Release Oxycodone Hydrochlorine (OxyContin)*,

however, each pill contains significantly more oxycodone than the Percocet or Percodan.<sup>132</sup> This enabled those suffering from serious pain to have a full night's sleep for the first time and it avoided the discomfort of patients having to wait for relief with each new dose.<sup>133</sup> Purdue Pharma, the manufacturer of OxyContin, was able to achieve this by putting high doses of oxycodone into a single pill with a built-in time-release mechanism that slowly delivered constant doses throughout the 12-hour time period it was active.<sup>134</sup>

This mechanism was also at the root of its third claim to innovation, which was that its time-release function would make it an unattractive candidate for abuse as those seeking to abuse the drug would not be interested in a drug that distributed its effect slowly over a long-period of time without an immediate euphoric effect.<sup>135</sup>

In connection with that theory, the FDA approved labeling in late 1995 that provided: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."<sup>136</sup>

Though the first claim – concerning the benefits of OxyContin for pain patients – would prove true, this second claim would turn out to be tragically mistaken. Within a few years of its introduction, abusers soon discovered that grinding up the pills would allow them to bypass the time-release mechanism and gain instant access to incredibly high doses of oxycodone.<sup>137</sup> According to officials familiar with opiate addiction, the same method of crushing up tablets for either injection or to be snorted has been used for abusing Percocet, Percodan and Tylox for years.<sup>138</sup> Why this was not raised as a red flag earlier in the process, by the

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15 CLIN. NURSE SPECIALIST 207, 207 (2001) (explaining that the 12 hour dose of OxyContin enables people to live a more normal life and carries fewer side effects than morphine).

<sup>132</sup>OxyContin is currently available in 10, 20, 40, and 80-milligram strengths. A 160-milligram was introduced in 2000, but was later withdrawn by Purdue because of abuse concerns in May 2001. By comparison, Percocet contains 5 milligrams of oxycodone, and Percodan 4.5 milligrams. See DEA, DRUG INTELLIGENCE BRIEF, OXYCONTIN: PHARMACEUTICAL DIVERSION (2002).

<sup>133</sup>See Meier supra note 12 at 84.

<sup>134</sup>See Heidrich supra note 127 at 207; See also Meier supra note 12 at 81 ("...company scientists went back to the drawing board, eventually coming up with a new timed-release system for OxyContin that used a synthetic acrylic, rather than wax, as the basis of the tablet. The design provided a quick burst of oxycodone for pain relief as the pill's outer coating dissolved in the stomach. Then, as it moved from the stomach into the intestines, the acrylic tablet continued to release a steady supply of the drug over twelve hours.")

<sup>135</sup>See Meier supra note 12 at 85-86.

<sup>136</sup>See *id.* at 87.

<sup>137</sup>See Timothy Roche, *The Potent Perils of a Miracle Drug*, TIME, Jan. 8, 2001.

<sup>138</sup>See John Burke, OXYCONTIN – A SENSE OF BALANCE, DEA-INDUSTRY COMMUNICATOR, OXYCONTIN SPECIAL (2001) (available at: <http://www.deadiversion.usdoj.gov/pubs/nwsltr/spec2001/oxy-spec.pdf>).

manufacturer Purdue, the FDA or the DEA would be a question fiercely debated in the years to come.<sup>139</sup> Regardless of its problems on the street, OxyContin has been an enormous financial success for Purdue Pharma. While prescriptions totaled 300,000 in 1995, the first year of OxyContin was on the market, they had grown to over 5.8 million five years later in 2000.<sup>140</sup> Even amid the growing media firestorm surrounding the OxyContin abuse, sales continued to soar. In 2002 alone, Purdue made \$4.67 billion from OxyContin, up 18% from its 2001 sales, and up 136% from 1998.<sup>141</sup> By 2000, OxyContin was both the most widely prescribed Schedule II drug in the country<sup>142</sup> and the most abused.<sup>143</sup>

2.

### *The Scope of the Problem*

Reports of serious abuse of OxyContin began to gain significant attention in both the media and in regulatory circles in the fall of 2000.<sup>144</sup> Abusers had begun injecting, chewing and snorting OxyContin to gain euphoric highs and to avoid withdrawal symptoms from heroin.<sup>145</sup> Recent reports from New York indicate that college students have begun to ingest OxyContin by putting it in a shot glass, pouring boiling water over it to dissolve the ingredients and then drinking it like a shot.<sup>146</sup>

The hardest hit areas were also the first to report abuse and included rural Maine, western Pennsylvania, and the Appalachian areas of Virginia, West Virginia, and Kentucky.<sup>147</sup> The problem, however, has since

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<sup>139</sup>See GAO, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM (December 2003).

<sup>140</sup>See Rubin supra note 1.

<sup>141</sup>See Anna Wilde Mathews & Gary Fields, *Federal Agencies Seek to Curb Abuse of Potent Painkillers*, WALL ST. J., Dec. 3, 2003.

<sup>142</sup>See DEA supra note 131.

<sup>143</sup>See Ralph Vartabedian, *Painful Rift Unnerves Doctors*, L.A. TIMES, Oct. 20, 2003.

<sup>144</sup>See Meier supra note 12 at 42-48.

<sup>145</sup>See DEA supra note 131.

<sup>146</sup>See Matthew Sweeney & Philip Messing, *Upscale Junkies – White Collar Abuse of OxyContin Skyrockets*, N.Y. POST, Feb. 16, 2004.

<sup>147</sup>See Tough supra note 125.

expanded nationwide, with some of the newest hard hit areas including Louisiana, Ohio, Arizona, and a number of urban areas.<sup>148</sup> By 2001, drug treatment programs in these regions were reporting that 30 to 90 percent of newly admitted patients cited OxyContin as their primary drug of abuse.<sup>149</sup> Between 1996 and 2000, emergency room admissions related to OxyContin tripled from 3,190 to 10,825.<sup>150</sup> In the New York metropolitan area alone, emergency room visits increased by more than 140% between 2000 and 2002.<sup>151</sup> One former sheriff in Hazard, Kentucky described the impact on his community as devastating: “It has demoralized our community. . . .It bankrupted spiritually, morally and financially people all over our area.”<sup>152</sup>

To make matters worse, the rate of abuse appears only to be growing. In 1999, persons reporting at least one non-medical use of OxyContin totaled 221,000.<sup>153</sup> By 2000, that figure had grown to nearly 400,000.<sup>154</sup> 2001 saw the total grow again to 957,000 and finally in 2002 it jumped to 1.9 million.<sup>155</sup>

Once addicted, the prospects for abusers are bleak. Even the self-proclaimed “most successful” detoxification program for OxyContin provided by the Weismann Institute<sup>156</sup> in Beverly Hills has only a 65% one-year success rate.<sup>157</sup> The closest competitor, Hazelden<sup>158</sup>, claims a 53% one-year success rate.<sup>159</sup> Both programs are incredibly expensive, however, with the Rapid Detox program at the Weismann Institute costing \$19,000 for a four week session and Hazelden costing upwards of \$10,000 for a three to four day program.<sup>160</sup> Most

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<sup>148</sup>See DEA supra note 113; See also Sweeney & Messing supra note 146.

<sup>149</sup>For example, a narcotic treatment program in southwestern Virginia reported that 80-85% of all new admissions were a result of OxyContin. The state of South Carolina reported that 30% of all new admissions were of similar origin. Numbers are similar in Louisiana and were last reported to be near 40%. Two centers in Pennsylvania report that 90% of all recent admissions are tied to OxyContin. See DEA supra note 131.

<sup>150</sup>*Id.*

<sup>151</sup>See Sweeney & Messing supra note 146.

<sup>152</sup>See Josh White, *OxyContin Abuse is Increasing, DEA Says*, WASH. POST, Dec. 12, 2001 (available at: <http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&node=&contentId=A28805-2001Dec11&notFound=true>).

<sup>153</sup>See 2002 National Survey on Drug Use and Health supra note 112.

<sup>154</sup>*Id.*

<sup>155</sup>*Id.*

<sup>156</sup>The website of the Weismann Institute can be found at <http://www.opiates.com>.

<sup>157</sup>See Jerry Adler, *In the Grip of a Deeper Pain*, NEWSWEEK, Oct. 20, 2003.

<sup>158</sup>The website of Hazelden can be found at <http://www.hazelden.org>.

<sup>159</sup>See Adler supra note 156.

<sup>160</sup>*Id.*

abusers, if they decide to enter rehab, must rely on traditional 12-step programs. For them, the prospect of relapse within the first year is 80%.<sup>161</sup>

The effects have not just been felt with abusers. OxyContin-related crime has also sharply increased in the most heavily abused areas. Violent crimes have included pharmacy robberies, attacks on customers as they leave pharmacies, and home invasions.<sup>162</sup> In recent years, as pharmacies stepped up security and physicians became more aware of deceptive patients seeking prescriptions for illicit uses, addicts have turned to more creative schemes to obtain their fix. In Virginia, for instance, addicts have been posing as home buyers, garage sale customers, building inspectors and even police officers in their attempt to gain access to legitimate patient's medicine cabinets or to unwary victim's credit cards and credit card receipts.<sup>163</sup> Other states have identified addicts using obituaries to identify homes that would be empty in order to stage break-ins to gain OxyContin or funds to buy OxyContin on the street.<sup>164</sup> Some of the most effected jurisdictions have reported as much as a 75% increase in property and other crimes attributable to OxyContin.<sup>165</sup>

This is not surprising, as not only are addicts pushed to crime, but the profit-incentive for non-users to find ways to get in on the illicit sale of OxyContin is substantial. Though OxyContin is sold in legitimate channels at approximately \$.09 to \$.13 per milligram, it can go for up to a \$1 a milligram on the street.<sup>166</sup> Thus a 40-milligram OxyContin obtained legitimately through a doctor would cost a patient approximately \$4 at a pharmacy, but could be sold on the street for upwards of \$40. In December of 2001, nine armed assailants attacked a pharmaceutical distributor in Mexico City and stole of 30,000 bottles of OxyContin, each containing 30 tablets of 20-milligram dose.<sup>167</sup> The total street value for the theft was estimated to be

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<sup>161</sup> *Id.*

<sup>162</sup> See Roche supra note 137; see also Rhonda Stewart, *Police Seek Two Suspects in Armed Drugstore Heist*, BOSTON GLOBE, Sep. 15, 2002.

<sup>163</sup> See Donna Leinwand, *Painkiller Thieves Get More Creative*, USA TODAY, Dec. 1, 2003.

<sup>164</sup> *Id.*

<sup>165</sup> See DEA, ACTION PLAN TO PREVENT THE DIVERSION AND ABUSE OF OXYCONTIN (2002).

<sup>166</sup> See DEA supra note 131.

<sup>167</sup> *Id.*

upwards of \$20 million and the eventual destination was predicted to be the American black market.<sup>168</sup>

The question of the number of deaths that have resulted from OxyContin has been hotly debated between members of the law enforcement community and Purdue Pharma. As of December 2001, the DEA had estimated that 145 deaths could be verified as being tied to OxyContin, with another 318 other deaths “likely related” to OxyContin.<sup>169</sup> In calculating this figure, the DEA counted a death as an “OxyContin-verified death” when medical reports or police information showed that an OxyContin tablet or prescription was present at the scene or at the autopsy.<sup>170</sup> This number, or similar figures, has been repeated in the media<sup>171</sup> and governmental agencies<sup>172</sup> on multiple occasions.

A study published by the *Journal of Analytical Toxicology* in 2003, however, takes issue with the death figures put forward by the DEA.<sup>173</sup> After examining the files and information of all 1,243 oxycodone-related deaths in 23 states between August of 1999 and January of 2002, the authors concluded that only 12 of the deaths could be said to have been caused by OxyContin, and that only 18 others were linked to oxycodone.<sup>174</sup> According to the study, 96.7% of the victims the DEA cited as OxyContin-linked deaths had at least three other drugs in their system – including alcohol, cocaine, marijuana, anti-depressants or other narcotics.<sup>175</sup>

There are indications that the DEA itself may not necessarily believe the numbers can be relied upon as

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<sup>168</sup>See White supra note 152.

<sup>169</sup>See Asa Hutchinson, Statement to House Committee on Appropriations, Subcommittee on Commerce, Justice, State, and Judiciary, December 11, 2001 (available at: <http://www.health.org/govpubs/dea/0112oxytestimony.aspx>).

<sup>170</sup>See Meier supra note 12 at 224; See also Ronald T. Libby, THE DEA’S OXYCONTIN ACTION PLAN: AN UNPROVEN DRUG EPIDEMIC, TESTIMONY AT HOUSE OFFICE BUILDING, Dec. 16, 2003 (available at: <http://www.aapsonline.org/painman/paindocs.htm>)

<sup>171</sup>See White supra note 152 (stating that Hutchinson testimony claimed 300 deaths linked to OxyContin, with perhaps 500 more related as well); Josh White, *Pill Probe Focuses on N. Va. Doctors*, WASH. POST, Aug. 4, 2002 (stating that OxyContin has “killed nearly 450 people”); Catherine Saillant, *Ventura County Doctor Focus of Painkiller Inquiry*, L.A. TIMES, Mar. 7, 2003 (“The narcotic, known as “hillbilly heroin” because its abuse first surfaced in Appalachia, has been linked to more than 100 deaths since 1998.” This is despite a story just four days earlier in the Los Angeles Times that questioned the validity of such numbers).

<sup>172</sup>See GAO report supra note 139 at 10 (citing the Orlando Sentinel story of 200 OxyContin-related deaths in Florida alone since 2000 as well as the 146 figure originally referenced by the DEA).

<sup>173</sup>See Edward J. Cone, et al., *Oxycodone Involvement in Drug Abuse Deaths: A DAWN-Based Classification Scheme Applied to an Oxycodone Postmortem Database Containing Over 1000 Cases*, 2 JOURNAL OF ANALYTICAL TOXICOLOGY 57, 57-67 (March 2003) (it should be noted that Purdue funded the study).

<sup>174</sup>*Id.*; see also Linda Marsa, *Medicine Drug Mix Proves Deadly*, L.A. TIMES, Mar. 3, 2003 (for summary of study’s findings).

<sup>175</sup>*Id.*

accurate.<sup>176</sup>

Some critics argue that the DEA has purposefully misstated the numbers surrounding abuse and deaths related to OxyContin in order to create a sense of crisis.<sup>177</sup> Others argue that the failure of the DEA and the media to site accurate figures regarding OxyContin-related deaths is part of a larger “false narrative” that asserts that the majority of OxyContin addicts are drug-naïve patients.<sup>178</sup> The reality, they argue, is that typical abuser is overwhelmingly likely to have a lengthy history of multiple-drug abuse – not the “accidental addict” often put forward by the media.<sup>179</sup> Other critics argue that even if the DEA numbers were accepted as true, 464 deaths would work out to only 8 deaths for every 100,000 OxyContin prescriptions – a number that would hardly be worthy of being called an “epidemic.”<sup>180</sup>

### *3. The Scope of the Problem*

Regardless of how one comes down on the question of OxyContin-related deaths, it is hard to deny that the effect on the hardest hit communities has been immense. With that in mind, in order to properly evaluate policy options that seek to maximize pain relief and minimize substance abuse, it is necessary to examine the exact reasons why OxyContin abuse was able to spread so quickly.

One large part of the explanation as to the initial outbreak of abuse can be traced back to the history and geography of regions where the abuse arose. As was mentioned earlier, the rural areas of Appalachia, western Pennsylvania and the rural south had a long history of oxycodone abuse.<sup>181</sup> Such regions favored oxycodone-

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<sup>176</sup> See Meier supra note 12 (relaying the story of how officials at the DEA seemingly conceded that the data could not support the stated fatality figures, and that FDA officials appeared to side with Purdue’s interpretation of the data).

<sup>177</sup> See Jane Spencer, *Crackdown on Drugs Hits Chronic-Pain Patients*, WALL ST. J., Mar. 16, 2004.

<sup>178</sup> See Maia Szalavitz, *The Accidental Addict, Clearing Away the Myths Surrounding the OxyContin “Epidemic,”* SLATE.COM, Mar. 25, 2004 (available at: <http://slate.msn.com/id/2097786>).

<sup>179</sup> *Id.*

<sup>180</sup> See Libby supra note 169.

<sup>181</sup> See Tough supra note 125; see also Burke supra note 138.

based opiates primarily because such areas were far away from the heroin and cocaine networks that service higher population urban areas.<sup>182</sup> In the absence of such networks, the doctor's office and pharmacy were the next best opportunity for access to a high.<sup>183</sup> Geography played another role as well – as in many cases, life in a rural area makes access to rehabilitation clinics far more inconvenient.<sup>184</sup>

Also unlike the traditional opiate analgesics abused by addicts, however, OxyContin was incredibly powerful – with a 40-miligram tablet containing eight times the amount of oxycodone of a previously popular oxycodone-based painkiller, Tylox.<sup>185</sup> Some researchers have also speculated that OxyContin may in fact provide a better high than similar drugs in its class like morphine and oxycodone – though more research needs to be done to make any conclusions on that front.<sup>186</sup>

Another differentiating factor with OxyContin was its vast availability. Many, in fact, have directly targeted Purdue Pharma and their massive marketing campaign surrounding the debut of OxyContin as the primary reason for the crisis of abuse that arose in 2000. Even pain treatment advocates, and supporters of OxyContin, like Dr. Russell Portenoy agree that no pharmaceutical company had ever promoted a high-strength narcotic to so wide an audience – including a large number of general practitioners who were untrained in sometimes sophisticated pain treatment techniques.<sup>187</sup> A large number of lawsuits against Purdue center around the question of misleading marketing practices and what they say was a deceptive attempt by the pharmaceutical company to downplay the dangers of abuse and addiction and to promote the use of the drug to patients who had equally effective, and much less dangerous, alternative treatments available.<sup>188</sup>

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<sup>182</sup> *Id.*

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*; see also Meier supra note 12 at 112.

<sup>185</sup> *Id.*; see also supra note 135.

<sup>186</sup> See Meier supra note 12 at 278.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.* at 92-104 (for a detailed account of Purdue's strategy in 1996 and 1997 to substantially expand the potential market for OxyContin); see also Heather Smith, *The Pain Continues*, THE AMERICAN LAWYER, Jan. 2004 (for a summary of the status of the 380 private suits brought against Purdue related to OxyContin).

A center point of the controversy surrounding Purdue's marketing is the question of OxyContin's iatrogenic addiction risk – addiction that arises in the course of legitimate treatment by a physician as opposed to when it is abused for non-medical purposes on the street.<sup>189</sup> Though relevant directly to the OxyContin issue, it is also central to the pain relief movement more broadly as the debate has begun to call into questions some of the most fundamental tenants of those who advocate for the use of opiates for the treatment of chronic pain – that the risk of addiction, when used properly, is minor. Purdue officials had argued, as late as 2000, that OxyContin's risk of addiction, when taken as prescribed, was one-half of one percent.<sup>190</sup> Meanwhile, critics of OxyContin were challenging the basic conclusions of the studies of the late 1970's and early 1980's that pain treatment advocates had relied on in making their case for opiate-based treatments.<sup>191</sup> Not only were the studies based on an extremely limited data set, the studies themselves did not even specifically address the addiction risk posed by the long-term use of opioids.<sup>192</sup>

Perhaps surprisingly, many of the staunchest advocates of the use of opiates in chronic pain treatment have acknowledged that the assurances about the low-rate of addiction may have very well been overstated. In a letter written to the *Journal of Pain and Symptom Management* in May 2001, Dr. Steven Passik admitted that a misperception of addiction risk had contributed to the explosion of OxyContin abuse:

Unfortunately, the problem of opioid abuse during the course of pain management is an issue over which—I'm afraid—those of us in the pain management community have been somewhat disingenuous. While I certainly believe that the risk of addiction, abuse and poor adherence (aberrant drug-related behavior) in the use of these medications is far less than was once believed to be the case, it is not zero. In our zeal to improve access to opioids and relieve patient suffering, pain specialists have understated the problem, drawing faulty conclusions from very limited data. In effect, we have told primary care doctors and other prescribers that the risk was so low that they essentially could ignore the possibility of addiction. We have also overstated the concept that long-acting drugs have a lower risk of abuse.<sup>193</sup>

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<sup>189</sup> See Barry Meier, *The Delicate Balance of Pain and Addiction*, N.Y. TIMES, Nov. 25, 2003.

<sup>190</sup> See Meier *supra* note 12 at 45.

<sup>191</sup> *Id.* at 173-75; see also Meier *supra* note 188 (detailing the critiques of the addiction-related studies of the late 70's and early 80's).

<sup>192</sup> *Id.*

Pain advocates are now moving toward a more nuanced view of addiction-risks – one that focuses more on an individualized determination of each patient, rather than on broad conclusions across patient types.<sup>194</sup> While it is generally accepted that the average biological addiction risk across the general population is somewhere around 10%, pain treatment advocates continue to maintain that addiction rate continues to be significantly lower than that in less-vulnerable populations such as older patients.<sup>195</sup> They do acknowledge, however, that the risk is much higher amongst some other groups, such as patients already addicted to other substances who are undergoing long-term opioid treatment for chronic pain.<sup>196</sup> There also seems to be a consensus across that board that significant additional study needs to be done on the question of iatrogenic addiction.

Though iatrogenic addiction is certainly one element of the OxyContin problem, another, much larger problem, is the problem of addiction associated with those using the drug for non-medical purposes. On this front, the problem that OxyContin presents is not one of medical judgment of addiction risk, but one of illegal diversion of prescription drugs for a non-medical use. Such diversion takes seven primary forms: 1) deceptive patients who mislead their doctors into prescribing pain medication they do not actually need; 2) physicians who wrongly dispense opiates because of a lack of proper training in their use; 3) physicians who are impaired; 4) corrupt physicians; 5) theft; 6) illegal internet distribution; and 7) foreign distribution and diversion.<sup>197</sup> Of these, deceptive patients are by far the most common source of diversion.<sup>198</sup> It is thus important when considering the policy options available to remember that the OxyContin problem is not simply one of corrupt doctors or iatrogenic addiction.

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<sup>194</sup>*Id.*

<sup>195</sup>See Portenoy interview supra note 15 (in reply to a question about OxyContin's risk of addiction: "If the outcome in question is true addiction, then the answer is considerably less than 10%. Ten percent is viewed as a reasonable estimate of the biological vulnerability to addiction in the overall population. Since chronic pain tends to occur disproportionately in the older population, and an older subpopulation is likely to have a lower prevalence of addictive disease risk than a younger one, it is likely that the risk in the subpopulation with chronic pain is substantially lower.").

<sup>196</sup>See Passik supra note 192.

<sup>197</sup>See Ziegler & Lovrich supra note 41 at 76; See also DEA intelligence brief supra note 131.

<sup>198</sup>See Bonnie B. Wilford et al, *An Overview of Prescription Drug Misuse and Abuse: Defining the Problem and Seeking Solutions*, 22 J.L. MED. & ETHICS 197, 199 (1994).

## IV. The Regulatory Framework and its Current Response

### *a. Regulatory Framework:*

#### *1. Federal Law – The Harrison Act*

Ever since the Harrison Narcotics Act's passage, signed into law in 1914, the federal government has regulated the sale and distribution of opiates intended for medical use.<sup>199</sup> The states themselves had been enacting laws regulating or prohibiting the sale of opiates, cocaine, and other substances for non-medical purposes since about 1900.<sup>200</sup> The Harrison Act, however, significantly expanded the federal role, and required for the first time that:

every person who produces, imports, manufactures, compounds, deals in, dispenses, distributes, or gives away opium or coca leaves or any compound, manufacture, salt, derivative, or preparation thereof, shall register with the collector of internal revenue of the district, his name or style, place of business, and place or places where such business is to be carried on.<sup>201</sup>

Upon registration, each registrant would then be obligated to pay an annual tax of \$1 to the US Treasury Department.<sup>202</sup> Physicians were required to keep detailed records of the date of the prescription, how much it was for and who it was written for and all of the information had to be kept for two years.<sup>203</sup>

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<sup>199</sup>Harrison Narcotic Act, Chap. 1 Public Law No. 223, 63rd Cong., approved December 17, 1914. (1914) (available at: <http://www.druglibrary.org/schaffer/history/e1910/harrisonact.htm>).

<sup>200</sup>See Acker supra note 68 at 33.

<sup>202</sup>*Id.*

<sup>203</sup>*Id.*

Though it appeared not to regulate the actual interaction between the patient and physician on its face, there was one sentence that provided federal officials with a window to crack down on more controversial medical uses of the opiates: “Nothing contained in this section shall apply. . . . To the dispensing or distribution of any of the aforesaid drugs to a patient by a physician, dentist, or veterinary surgeon registered under this Act *in the course of his professional practice only*.”<sup>204</sup> Violations of the Act carried the potential of a \$2000 fine and/or 5 years in prison.<sup>205</sup>

Though most physicians at the time felt that they were free to continue to prescribe opiates as they saw fit as long as they adhered to the registration and record keeping requirements, it quickly became clear that the Treasury Department was going to prosecute doctors who issued prescriptions for the purpose of managing the addiction of those dependent on narcotics.<sup>206</sup> It quickly became known in the medical community that Treasury officials were on the lookout for physicians who were accepting large numbers of addicts as patients.<sup>207</sup> As the gatekeepers to the only legal channel of obtaining opiates, “physicians became increasingly wary of patients complaining of mysterious pains and demanding relief through drugs.”<sup>208</sup> Though many physicians and lawyers speculated that such regulation was unconstitutional and an inappropriate incursion on the independence of the medical profession, the threat of negative publicity resulting from an investigation, even if it didn’t result in a conviction, was enough to deter physicians from prescribing opiates.<sup>209</sup>

Finally, in 1919, the Supreme Court upheld the lawfulness of such prosecutions in the case of *United States v. Doremus*,<sup>210</sup> The court held that a prescription for opiates to a person known as a “dope fiend” was not a “legitimate practice” of the medical profession, and that it was within the constitutional powers of the federal government to prosecute such violations.<sup>211</sup> Though the question in 1919 was that of prescription

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<sup>204</sup> *Id.* (italics added).

<sup>205</sup> *Id.*

<sup>206</sup> See Acker supra note 68 at 35.

<sup>207</sup> *Id.* at 51.

<sup>208</sup> *Id.* at 62.

<sup>209</sup> *Id.* at 51.

<sup>210</sup> See *United States v. Doremus*, 39 S.Ct. 214 (1919).

<sup>211</sup> *Id.*

of opiates for the purpose of maintaining addiction – a practice that was later federally funded in the 1970’s with the establishment of methadone clinics across the country<sup>212</sup> – the issues of chill and fear of prosecution for the practice of medicine involving opiates is remarkably similar to the application of today’s federal drug laws to physicians engaged in sometimes controversial treatment of chronic pain.<sup>213</sup>

## 2. Federal Law – The Modern Structure

Today, the primary legislation<sup>214</sup> governing the federal government’s regulation of opioid analgesics such as OxyContin is the Controlled Substances Act (CSA) – enacted in 1970.<sup>215</sup> In enacting the CSA, Congress explicitly acknowledged that “many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.”<sup>216</sup> Following that opening statement, the CSA goes on to declare that “the illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.”<sup>217</sup> It is this tension between medical and criminal that lies at the heart of the debate of the federal role in the regulation of opiates used to treat moderate to severe pain. If the balance is struck incorrectly, the potential for needless suffering on either

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<sup>212</sup>See Acker supra note 68 at 218.

<sup>213</sup>See Josh White, *Pill Probe Focuses on N. Va. Doctors*, WASH. POST, Aug. 4, 2002 (quoting Dr. William Hurwitz, a well-known Virginia pain specialist currently being prosecuted by federal officials for distribution of controlled substances outside of legitimate medical practice: “this is a symbolic investigation with a political agenda to squelch OxyContin and other pain medications. . . . It’s easy to put fear in the mom-and-pop pharmacies and into the doctors because we are easy to scare to death. They’re looking at us as Mafia dons and the heads of drug cartels, while we’re just trying to help patients who are in serious pain and are in dire need of help.”).

<sup>214</sup>The Federal Food, Drug, and Cosmetic Act also plays a role as it grants the Food and Drug Administration the authority to evaluate and approve drugs prior to becoming eligible for distribution for medical use. Because pre-market approval of pain relief medications is not a primary focus of this paper, however, it will not be discussed at length. For a discussion of the role of the FDA in the pain relief debate see Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55 (2003).

<sup>215</sup>See Controlled Substances Act, Pub. L. No. 91-513, title II, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§801-904 (2000)).

<sup>216</sup>21 U.S.C. §801(1).

<sup>217</sup>21 U.S.C. §801(2).

side of the balance is substantial.

Under the CSA, all federally regulated drugs are organized into one of five “schedules.”<sup>218</sup> Each substance is classified depending on whether it has a “currently accepted medical use,” whether it is safe for use “under medical supervision,” whether there is a danger of abuse, and whether it may lead to physical or psychological dependence.<sup>219</sup> OxyContin and other oxycodone-based pain relievers are Schedule II drugs which means that they are highly subject to abuse and dependence, but also have an accepted medical use<sup>220</sup> (as opposed to Schedule I drugs that are subject to abuse and have no accepted medical use such as heroin, and Schedule III, IV, and V drugs that have progressively less danger for abuse and dependence).<sup>221</sup>

In order to prescribe Schedule II drugs such as OxyContin, physicians must register with the Attorney General.<sup>222</sup> The Attorney General will register a physician unless he deems it to be “inconsistent with the public interest.”<sup>223</sup> In determining whether or not a registration is inconsistent with the public interest, the Attorney General must consider the following factors:

1.

Maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

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<sup>218</sup>21 U.S.C. §812.

<sup>219</sup>21 U.S.C. §812(b).

<sup>220</sup>21 U.S.C. §812(b)(2).

<sup>221</sup>See 21 U.S.C. §812(1)-(5).

<sup>222</sup>See 21 U.S.C. §822(a).

<sup>223</sup>21 U.S.C. §823(b).

2.

Compliance with applicable State and local law;

3. Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

4. Past experience in the distribution of controlled substances; and

5. Such other factors as may be relevant to and consistent with the public health and safety.<sup>224</sup>

There are other unique restrictions that apply to Schedule II substances as well. Prescriptions must be written, not phoned in or faxed.<sup>225</sup> They also cannot be refilled.<sup>226</sup> Manufacturers must register with the Attorney General as well,<sup>227</sup> and follow DEA-set production quotas.<sup>228</sup> Furthermore, a regulation was promulgated pursuant to the CSA shortly after its passage that bears directly on the question of physicians and pharmacists concerned with the prospect of regulatory scrutiny for dispensing significant amounts of opiate analgesics for the treatment of moderate to severe pain. It reads:

a prescription for a controlled substance to be effective *must be issued for a legitimate medical purpose* by an individual practitioner acting in the *usual course of his professional practice*. . . . An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning of section 309 of the Act. . . (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations for the provisions of law relating to controlled substances.<sup>229</sup>

As the Court explained in *United States v. Moore*, “physicians who stepped outside the bounds of profes-

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<sup>224</sup>21 U.S.C. §823(b)(1)-(5).

<sup>225</sup>21 U.S.C. §829(a).

<sup>226</sup>*Id.*

<sup>227</sup>21 U.S.C. §823(a).

<sup>228</sup>21 U.S.C. §826.

sional practice could be prosecution under the Harrison Act (Narcotics) of 1914,” and the CSA “was intended to ‘strengthen,’ rather than to weaken, ‘the previously existing federal law enforcement authority.’”<sup>230</sup>

For the physician aggressively treating pain with opioids, the question of how the terms “legitimate medical purpose” and “usual course of his professional practice” will be of central importance to their incentive structure in treating patients in the future. Unfortunately for many physicians, the current behavior of the DEA and Department of Justice seems to be creating more confusion on this front than clarity – and the effect on pain treatment has been significant.

### *3. State Law*

Though federal law dictates many of the legal aspects related to the distribution, sale and transport of controlled substances, state law almost always governs the medical use of such substances – usually through the mechanism of state medical boards who are charged with investigating complaints against physicians for unprofessional practice and disciplining them for violations if they are found to exist.<sup>231</sup> When DEA investigations find no evidence of illicit use or diversion, they will often turn over investigations of physicians to state medical boards to determine if the treatment was nonetheless within the course of professional conduct.<sup>232</sup>

Each state sets their own standards, and as such there are a variety of approaches across the country to

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<sup>230</sup>423 U.S.122, 132 (1975) (In Moore the Court upheld the conviction of a physician who was “drug trafficking” and selling drugs not for medical reasons, but for profit purposes).

<sup>231</sup>See Martino supra note 36 at 332

<sup>232</sup>See Rich supra note 11 at 48.

the question of opioid use to treat pain.<sup>233</sup> Additionally, there has been a substantial amount of change in these policies over the past ten years. For instance, prior to 1989, there were few state medical boards that had policies on the question of pain relief.<sup>234</sup> Since then, however, forty-one states have adopted guidelines, regulations or policy statements to provide guidance on the prescription of opiates to treat chronic pain and pain at the end of life.<sup>235</sup> Whether or not this guidance has helped to make progress in the effort to address undertreated pain is a question addressed in the section following.

It should also be noted that in certain extreme cases, physicians prescribing opiates are sometimes subject to state criminal prosecution for manslaughter or murder. This usually occurs in the context of end of life care where a physician is accused of causing the death intentionally<sup>236</sup> or where opioid prescriptions are linked to the death of a patient.<sup>237</sup>

## ***b. Current Response***

### *1. The Federal Response*

In looking over the policy changes of the past decade, there are valid grounds, at least on paper, to argue that federal policy has shifted toward a recognition that undertreatment of pain is a serious public health issue. Unfortunately for physicians and patients who are currently undertreated, actions have spoken much

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<sup>233</sup> See Joranson et al. supra note 14 (providing a survey of the 50 states regulatory board's approach toward the use of opioids to treat pain).

<sup>234</sup> *Id.*

<sup>235</sup> *Id.*

<sup>236</sup> See Ann Alpers, *Criminal Act or Palliative Care? Prosecutions Involving Care of the Dying*, 26 J.L. MED. & ETHICS 308 (1998) (examining recent criminal prosecutions against doctors related to care at the end of life).

<sup>237</sup> Cases related to overdose deaths connected to physician-prescribed OxyContin are one example of such a case that have become more frequent in recent years, and they will be discussed in the next section. For example, see Bill Kzczor, *PanHandle Doctor's OxyContin Conviction to Send Message*, DENVER ROCKY MOUNTAIN NEWS, Feb. 20, 2002. (discussing the case of Dr. James Graves, convicted of manslaughter in Florida in connection to the OxyContin-related overdose deaths of four of his patients. He was sentenced to 63 years in prison.).

louder than words.

In 1992, for instance, the Agency for Health Care Policy and Research, a branch of the Department of Health and Human Services, issued guidelines recognizing the failure to manage acute pain resulting from surgery and encouraging the use of opioid analgesics.<sup>238</sup> Two years later, the same agency issued similar guidelines for the treatment of cancer pain.<sup>239</sup> In 2000, Congress went so far as to declare the coming ten years the “Decade of Pain Control and Research.”<sup>240</sup> In 2001, the Joint Commission on Accreditation of Health Care Organizations began requiring that the 19,000 hospitals and care facilities that it accredits implement new heightened pain management standards.<sup>241</sup>

In 1997, the Supreme Court rejected two 14<sup>th</sup> Amendment challenges to state prohibitions to assisted suicide.<sup>242</sup> In doing so, however, some believe some of the justices, if not a majority, may very well have recognized a constitutional right to palliative care, at least at the end of life.<sup>243</sup>

In recent public statements, the DEA and its officers have also seemingly embraced the need to bring legitimacy to the use of opioid analgesics in treating pain. In fact, as far back as 1988, the DEA has seemingly backed such a stance, stating: “The CSA requirement for a determination of legitimate medical need is based on the undisputed proposition that patients and pharmacies should be able to obtain sufficient quantities...of any schedule II drug, to fill prescriptions. A therapeutic drug should be available to patients

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<sup>238</sup> See AGENCY FOR HEALTH CARE POLICY AND RESEARCH, ACUTE PAIN MANAGEMENT: OPERATIVE OR MEDICAL PROCEDURES AND TRAUMA 1 (1992).

<sup>239</sup> See Agency for Health Care Policy and Research, Management of Cancer Pain (1994).

<sup>240</sup> See H.R. 3244, Title VI, §1603 (2000).

<sup>241</sup> See Carolyn Kleiner, *A Curse and a Cure*, U.S. NEWS & WORLD REPORT, Aug. 6, 2001. (information on the guidelines available at: <http://www.jcaho.org/news+room/health+care+issues/jcaho+focues+on+pain+management.htm>)

<sup>242</sup> See *Washington v. Glucksberg*, 521 U.S. 702 (1997); *Vacco v. Quill*, 521 U.S. 793 (1997).

<sup>243</sup> See Robert A. Burt, *The Supreme Court Speaks: Not Assisted Suicide but a Constitutional Right to Palliative Care*, 337 NEW ENG. J. MED. 1234, 1234-35 (1997); see also Jesse Chipper, *On the Court's 1996-1997 Term*, 19 CARDOZO L. REV. 2259, 2281 (1998) (arguing that Justice O'Connor's concurrence in *Glucksberg* indicated a right to palliative care, even when hastening death, and that at least three other justices would agree with her on that point.); see also Susan Wolf, Foreword: Facing Death, 82 Minn. L. Rev. 885, 889 (1998) (arguing that at least two justices indicated a constitutional right to adequate pain relief.).

when they need it. . . .”<sup>244</sup> In 2001, the DEA joined with a collection of 21 pain-treatment advocacy groups to issue a joint statement indicating that “preventing drug abuse is an important societal goal, but there is a consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients’ ability to receive the care they need and deserve.”<sup>245</sup> The statement went on to acknowledge that “for many patients, opioid analgesics – when used as recommended by established pain management guidelines – are the most effective way to treat their pain, and often the only treatment option that provides significant relief.”<sup>246</sup> Finally, the DEA addressed, and attempted to refute, one of the most common charges against them: “Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties.”<sup>247</sup>

DEA officials have stated similar goals in public statements surrounding the recent OxyContin developments as well. In a 2001 appearance before the House Subcommittee on Commerce, Justice, State, and Judiciary, the DEA Administrator at the time, Asa Hutchinson, assured committee members that the DEA did not “intend to restrict legitimate use of OxyContin, nor prevent practitioners acting in the usual course of their medical practice from prescribing OxyContin for patients with a legitimate medical purpose.”<sup>248</sup> In a statement made just last month, the message from the current DEA Administrator Karen Tandy was almost identical: “I don’t want legitimate patients in pain undertreated because of fears of criminal prosecution.”<sup>249</sup> The message that physicians and pain treatment advocates are getting from the DEA in recent years, however, is quite different. In a number of recent high-profile cases, the DEA has made it clear that physicians will be a major target of the agency’s efforts to clamp down on the problem of OxyContin diversion. One

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<sup>244</sup>53 Federal Register 50593 (1988).

<sup>245</sup>A JOINT STATEMENT FROM 21 HEALTH ORGANIZATIONS AND THE DRUG ENFORCEMENT ADMINISTRATION (2001) (available at: <http://www.ampainsoc.org/advocacy/promoting.htm>).

<sup>246</sup>*Id.*

<sup>247</sup>*Id.*

<sup>248</sup>*See* Hutchinson *supra* note 20.

<sup>249</sup>*See* Spencer *supra* note 77.

such case is the prosecution of well-known pain specialist Dr. William Hurwitz and pharmacist who filled his prescriptions, Joseph Statkus.<sup>250</sup> Prosecutors say that “through willful blindness, deliberate ignorance, if not intent” the pair, through their medical practice, provided OxyContin to dozens of individuals who later sold the drugs on the illegal market throughout the south.<sup>251</sup> They were indicted in September of 2003 on 49 counts ranging from drug trafficking resulting in death and serious injury to engaging in a criminal enterprise and health care fraud.<sup>252</sup> If convicted the pair faces life in prison.<sup>253</sup>

The facts of the case will not be clear until trial, but what is clear is that the case has exposed once again the deep tension that exists between the pain treatment community and the law enforcement officials they believe are out to get them.<sup>254</sup> Critics of the federal response argue that the new, aggressive stance of law enforcement has tipped the delicate balance between pain treatment and preventing diversion of controlled substances “drastically in the direction of ruthless drug control.”<sup>255</sup>

They point to the sometimes-fierce rhetoric of federal officials who they say are unfairly targeting doctors who are just trying to treat their patient’s pain. In discussing the investigation surrounding the Hurwitz case, a federal prosecutor explained the government’s strategy less than a year after September 11<sup>th</sup> by stating that,

the growing national plague of Oxy addictions, overdoses and deaths caused by the illegal activity of some doctors, pharmacists and patients has been focused on like a laser beam by this office and other U.S. attorney’s offices,...If any person falls into one of those three categories, *our office will try our best to root that person out like the Taliban.*<sup>256</sup>

Attorney General John Ashcroft, while not mentioning the role that drugs like OxyContin play in the treatment of pain, commented on the indictment of Hurwitz: “The indictment and arrests in Virginia demonstrate

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<sup>250</sup> See Josh White, *Virginia Doctor Indicted in OxyContin Scheme*, WASH. POST, Sep. 26, 2003.

<sup>251</sup> See Josh White, 2 N. Va. Doctors Linked to Deluge of Illegal Drugs, WASH. POST, Dec. 23, 2002.

<sup>252</sup> See White supra note 250.

<sup>253</sup> *Id.*

<sup>254</sup> See Vartabedian supra note 143.

<sup>255</sup> *Id.* (quoting David Brushwood, a lawyer and professor of pharmacology at the University of Florida).

our commitment to bring justice to all those who traffic in this very dangerous drug... We will continue to pursue vigorously physicians and others who are responsible for turning OxyContin from a legitimate painkiller to a vehicle of addiction and death.”<sup>257</sup> Another federal prosecutor in the case recently referred to Hurwitz as a “street-corner crack dealer.”<sup>258</sup> Though they ultimately did not pursue the course, federal prosecutors in the case also initially threatened to seek the death penalty against Hurwitz under laws originally designed to target drug kingpins.<sup>259</sup>

A surprising number of medical organizations and pain-treatment advocates have come out in support of Dr. Hurwitz<sup>260</sup> and warn that a continued strategy of targeting physicians will serve only to hurt millions of innocent patients who will find it increasingly more difficult to find access to legitimate pain treatment. Dr. Russell Portenoy fears that “fifteen years of progress in treating patients in chronic pain could really be wiped away if these prosecutions continue... what’s happening now is that the medical ambiguity is being turned into allegations of criminal behavior.”<sup>261</sup> The Association of American Physicians and Surgeons – an organization representing 4,000 physicians nationwide – claims that “physicians are being threatened, impoverished, delicensed, and imprisoned for prescribing in good faith with the intention of relieving pain, and their patients become the collateral damage in this trumped-up war.”<sup>262</sup> Dr. Michael Fleming, President of the 94,000 member American Academy of Family Physicians agrees that physicians are growing more concerned with the threat of regulatory scrutiny: “There is no question that doctors now fear being held liable if they prescribe painkillers.”<sup>263</sup> Rebecca Patchin, a board member of the American Medical Association

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<sup>257</sup> See White supra note 250.

<sup>258</sup> See Josh White & Marc Kaufman, *U.S. Compares Va. Pain Doctor to “Crack Dealer,”* WASH. POST, Sep. 30, 2003.

<sup>259</sup> See White supra note 251.

<sup>260</sup> Those publicly supporting Dr. Hurwitz include the Association of American Physicians and Surgeons, the Pain Relief Network, the American Pain Institute, and the National Foundation for the Treatment of Pain. See Vartabedian supra note 143.

<sup>261</sup> See Kaufman supra note 22; In a recent interview Dr. Portenoy confirmed the level of fear is high: “most pain specialists perceive a much higher level of fear in the physician community.” See Portenoy interview supra note 15.

<sup>262</sup> See Florida’s War on Drugs Now a War on Doctors Says Association of American Physicians and Surgeons, Newswire, Jan. 16, 2004.

<sup>263</sup> See Vartabedian supra note 251.

also believes that the effect of the prosecutions will ultimately be to hurt legitimate pain patients.<sup>264</sup>

Some critics of the federal response to the OxyContin crisis also point to the recent attempt by the Department of Justice to revoke physician's controlled substance registration for participating in Oregon's Death with Dignity Act as another example of the federal government unnecessarily using the CSA to chill pain treatment. For the first time the Attorney General and the DEA are asserting the right to define nationally what constitutes a "legitimate medical purpose" for the purposes of the CSA.<sup>265</sup> Under the Attorney General's interpretation of the CSA, any Oregon physician assisting a patient in utilizing their right under the state's Death with Dignity Act would face revocation of their registration to dispense Schedule II drugs.<sup>266</sup>

Not only does the goal of the Attorney General's effort seem tangentially related to the purpose of avoiding the diversion of drugs into illegal channels – the motivating force behind the implementation of the CSA<sup>267</sup> – many pain relief advocates who do not support physician-assisted suicide fear that the regulation will further deter doctors everywhere – not just in Oregon – from properly treating pain.<sup>268</sup> First and foremost, critics argue that physicians at the end of life who are not necessarily familiar with the nuances of law may avoid

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<sup>264</sup>See Kaufman supra note 22. ("Doctors hear what's happening to other physicians, and that makes them very reluctant to prescribe opioids that patients might well need.")

<sup>265</sup>The relevant portion of the Ashcroft Directive reads: "I hereby determine that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. §1306.04 (2001), and that the prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA." See Memorandum from U.S. Attorney General John Ashcroft to DEA Administrator Asa Hutchinson, 66 Fed. Reg. 56,607 (Nov. 9, 2001), reprinted in 17 Issues in Law & Med. 265 (2002). This interpretation is directly contrary to Attorney General Janet Reno's interpretation of the CSA issued in 1998: "There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice." See Letter from Janet Reno, U.S. Attorney General, to Henry J. Hyde, Chairman, Committee on the Judiciary, U.S. House of Representatives (June 5, 1998) (available at <http://www.house.gov./judiciary/attygen.htm>).

<sup>266</sup>See Memorandum from U.S. Attorney General John Ashcroft supra note 265.

<sup>267</sup>See *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077, 1090 (D. Or. 2002) (holding that "Defendants cannot seriously conclude... that Congress delegated to federal prosecutors the authority to define what constitutes a legitimate medical practice."

<sup>268</sup>See Brief of Amici Curiae for the American Academy of Pain Management et al. (available at: [http://www.compassionindying.org/ashcroft\\_ruling/patient\\_brief.pdf](http://www.compassionindying.org/ashcroft_ruling/patient_brief.pdf)). (those signing onto the amicus included the Academy of Pain Management, the California Medical Association, the American Geriatrics Society, The Society of General Internal Medicine, Dr. Russell Portenoy, Ann Jackson (Executive Director of the Oregon Hospice Association), Dr. Charles F. McKhann (Professor of General Surgery and Surgical Oncology, Yale University School of Medicine) and Dr. Robert V. Brody (Chair, Ethics Committee, San Francisco General Hospital).

prescribing sufficient doses of opioids or other drugs at the end of life to avoid DEA investigation.<sup>269</sup> Such an effect would run contrary to the endorsement of aggressive pain treatment, double effect, and terminal sedation by the Supreme Court just five years ago in *Washington v. Glucksberg*.<sup>270</sup> As one expert noted, the Ashcroft interpretation of the CSA would allow DEA agents “with absolutely no experience in end-of-life care” to determine “if large doses of medication physicians sometimes prescribe to treat terminally ill patients are used with the intent of hastening death or relieving pain.”<sup>271</sup>

Further, many worry that a move toward allowing a law enforcement official or agency – rather than the medical community and states – to define what constitutes a “legitimate medical purpose” will undue the significant efforts of the states to clarify pain treatment guidelines to reassure physicians undertaking appropriate pain treatment that they will not face disciplinary or criminal sanctions.<sup>272</sup> In just 1998, the Chief of the Liaison and Policy Section of the DEA’s Office of Diversion made the following statement in an attempt to reassure doctors prescribing opioids that the DEA would not second-guess the judgments of the medical community on the question of the legitimate use of opioids: “the CSA by design does not define ‘legitimate medical purpose’ nor does it set forth standards of medical practice. These issues can only be defined by the medical community and its internal review processes.”<sup>273</sup>

## 2. *The Response of the States*

States have also had difficulty in dealing with the conflicts between law enforcement efforts and the attempt to make progress against pain. In 1998, in response to a call for more clarity in state regulatory policy toward

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<sup>269</sup> *Id.*

<sup>270</sup> See *Washington v. Glucksberg*, 521 U.S. 702, 737-38 (J. O’Connor concurring) (“There is no dispute that dying patients... can obtain palliative care, even when doing so would hasten their deaths.”)

<sup>271</sup> Dr. Jerome Groopman, *Separating Death From Agony*, N.Y. TIMES, Nov. 9, 2001.

<sup>272</sup> See Amici supra note 268.

<sup>273</sup> Speech by Patricia M. Good before the Federation of State Medical Boards Symposium on Pain Management and State Regulatory Policy (March 17, 1998) (available at: <http://www.medsch.wisc.edu/painpolicy/domestic/dea98.htm>).

the use of opioids in pain treatment, and physicians' liability for such use, the Federation of State Medical Boards of the United States issued model guidelines for the use of controlled substances in the treatment of pain.<sup>274</sup> In the preamble, the guidelines recognize that "controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins."<sup>275</sup> Furthermore, while acknowledging that physicians must be diligent to prevent diversion and abuse, there is an attempt to provide physicians with a safe-harbor from regulatory scrutiny:

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.<sup>276</sup>

In order to provide further guidance to physicians seeking assurances that they will not be punished, the guidelines lay out six guidelines for physicians to follow in treating patients with opioid analgesics:

1.

A complete medical history and physical examination must be conducted and documented in the medial record.

2. A treatment plan must be completed.

3.

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<sup>274</sup>THE FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN (1998) (available at: <http://www.medsch.wisc.edu/painpolicy/domestic/model.htm>).

<sup>275</sup>*Id.*

The patient should be notified of the risks and benefits of the use of controlled substances. The doctor should also consider a written agreement with the patient outlining patient responsibilities.

4.

The physicians should undertake periodic reviews of the course and success of the treatment and make necessary adjustments in treatment.

5.

The physician should be willing to refer the patient for additional evaluation if necessary, and special attention should be paid to patients who are at higher risk of misuse or diversion (such as those with a history of substance abuse or psychiatric disorders).

6.

Complete and accurate medical records should be kept.

7. Physicians should comply with federal and state laws for registration.<sup>277</sup>

As of this year, six states have adopted the model guidelines described above.<sup>278</sup> Another sixteen states have adopted a portion of the model guidelines.<sup>279</sup> Even the DEA has expressed its support of the guidelines.<sup>280</sup> States that have not adopted the Model Guidelines have nonetheless made progress in changes to state regulatory board policy so as to encourage pain management and the use of opioids.<sup>281</sup> Studies indicate, however, that such changes have not substantially addressed physicians' concern about regulatory scrutiny.<sup>282</sup>

One primary reason for this has been an increase in high profile prosecutions at the state level related to

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<sup>277</sup> *Id.*

<sup>278</sup> Those states are Kentucky, Massachusetts, Missouri, Nevada, New Mexico, and Texas. *See* Joranson et al. supra note 14.

<sup>279</sup> *See* Aaron M. Gilson et al., *Improving State Medical Board Policies: Influence of a Model*, 31 J.L. MED. & ETHICS 119, 120 (2003).

<sup>280</sup> *See* supra note 273.

<sup>281</sup> *See* Joranson supra note 14. (surveying the positive changes that have occurred between 2000 and 2003).

<sup>282</sup> *See* Gilson supra note 279 and 129; *see also* Joranson supra note 14 at 18 ("Achieving balance and consistency in pain policy among the states remains an elusive goal.")

the prescription of opiates. One of the most dramatic cases involved Dr. Frank Fisher who was arrested by California state authorities in February of 1999.<sup>283</sup> He was charged with three counts of murder in connection with the oxycodone-related overdose deaths of three of his patients.<sup>284</sup> He was also charged with conspiring to defraud the state by filing \$2 million in false medical claims.<sup>285</sup> In 1998, Fisher had written 46% of all the prescriptions for 80-milligram OxyContin in the state.<sup>286</sup> The prosecutor explained the charges as follows: “It is the staggering amounts of this drug that were made available and under circumstances where it was reasonably foreseeable that these drugs would leak on to and become part of the illicit street market the forms the basis of the homicide charge.”<sup>287</sup> After spending four months in jail while facing charges, Fisher was released after his murder charge was reduced to manslaughter.<sup>288</sup> Finally, in 2003, all charges against Fisher were dropped, though he now is financially ruined and has been forced to move into his father’s home.<sup>289</sup>

Similar prosecutions have been undertaken across the country. Florida became the first state to convict a physician of manslaughter in 2002 when Dr. James Graves was sentenced to 63 years in prison in connection with the OxyContin-related overdoses of four of his patients.<sup>290</sup> Calling the death toll from prescription drug abuse “mass murder,” the Director of the Office of Drug Control for the state of Florida indicated that the case was intended to send a message: “We want to make an example out of those doctors who are violating the Hippocratic oath and the law. . . . Any professional who does that will suffer the consequences.”<sup>291</sup> In another case in California, Dr. Michael Huff and pharmacist Richard Ozar were charged in a 90-count

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<sup>283</sup> See Meier supra note 13 at 254-63 (for an overview of the Fisher case prior to all charges being dropped).

<sup>284</sup> *Id.* at 254.

<sup>285</sup> *Id.*

<sup>286</sup> *Id.* at 255.

<sup>287</sup> *Id.*

<sup>288</sup> *Id.* at 263.

<sup>289</sup> See Vartabedian supra note 143.

<sup>290</sup> See AP, *Doctor Given Long Prison Term for 4 Deaths Tied to OxyContin*, N.Y. TIMES, Mar. 23, 2003; see also Bill Kaczor, *Panhandle Doctor’s OxyContin Conviction to Send Message*, DENVER ROCKY MOUNTAIN NEWS, Feb. 20, 2002.

<sup>291</sup> See Fred Schulte, *State Drug Czar Pledges to Stem Painkiller Abuse*, BRADENTON HERALD, Aug. 1, 2003.

indictment for conspiracy and unlawful distribution of a controlled substance.<sup>292</sup> They face 20 years in prison for each of the 89 counts of unlawful distribution and 15 for the conspiracy count.<sup>293</sup> The assistant chief of the California Department of Justice indicated that the arrest was just the tip of the iceberg and that other arrests should be anticipated.<sup>294</sup> The merits of the above cases are not to be evaluated in this forum, and most, if not all, of them very well may have been legitimate actions to protect the public, but the effect they have on legitimate pain treatment is significant nonetheless.

Some states have also sent mixed messages about their commitment to addressing the problem of undertreatment of pain by placing additional obstacles in the way of legitimate pain patients obtaining the medication they need. In response to the OxyContin abuse problem, at least nine states have imposed restrictions on Medicaid payments for the drug.<sup>295</sup> Vermont was the first state to take this step when then-Governor Howard Dean ordered a halt to not only Medicaid payments for OxyContin, but also to all state-funded health care payments for the drug.<sup>296</sup> Though he left an exception for terminal cancer patients and those suffering from sickle-cell anemia, he nonetheless suggested pharmacies remove the drug from their shelves.<sup>297</sup> South Carolina instituted similar restrictions, though they also allowed an exception for AIDS patients.<sup>298</sup> Alabama, Maine, Florida, Michigan, Mississippi, North Carolina and West Virginia have placed limits on the amount of the drug a Medicaid patient can receive without prior approval from a state official.<sup>299</sup>

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<sup>292</sup> See Amanda Covarrubias, *Doctor, Pharmacist Arrested Over Pills*, L.A. TIMES, Dec. 3, 2003.

<sup>293</sup> *Id.*

<sup>294</sup> *Id.*

<sup>295</sup> See Linda Marsa, *OxyContin Abuse May Curb Progress in Pain Field*, L.A. TIMES, Aug. 13, 2001.

<sup>296</sup> See *Vermont State Will Stop Paying for Painkiller OxyContin*, L.A. TIMES, Jul. 20, 2001.

<sup>297</sup> See Charley Gillespie, *Getting OxyContin Can Be Ordeal for Those Who Need It*, L.A. TIMES, Oct. 14, 2001.

<sup>298</sup> *Id.*

<sup>299</sup> *Id.*

## V. Principles for Reform

### *a. The Need for Balance*

If there is something that all sides agree on in the debate over prescription drug abuse and the undertreatment of pain it is that the status quo is not working. Physicians feel persecuted, patients suffering from chronic and end of life pain are still vastly undertreated, and the destruction caused by prescription drug abuse and diversion is only growing. The answer to the policy dilemmas will not be found, however, until balance is restored to the debate and both sides – the pain relief community and law enforcement officials – realize that the other has legitimate and necessary goals to pursue. As the World Health Organization Expert Committee on Cancer Pain Relief and Active Supportive Care articulated their vision for reform: “. . . governments have the right to impose further restrictions if they consider it necessary, to prevent diversion and misuse of opioids. However, this right must be continually balanced against the responsibility to ensure opioid availability for medical purposes. . . .”<sup>300</sup>

As it currently stands, some vocal players in the debate are pursuing solutions that ignore the need for this balance. On the law enforcement, anti-addiction side, a small minority is advocating an outright prohibition on opiates like OxyContin.<sup>301</sup> A larger number, including the DEA, seek to stem the problem of OxyContin by limiting its availability to only those in severe pain, and to only allow pain specialists to prescribe the drug.<sup>302</sup> A recent FDA advisory committee rejected both of those proposals late last year.<sup>303</sup> A proposal to limit its availability to patients in severe pain was defeated by a vote of 13-5 with opponents of the

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<sup>300</sup>See WORLD HEALTH ORGANIZATION, *CANCER PAIN RELIEF: WITH A GUIDE TO OPIOID AVAILABILITY*, 55 (1996) (available at: <http://whqlibdoc.who.int/publications/9241544821.pdf>).

<sup>301</sup>See *West Virginia Bill Sought to Ban OxyContin*, PHARMACIST.COM, Mar. 15, 2002 (available at: [http://www.pharmacist.com/articles/d\\_dn\\_0009.cfm](http://www.pharmacist.com/articles/d_dn_0009.cfm)) (the state senator who sponsored the bill sought to ban OxyContin within West Virginia because “people just can’t handle it, and it’s costing our state untold millions already. . . that’s just dollars, not to mention destroyed lives.” The bill did not make it out of committee).

<sup>302</sup>The DEA and Rep. Hal Rogers of Kentucky recently recommended that the FDA restrict access to OxyContin only to patients with “severe pain” and to prohibit non-pain specialists from prescribing it. See Doris Bloodsworth, *FDA Urged to Get Tougher on Drug’s Maker*, ORLANDO SENTINEL, Oct. 19, 2003.

<sup>303</sup>See Gardiner Harris, *Drug Panel Rejects Plea to Curb Sales of a Widely Abused Painkiller*, N.Y. TIMES, Sep. 11, 2003.

proposal arguing that such ambiguity would hurt legitimate pain patients and invite prosecutions or fear of prosecution.<sup>304</sup> Restrictions on access to the drug to pain clinics or pain specialists were also rejected with the panel citing the effect that such restrictions would have on legitimate patients in rural areas.<sup>305</sup>

Similarly, those who seek to advocate pain advocacy must also acknowledge and confront the legitimate problems of addiction and abuse that come along with large-scale use of opioid analgesics. Though some advocates seem unwilling to acknowledge that corrupt doctors exist, there are legitimate cases where physicians have misused their position as a gatekeeper to controlled substances for improper ends.<sup>306</sup> Law enforcement should be commended for identifying and punishing such criminals, and pain-relief advocates should actively seek to cooperate to develop strategies to combat such abuse. They should also acknowledge, as Russell Portenoy has done, that pain-relief advocates have, at times, failed to adequately confront the policy challenges and trade-offs that come with pursuing an aggressive pain treatment agenda. As he explains it, there had been

a tacit reluctance on the part of supporters, including pain specialists, those in the media who had been portraying the problem of undertreatment, patient advocates and industry to discuss the legitimate risk associated with opioid toxicity and abuse addiction because of the concern that if we opened up Pandora's box and talked about addiction and abuse, all of the progress that had been made during the past ten years would be lost. . . . There has been a bit of a tacit understanding that we won't talk about it too much. We do need to talk about it.<sup>307</sup>

In order for workable policy solutions to be crafted, both sides must lend their expertise to the challenge with a joint commitment to a balanced policy that takes the threat of both the epidemics of undertreatment of pain and of prescription drug abuse seriously.

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<sup>304</sup> *Id.*

<sup>305</sup> *Id.*

<sup>306</sup> See, for example, *Doctor Pleads Guilty in Prescription Case*, N.Y. TIMES, Mar. 15, 2004 (physician convicted for dispensing OxyContin prescriptions in exchange for clients posing in various states of undress); Torsten Ove, *Doctor Guilty on 153 Drug Charges*, PITTSBURGH POST-GAZETTE, Mar. 10, 2004 (doctor convicted of 153 counts of distributing OxyContin and other controlled substances to female patients in exchange for sex).

*b. The Need for More Research*

Considering the number of people adversely affected by the undertreatment of pain and the abuse of prescription drugs, it is remarkable that there has not been more research done on some of the questions central to the most important policy debates. One of the most important questions that requires further study is the true addiction rate for long-term use of opioid analgesics in chronic pain patients. It appears that the previous studies relied upon by pain-relief advocates have been deemed inconclusive at best.<sup>308</sup> Even leading physicians in the pain relief movement cannot say with confidence what the average rate of addiction will be in such a context.<sup>309</sup> Being able to accurately identify the rate of iatrogenic addiction with opioid analgesics is of paramount importance in providing physicians with enough data to make appropriate medical judgments when confronted with chronic pain patients.

Additional data that policy makers require, but that is not currently available is the percentage of the OxyContin abuse problem that can be traced back to various origins.<sup>310</sup> How many OxyContin addicts became addicted through legitimate physician-initiated prescriptions? What percentage instead is made up of heroin users who use OxyContin as a substitute when heroin is not available? How many OxyContin addicts are poly-drug addicts who began using OxyContin as a compliment to their other use? How many addicts only abuse opioids regardless of where their addiction originated? Researchers have recently found that while some powerful painkillers such as hydrocodone have abuse rates that track proportionally to the amount of production, OxyContin abuse is outstripping production levels.<sup>311</sup> Explanations for this different trajectory are currently lacking and need to be explored further.

Too much of the current policy debate operates as if the elimination of OxyContin would end the abuse

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<sup>308</sup> See supra note 193.

<sup>309</sup> See James Zacny, *Trends in the Abuse of Prescription Opioid Drugs*, February 6, 2002 (available at: [www.painandchemicaldependency.org/presentations/FRIDAY/GRANDBALLROOM/3Zacny900am.pdf](http://www.painandchemicaldependency.org/presentations/FRIDAY/GRANDBALLROOM/3Zacny900am.pdf)).

<sup>310</sup> *Id.*

<sup>311</sup> *Id.*

problem. Similarly, too many on the other side of the debate argue on the assumption that eliminating deceptive patients and uneducated physicians would eliminate the problem of abuse all together. In fashioning policy to minimize abuse, it is essential that policy makers are able to properly identify the origins and scope of the abuse in question.

One area of research that is currently moving forward and carries great potential is the current search for a method to produce opioid analgesics like OxyContin in a way that eliminates, or significantly lowers, the potential for abuse.<sup>312</sup> Purdue Pharma has already invested more than \$150 million in developing an antagonist—a second drug added to the original drug that seeks to counter certain negative effects—that would neutralize the euphoric effect of the drug if was tampered with.<sup>313</sup> For those who took the pill as directed, the pill would dissolve in the stomach as intended and deliver the necessary pain relief.<sup>314</sup> Purdue is hopeful that this new version of OxyContin, incorporating an antagonist, will be available by 2007.<sup>315</sup> Though such attempts to find a “magic bullet” to the opioid problem have been ongoing for over eighty years<sup>316</sup> – with creative addicts frequently finding ways to defeat the systems developed – it is a path of research that has the potential to benefit society significantly, and as such it an effort that should be supported not only by the private sector, but by the public sector as well.

### *c. Creating Safe Harbors*

In light of the fact that fear of sanction is a leading reason cited by physicians for their failure to properly

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<sup>312</sup>See Blakeslee supra note 108.

<sup>313</sup>See Andrew Pollack, *Company Said to Develop Substitute for Painkiller*, N.Y. TIMES, Nov. 25, 2003. (also discusses a claim by another company, Pain Therapeutics, that claimed it had developed a tamper-proof substitute for OxyContin); see also Blakeslee supra note 108.

<sup>314</sup>*Id.*

<sup>315</sup>*Id.*

<sup>316</sup>See Acker supra note 67 at 74-93 (for an overview of the effort in the 1920's to find a non-addicting opioid analgesic); see also Blakeslee supra note 108 (describing addicts successful effort to subvert technology to counter the addictive tendencies of opiates in 1900's).

treat pain, it seems logical that efforts should be made to refine state and federal laws to provide clear safe harbors for physicians treating pain according to accepted treatment guidelines. There are a number of provisions to state pain policies that have been cited as likely to encourage further pain treatment.<sup>317</sup> Some of these include:

1. The recognition that controlled substances are necessary to the public health.
2. The recognition of pain management as a part of general medical practice.
3. The recognition that the medical use of opioids is a legitimate professional practice.
4. The encouragement of pain management
5. Concerns about regulatory scrutiny should be addressed and recognized
6. A prescription amount on its own is not sufficient to determine the legitimacy of a prescription
7. Physical dependence and tolerance are not confused with “addiction.”<sup>318</sup>

Provisions that currently exist in a number of state pain policies that deter adequate pain treatment include:

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<sup>317</sup> See Joranson et al, supra note 14.

1.

A statement that opioids should only be used as a treatment of last resort.

2. Provisions where the belief that opioids hasten death is perpetuated

3.

Provisions are ambiguous regarding liability<sup>319</sup>

Certainly such reforms should be encouraged. It must be acknowledged, however, that reforms in terms of safe harbor provisions can only achieve so much. In fact, studies have found that physicians vastly overestimate the potential for regulatory or criminal sanction that may result from aggressive pain treatment.<sup>320</sup> While certainly the increase in prosecutions at the federal and state levels in recent years should be of concern to doctors, simply asserting a fear of regulation, even when clear standards of appropriate pain care are available, is not a sufficient justification to ignore the pain needs of a patient in most cases.<sup>321</sup> As Ben Rich argues:

Rather than continuing the rhetoric of the last quarter century that speaks of scaling these barriers with no accountability on the part of the health care system for reform, we should design strategies for eradicating them which entails the active involvement of the medical profession as a whole. Nothing would bring these long-standing barriers down more quickly than a concerted effort on the part of organized medicine.<sup>322</sup>

### *c. Education*

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<sup>320</sup> See Martino *supra* note 36 at 332 (“the perception of regulatory risk far exceeds the reality”); *see also* Lovrich Jr. & Ziegler *supra* note 41; Alpers, *supra* note 36.

<sup>321</sup> See Rich *supra* note 11 at 64-67 (calling on physicians to take the moral responsibility to ensure that their patients are treated adequately).

Building on Rich's argument, the medical establishment does bear a great deal of responsibility for the failure to properly address the problem of pain both currently and in the past. Vast numbers of physicians lack the proper training to treat pain adequately and thus could not make progress in alleviating suffering even if the threat of regulatory discipline ceased to be an issue.<sup>323</sup> Indeed, a lack of proper education in pain education has been cited by many as major contributing factor to the explosion of OxyContin abuse – doctors simply did not understand how to use opioid analgesics, nor did they understand how to identify and prevent abuse. As Russell Portenoy—a champion of encouraging aggressive opioid-based pain treatment—explained the problem:

Generalists are adopting the therapy without adequate knowledge of pain management principles. . . .but without adequate knowledge of opioid pharmacology and addiction medicine principles and thereby perhaps placing patients at risk for the adverse effects of opioid drugs in this broad phenomenon of chemical dependency that wouldn't be there if the clinicians had better skills and training in addiction medicine principles.<sup>324</sup>

If serious progress is going to be made on either the pain or the abuse front, immediate steps must be taken to both require pain education in medical school and to require it on an ongoing basis throughout physicians' careers.

To achieve this, several immediate steps could be taken. First, the federal government could require that medical schools institute pain and palliative care training as a condition of federal funds.<sup>325</sup> Second, the federal government could require physicians take continuing education classes in both pain treatment and in the identification and prevention of addiction and abuse before they were granted registration to dispense

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<sup>323</sup> See supra Section II, B, 2.

<sup>325</sup> See Amy J. Dilcher, *Damned if They Do, Damned if They Don't: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain*, 13 ANNALS HEALTH L. 81, 120 (2004).

controlled substances.<sup>326</sup> Both state medical boards and DEA officials should be also required to take similar training courses to ensure that their knowledge is in line with the state of the art in pain management techniques.

#### *d. Accountability*

Though legislative reform of safe harbors and increased education can certainly help to make progress in encouraging adequate pain care, some argue that simply stopping there will not be enough. Advocates such as Kathryn Tucker of Compassion in Dying and Ben Rich argue that physicians should be held up to regulatory scrutiny and civil suits not just for overtreatment of pain, but also for undertreatment of pain as well.<sup>327</sup> Certainly, there is evidence to suggest that the mere existence of available education and regulatory safe harbors will sometimes be inadequate to change physician behavior on its own.<sup>328</sup>

That being said, increased liability exposure and regulatory scrutiny in this area may have the effect of driving future doctors away from pain-relief intensive practices and further add to the cloud of regulatory scrutiny that has already been cited as a source of concern in the medical profession.<sup>329</sup> While disciplinary action for undertreatment should always be available for egregious cases of negligence, it is not a spirit of confrontation, but rather a spirit of partnership between physicians, state medical boards and law enforcement that needs

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<sup>326</sup>A number of states have begun requiring similar training. See Cal. Bus. & Prof. Code §§ 2089, 2190.5 (West 2003) (requiring medical training and continuing education in pain management and end-of-life care); W. Va. Professions and Occupations Code § 30-1-7a (2001) (mandating continuing education in end-of-life pain treatment).

<sup>327</sup>See Kathryn Tucker, *A Piece of the Puzzle: Bringing Accountability to Failure to Treat Adequately*, 6 JOURNAL OF PALLIATIVE MEDICINE 615, 615-617 (2003); Kathryn Tucker, *Improving Pain Care: A Safe Harbor is Not Enough*, 11 HEALTH LAWYER 15 (1999); supra Rich note 11 at 70-90.

<sup>328</sup>Another finding of the SUPPORT study discussed earlier was that even after an intensive period of physician education regarding the state of mind of patients and the physician's legal protections, the failure to abide by end of life wishes and the undertreatment of pain at the end of life continued to persist at the previous troubling levels. See supra note 6.

<sup>329</sup>See Martino supra note 36 at 344.

to be fostered to at this time to begin to make progress again against the undertreatment of pain.

*d. Cultural Shift & Partnership*

If real progress is going to be made in finding an acceptable policy balance, strategies must be implemented to build trust between law enforcement and physicians. Unlike the traditional model of law enforcement toward illegal drugs, there is no reason to believe that the overwhelming majority of physicians don't have the same policy goals in terms of stemming abuse and addiction as their law enforcement partners. In that vein, law enforcement should work to develop ways to integrate the medical profession as partners, rather than adversaries, in the mission to stem the tide of opioid abuse. Similarly, physicians must begin to take personal and institutional responsibility for the epidemic of undertreatment and take immediate steps, beyond simply decrying physician prosecutions, to institute radical policy changes to ensure that all physicians are adequately trained in pain relief and the identification of prescription drug abuse and addiction. Together with this, they must actively engage law enforcement in a constructive fashion to development joint plans for curbing abuse of prescription drugs.

**VI. Conclusion**

Tens of millions of Americans suffer, and are in some cases debilitated, by chronic pain. Most Americans, at some point, will be faced with terminal illness. Pain is a problem that has existed for as long as man itself. For the first time, however, there is medical technology available that can allow those who previously had to suffer the chance to regain their independence or to enjoy the final days life in peace. It is an opportunity that

must be seized and the continuation of unnecessary suffering is shameful both to the medical establishment and to policy makers who contribute to the problem.

With that in mind, it must be remembered that policy choices are not made in vacuums. As the OxyContin crisis has shown, even well intentioned pain relief efforts can have dramatic and devastating unintended consequences. Though millions benefit from the use of opioid analgesics, millions also suffer from them as well. Though many see opioid analgesics such as OxyContin as a miracle drug, dozens of communities in Virginia, Kentucky and Maine see it as a source of financial, moral and social destruction.

It is the challenge of policy makers in the next decade, within both the medical profession and in law enforcement to take suffering, suffering of all forms, seriously. Cooperation, therefore, must be a paramount guiding principle. As Bruce Levin, a pain management fellow at Bellevue Hospital in New York City explains his goal in treating pain patients, “We can’t take away pain altogether, but we can modulate it. . . We kind of see ourselves as the last barrier between the patient and a life of agony.”<sup>330</sup> For law enforcement officers seeking to counter the agony inflicted on families and communities by prescription drug abuse, it is a message to which they certainly can relate.

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<sup>330</sup>Dr. Sandeep Jauhar, *Calling in the Pain Team, Specialists in Suffering*, N.Y. TIMES, June 23, 2002.