



The Use and Misuse of OxyContin

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The Use and Misuse of OxyContin

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Abstract

This paper examines the phenomenon of OxyContin abuse over the past two years. The prescription painkiller has been hailed as both a wonder drug and a killer. Both descriptions are accurate. The trouble is not with the pill itself but rather the environment into which it was released. The medical community lacked the experience with pain and addiction necessary to prescribe the powerful drug appropriately. As OxyContin was released in 1995, neither its manufacturer nor governmental agencies did anything to remedy these circumstances or protect against the eventual outcome. After nearly four successful years on the market,

ubiquitous reports of addiction and overdoses filled the headlines. While in many ways the extent of the problem has been overstated by the media, that one exists is undeniable. Distinct from the concurrent growth of prescription drug abuse in general, OxyContin abuse has been particularly devastating to those individuals and areas affected. The best solutions focus on deterring and combating abuse and diversion, while ensuring access to the drug for the millions who benefit from it.

Table of Contents

I. The Environment	5
II. The Product	16
III. The Problems	24
IV. The Causes and Responses	45
V. The Lessons and Solutions	67

The Use and Misuse of OxyContin

Over the past year a flood of articles have appeared across the nation detailing the saga of the prescription painkiller OxyContin. Generally, the abuse of prescription drugs has been left out of the journalistic spotlight. With complicated names and a stamp of approval from the FDA and medical community, these drugs, while widely used and abused, do not make for hot-selling stories. For a number of reasons, though, OxyContin has managed to grab the nation's attention. A January 8th article in the *Boston Herald* epitomizes the type of story to which the public has become accustomed regarding this controversial drug. A retired disabled firefighter in Massachusetts, a state that has been devastated by the criminal side effects attributed to OxyContin, robbed an OSCO pharmacy of 500 doses of the drug. No money was asked for or taken. The firefighter explained that his legitimate prescription of the drug, that had been prescribed to treat chronic pain from injuries he sustained on the job, was stolen and that his doctor refused to prescribe more. Out of desperation he robbed the pharmacy. Even police officers involved with the arrest described the man as a "really sad case."¹ What would drive a retired firefighter to hold-up a pharmacy for pills? Why would his doctor not just have prescribed more? These questions have brought OxyContin into a national debate and, in the process, raised a whole host of new questions.

I. The Environment

OxyContin is manufactured by Purdue Pharma L.P. (Purdue), a pharmaceuticals company based in Stamford, Connecticut. As a private family owned business, Purdue is a relative rarity in the continuously

¹Tom Mashberg, 'Sad Case' Suspect Held in OxyContin Heist, B. HERALD , Jan. 8, 2002, at 14.

consolidating pharmaceuticals industry. Rather than a faceless conglomerate, as one might expect to find in a modern pharmaceuticals scandal, Purdue is owned by two brothers in their 80's, Drs. Mortimer and Raymond Sackler. Under their ownership, a global company with over \$1.5 billion in annual revenue has grown from a small Greenwich Village operation (Purdue Frederick Co.) with \$20,000 in revenue.² Today Purdue Frederick Co. operates as a subsidiary of Purdue, handling over-the-counter products, while Purdue Pharma L.P., which was created by the Sacklers in 1991, develops and markets new prescription drugs, such as OxyContin. Other Purdue subsidiaries are Purdue Biopharma L.P., Mundipharma International Ltd. and Napp Pharmaceuticals.³ The brothers are prodigious philanthropists and have been honored around the world. Despite their public generosity, though, the founders have remained very private in their personal and business affairs. In addition, the private legal character of their companies makes any analysis of it or its internal workings difficult. Unlike a public corporation, the Sacklers' businesses are not subject to the stringent SEC reporting requirements.

The Sackler brothers and the team they assembled in the various Purdue companies have become pioneers in the treatment of pain in recent years. The Sacklers first began to work on prescription pain medication through Napp Pharmaceuticals, which operates out of Cambridge, England. Napp was asked by a hospital in London to develop a morphine pill for their patients in the late 1970's. Previously, the hospital had delivered morphine intravenously, which did not provide sustained relief and limited patients' mobility. In response, Napp introduced MsContin in 1984. During it's peak in the late 1990's MsContin brought in approximately \$170 million in revenue each year, which is significant, but pales in comparison to later sales of OxyContin.⁴

²Stacy Wong, *Thrust Under Microscope; Stamford Drug Company's Low Profile Shattered by Controversy Over Abuse of Painkiller OxyContin*, THE HARTFORD COURANT, Sept. 2, 2001, at D1.

³DIRECTORY OF CORP. AFFILIATIONS: U.S. PRIVATE COMPANIES (National Register Publishing 2001).

⁴Wong, *supra* note 2.

Purdue’s amazing growth is in many ways a testament to the large market for pain relieving products. The treatment of pain has only in recent years become a priority for medical professionals. Even the federal government has taken notice of the trend, declaring the current decade the “Decade of Pain Control and Research.”⁵ The scope of the problem of pain and its effects is enormous. Studies estimate that up to 50 million Americans suffer from chronic pain.⁶ Pain specialists often classify pain into three categories: acute pain, cancer-related pain and chronic non-cancer related pain. Acute pain is the type that results from tissue damage during trauma or surgery and usually heals quickly. Chronic non-cancer pain, which is usually found in the joints, back, neck and head, is usually defined as pain that lasts longer than the expected time frame for healing and is not associated with progressive non-cancer disease. Cancer-related pain refers to pain associated with cancer and its treatment.⁷ Studies focusing on cancer-related pain have found that 30 percent of patients have pain at the time of their diagnosis, while in the advanced stages 65 to 85 percent report chronic pain.⁸ Studies estimate the costs associated with chronic pain in the U.S. at approximately \$100 billion.⁹ There are many ways in which pain inflicts harm in economic terms. Treated improperly, pain results in missed workdays, unnecessary doctor visits and hospital stays, unnecessary medical procedures, ingestion of inappropriate medication, and costs associated with patient self-treatment.

Despite such high physical and financial costs, throughout the years pain has not been a priority of the medical profession and has consistently gone under-treated. One major barrier to effective treatment has been a lack of focus on the issue in medical education. According to the Association of American Medical

⁵*Decade of Pain Control Research Begins January 1, 2001*, AM. ACAD. OF PAIN MED., at http://painmed.org/news/pdf/decade_statement.pdf (Oct. 31, 2000).

⁶Carolyn Kleiner, *A Curse and a Cure*, U.S. NEWS & WORLD REP., Aug. 6, 2001, at 42.

⁷Michael A. Ashburn & Peter S. Staats, *Management of Chronic Pain*, 353 LANCET 1865 (1999).

⁸Michael H. Levy, *Pharmacologic Treatment of Cancer Pain*, 335 NEW ENG. J. MED. 1124 (1996).

⁹Jane E. Brody, *Misunderstood Opioids and Needless Pain*, N.Y. TIMES, Jan. 22, 2002, at F8.

Colleges, only 1 of the 125 accredited U.S. medical schools requires a separate course on pain management. While pain management is a component of a required course at 113 of the schools, only 44 offer a separate course on the topic as an elective.¹⁰ This lack of formal training is reflected in a lack of confidence on the part of practitioners when confronted with the treatment of pain. A recent study in the Journal of the American Medical Association (JAMA) reported that 25 percent of family medicine residents and 27 percent of internal medicine residents felt unprepared to manage pain.¹¹ The lack of formal training not only leaves many physicians unprepared to address pain appropriately and effectively, but also adds an air of informality to the treatment. While the practice of medicine and the treatment of disease are highly quantified and regimented, the treatment of pain has, until recently, been a much more ad hoc practice, leaving doctors in many ways free to deal with it as they see fit.

For the aforementioned reasons, then, a uniform approach to the identification and treatment of pain has been slow to develop. In addition, a lack of communication between patients and medical professionals also inhibits more effective treatment. Due to their lack of training on the topic doctors often may not even inquire as to a patient's pain. In addition, studies have shown that when they do inquire, doctors tend to discount the severity, believing patients to be poor judges and prone to exaggeration.¹² Finally, patients, themselves, may underreport pain for a number of reasons, such as a fear that acknowledging pain is an acknowledgment of illness and the virtue attributed to a stiff upper lip. As pain is a subjective phenomena, patient reticence on the matter can impede treatment seriously.

Overall, then, doctors' lack of training and confidence in the treatment of pain and the inherent difficulties of diagnosing it, suggest great opportunities for improvement. When combined with the prevalence and scope of

¹⁰LIASON COMM. ON MED. EDUC. PART II, AAMC INSTITUTIONAL PROFILE SYS., ANNUAL MEDICAL SCHOOL QUESTIONNAIRE FOR 1999-2000, available at <http://www.aamc.org> (last visited Apr. 27, 2002)

¹¹David Blumenthal et al., *Preparedness for Clinical Practice: Reports of Graduating Residents at Academic Health Centers*, 286 JAMA 1027, 1028 (2001).

¹²Rebecca Drayer et al., *Barriers to Better Pain Control in Hospitalized Patients*, 17 J. PAIN SYMPTOM MGMT. 434, 434-439 (1999).

pain in this country, one can see how a product like OxyContin could grow so rapidly, while at the same time raise so many questions. A final major hurdle to effective pain treatment, though, is particularly relevant to an examination of the use and misuse of OxyContin. While many doctors' experience with the treatment of pain is largely anecdotal, one fairly consistent thread is a fear of patient addiction to medication. Particularly, the utilization of opioid analgesics to treat chronic pain has been limited by such concerns. Short-acting opioids like Percocet are freely used to treat acute pain, where due to the short-term time frame of the treatment, addiction is less likely.¹³ Doctors fears of prescribing opioids for chronic pain were reinforced by state medical boards, which recommended against the practice and considered investigating any physician who prescribed them.¹⁴ Opioids work by attaching to proteins called opioid receptors in the brain, spinal cord, and gastrointestinal tract and blocking the transmission of pain messages to the brain. Opioid drugs also can cause euphoria by affecting the areas of the brain that moderate pleasure. In addition, opioids can induce drowsiness, constipation, and, if taken in large amounts, depress respiration.¹⁵

For centuries, opium and its derivatives have been thought of as a "double-edged sword – the most effective painkiller on earth and also the most addictive substance."¹⁶ Both morphine and oxycodone, the primary chemical ingredient in OxyContin, fall into this category, although morphine is more popularly known. Illicit drugs, most notably heroin, also belong to the group. In many ways, it was morphine's infamy as a highly addictive and abused drug that led scientists to work on alternative opioid analgesics. Both patients and doctors were hesitant to use morphine due to its negative connotation even when its use was appropriate.

Pharmacologically, oxycodone is a semi-synthetic opioid, similar in structure to codeine and equivalent to

¹³*Drawing the Line Between Pain Management and Addiction*, 9 PSYCHOPHARMACOLOGY UPDATE 1, 3 (2001).

¹⁴*Hearing on the Dangers of OxyContin, Before the House Appropriations Committee*, 107th Cong. 98 (Dec. 11, 2001) [hereinafter *House Hearing*] (statement of Peter Staats, Director, Division of Pain Medicine, Johns Hopkins).

¹⁵Claudia Kalb et al., *Playing with Pain Killers*, NEWSWEEK, Apr. 9, 2001, at 44.

¹⁶Paul Tough, *The Alchemy of OxyContin*, N.Y. TIMES MAG., July 29, 2001, at 32.

morphine in its production of opioid effects. The first published report of oxycodone and its “euphoria-like” effects was in 1920’s Germany.¹⁷ As an analgesic, oxycodone is especially valued for its potency. 5 milligrams (mg) of orally administered oxycodone has the equivalent analgesic effect as 30 mg of codeine or a 10 mg dosage of morphine.¹⁸ In this way, although structurally related to codeine, oxycodone is widely described as morphine-like in all respects, including its potential for dependence.

In the field of addiction, a distinction has been drawn between tolerance and physical dependence on the one hand and addiction on the other. Addiction is generally defined as the “repeated, compulsive use of a substance despite adverse social, psychological and/ or physical consequences.”¹⁹ Alternatively, a patient who has developed a tolerance to a medication will require higher dosages to obtain similar levels of relief over time. The physical dependence associated with some drugs can be treated by gradually reducing the dosages of the medication to the point where a patient is drug-free and has no withdrawal symptoms or craving. After such a process, though, an addict, as opposed to someone who was only physically dependent on the drug, will continue to have severe and uncontrollable cravings that will frequently result in a return to the drug.²⁰ This distinction is very important to proponents of opioid therapy, particularly for the treatment of chronic pain. As described earlier, one of the major inhibitors of effective pain treatment in modern medicine has been a fear of addiction. If doctors believe that patients who are prescribed opioid analgesics are likely to become addicted and abuse these drugs, they are unlikely to prescribe them. While tolerance and physical dependence can be effectively counteracted, addiction is not so easily treated.

It was not until the late 1980’s that modern medicine began to become comfortable with the use of opioids

¹⁷LAURA M. NAGEL & PATRICIA M. GOOD, DEA INDUSTRY COMMUNICATOR: OXYCONTIN SPECIAL (2001).

¹⁸G.B. Curtis et al., *Relative Potency of Controlled-Release Oxycodone and Controlled-Release Morphine in a Postoperative Pain Model*, 6 EUR. J. CLIN. PHARMACOLOGY 425 (1999).

¹⁹*Drawing the Line Between Pain Management and Addiction*, *supra* note 13.

²⁰*Id.*

to treat pain. During the following years, the under-treatment of pain became more highly publicized, with many studies backing up the claims. The medical community began to rethink its staunch resistance to the use of opioids, especially in the treatment of cancer pain. The shift in perception had tangible results, as evidenced by a 59 percent increase in medically prescribed morphine use between 1990 and 1996.²¹ As described earlier, this is also the time period in which Purdue released its morphine-based pain medication, MsContin.

As the medical community became more comfortable with the use of opioids, prior unsubstantiated fears of addiction were replaced by a more nuanced picture. For example, a report by the National Institute of Drug Abuse indicates that that “properly managed medical use of opioid analgesic drugs is safe and rarely causes clinical addiction.”²² A study in JAMA found that between 1990 and 1996 there was a 23 percent increase in the medical use of oxycodone, but a 29 percent decrease in mentions of abuse. The study concluded that the increased medical use of opioid analgesics did not appear to contribute to increases in the health consequences of opioid abuse.²³ A number of other studies have shown that patients properly treated with opioids have about a 1 percent chance of becoming addicted. One pain specialist describes the effects on patients of properly prescribed opioids as, “[t]hey don’t get goofy, high, or giddy and there’s no euphoria—the pain is simply gone.”²⁴ In this way, then, the use of opioids to treat long-term pain came to be seen as more acceptable. Whereas, previously, much of the medical community would have only considered this type of treatment for cancer pain, doctors began to see opportunities in the treatment of chronic non-cancer pain.

For example, one study, sponsored by Purdue, and published by the Archives of Internal Medicine, found

²¹David E. Joranson et al., *Trends in Medical Use and Abuse of Opioid Analgesics*, 283 JAMA 1710, 1710-14 (2000).

²²NAT’L. INST. ON DRUG ABUSE, PRESCRIPTION DRUGS: ABUSE AND ADDICTION, at <http://165.112.78.61/ResearchReports/Prescription/prescription2.html#Safe> (last modified Feb. 21, 2002).

²³Joranson et al., *supra* note 21.

²⁴Kleiner, *supra* note 6.

that around-the-clock controlled-release oxycodone therapy was safe and effective for patients with moderate to severe chronic osteoarthritis-related pain.²⁵

The use of opioid analgesics, though, is clearly not without risks. As the aforementioned studies noted, even in properly administered programs, there is a small risk of addiction. In addition, perhaps most under-emphasized in these studies, and more importantly by those who read them, was that opioid analgesics were not addictive only when taken according to appropriate directions. Taken improperly, these drugs can have the same addictive qualities as heroin. Doctors' inexperience with the treatment of pain and the appropriate use of opioids is matched, in many ways, by their lack of training regarding addiction. As explained, the use of opioid analgesics over an extended period necessarily involves consideration of both tolerance and physical dependence. These aspects of the medication are common and standard practice provides for them. The conditions and onset of addiction, on the other hand, are not so clear nor easily treatable. Addiction is a result of numerous factors, distinct from those which affect tolerance and physical dependence. These factors, though, are not well understood by a large portion of the medical community. A recent survey of primary care physicians found that, as in the case of the treatment of pain, inadequate coverage of substance abuse in medical school left many doctors unprepared to diagnosis addiction in their patients. Only 30 percent of physicians felt that they were "very prepared" to identify prescription drug abuse, while more than 80 percent felt very prepared to diagnose other common conditions, such as hypertension and diabetes (even 44 percent considered themselves very prepared to diagnose depression).²⁶ In this way, then, addiction is not very well understood by much of the medical community.

In many ways, OxyContin was released into a medical environment ill prepared to deal with it. As a powerful

²⁵Sanford H. Roth, MD et al., *Around-the-Clock, Controlled-Release Oxycodone Therapy for Osteoarthritis-Related Pain*, 160 ARCH. INT. MED. 853, 853 (2000). See also Russell K. Portenoy, *Current Pharmacotherapy of Chronic Pain*, 19 J. PAIN SYMPTOM MGMT. S16 (2000) (discussing the evolving role of opioids in the treatment of non-cancer pain).

²⁶CTR. ON ADDICTION AND SUBSTANCE ABUSE (CASA) AT COLUM. U., THE CASA NATIONAL SURVEY OF PRIMARY CARE PHYSICIANS AND PATIENTS ON SUBSTANCE ABUSE (2000), available at http://www.casacolumbia.org/publications1456/publications_show.htm?doc.id=29109 (last visited Apr. 27, 2002).

opioid analgesic, OxyContin was developed to treat a condition not very well understood by physicians (pain) with potential side effects (addiction) that physicians were not trained to identify. This state of affairs set the stage for a product with remarkable possibilities, both positive and negative. It is unsurprising, then, that both ends of the spectrum have been realized. The development and release of OxyContin, though, did not take place in a vacuum. The evolving attitudes towards and acceptance of the use of opioid analgesics to a large degree coincided with the release of more of these products. While the chemical and physical properties of the medications, themselves, are relatively well known, the circumstances surrounding the actual distribution and acceptance of the medication involve a complex mixture of circumstances.

In the treatment of chronic pain, both cancer and non-cancer, there are three generally recognized alternatives. Adjuvant analgesics are medications whose primary indications are not for pain relief, but nevertheless can reduce pain in some cases. Antidepressants are an example of this relatively uncommon type of analgesic, which have limited applicability. Much more common are non-opioid analgesics, such as acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs), like aspirin or Aleve.²⁷ These analgesics, though, have numerous drawbacks. Acetaminophen has been shown to cause liver damage when used in high doses or over long periods of time. It was the fifth most common drug mentioned in drug-related visits to hospital emergency rooms in 2000 (the top four were alcohol-in-combination, cocaine, heroin/morphine and marijuana, while oxycodone ranked fourteenth).²⁸ NSAIDs also pose serious risks to health and are associated with major gastrointestinal damage, including ulcers. In 2000, approximately 16,000 people died from treating their arthritis with NSAIDs.²⁹ As a result, their use in the treatment of moderate chronic pain, such as

²⁷Portenoy, *supra* note 25.

²⁸OFFICE OF APPLIED STUD., SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION [hereinafter SAMHSA], YEAR-END 2000 EMERGENCY DEPARTMENT DATA FROM THE DRUG ABUSE WARNING NETWORK [hereinafter DAWN], DAWN SERIES D-18 (2001).

²⁹Eric Cheven, *A Bad Prescription from the DEA: The Drug Agency's Misguided Campaign Against a Painkiller*, WEEKLY

arthritis, is limited due to the potential for serious side effects. While the risks of these drugs are clearly very high, their potential benefits are limited. Most limiting is the fact that they are ineffective in treating severe pain. NSAIDs have a ceiling effect beyond which taking more of the medication will not result in more pain relief. Therefore, the pain medications most commonly used until recently had real shortcomings. It is within this niche, the treatment of moderate to severe chronic pain, that a drug like OxyContin was most needed. Of the available medications, opioids were seen as the only ones which could treat serious pain while not causing serious harm themselves. The side effects of the drugs, as mentioned earlier, are nausea, sedation, dry mouth, constipation, and, in extreme cases, respiratory depression. Despite these relatively minor side effects, the medical community was initially reluctant to utilize the drugs. Concerns about patients developing tolerances to and physical dependence on opioids, when conflated with uninformed fears of addiction, made their use uncommon and unpopular. This is not to say that opioids are safer than aspirin and should be as easily available. While the side effects of opioids, especially with high or long-term doses, are less than those of possible alternatives, under certain circumstances the drugs are extremely vulnerable to abuse. Oxycodone has been available in the U.S. since the 1960's, but was classified as a Schedule II narcotic by Congress under the Comprehensive Controlled Substances Act of 1970.³⁰ Schedule II drugs are seriously restricted due to their high potential for abuse and ability to cause psychological or physical dependence. Drugs in this category include morphine, methadone and methamphetamines. Schedule I drugs, such as LSD, have no approved medical uses and cannot be prescribed. While Schedule II drugs can be prescribed, they must be prescribed each time, i.e. no non-prescribed refills.³¹

II. The Product

STAND., June 4, 2001, at 16.

³⁰NAGEL & GOOD, *supra* note 17.

³¹Laura M. Nagel, *OxyContin Caution*, WEEKLY STAND., July 23, 2001, at 6.

OxyContin (generic name: oxycodone hydrochloride controlled-release tablets) was developed by Purdue in the early 1990's to fill this void in treatment options. The traditional reluctance to prescribe opioids for pain was reinforced by the fact that, until OxyContin, patients would have to take dosages every four hours or so due to the rapid absorption of the medication by the body. This limited period of pain relief not only made opioid treatment inconvenient for chronic pain sufferers, but also made doctors and patients even more reluctant to use them because of the large number of pills required to relieve pain over the course of a day.³² OxyContin is an oral, controlled-release form of oxycodone. The breakthrough over prior opioid medications is the combination of the controlled-release mechanism with oxycodone (MsContin utilized a similar controlled-release system to deliver morphine, which was much more heavily stigmatized and, as a result, less marketable). Whereas other opioid medications, for example Percocet and Tylox, contain as little as 5 mg of oxycodone, OxyContin contains much more. When originally offered for sale in late 1995, OxyContin was available in oxycodone dosages of 10 mg, 20 mg, 40 mg and 80 mg (80 mg tablets were approved in a separate FDA application in 1996). The pills are essentially pure oxycodone. The controlled-release mechanism, though, regulated release of the painkiller into the system over a 12 hour period, with analgesic onset beginning within an hour of taking the pill.³³ Doctors and patients saw this as a real breakthrough. Chronic pain sufferers could now get complete relief throughout the night without having to get up to take more medication. Purdue also made "rescue medications" available in case full relief was not obtained over the twelve hours.³⁴ OxyFast (5 mg of immediate-release oxycodone) and OxyIR (20 mg of immediate-release oxycodone) are described in the prescribing information for OxyContin. They are

³²Josh White, *Painkiller a Headache for Polic; Abuse of OxyContin Leads to Arrests, Deaths in the Region*, WASH. POST, May 2, 2001, at A1.

³³ME Hale et al., *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, 15 CLINICAL J. PAIN 179 (1999).

³⁴PHYSICIANS' DESK REFERENCE, (David W. Sifton et al. eds., 2001).

advised to be used when a patient's pain resumes during the day or before a patient engages in activity that tends to aggravate their pain. In general, though, fewer pills were required throughout the day and pain sufferers suddenly faced the possibility of passing whole days without pain. In addition, OxyContin avoided the stigma attached to other opioid medications, both for doctors and for patients.³⁵ Finally, many doctors believed that the time-release quality would lessen the chances of addiction. According to these doctors, the "rate hypothesis" suggests that an opioid's euphoric effect is determined by the rate the medication enters the brain. The faster the rate, the greater the euphoric effect and the larger the likelihood of addiction and abuse. The controlled-release function of OxyContin, then, limited the flow of oxycodone throughout the day, and, as a result, limited the addictive qualities of the drug.³⁶

While, in many ways, the release of OxyContin marked a revolution in the treatment of pain, the conditions that made its success possible were created in the early 1990's. As explained, in earlier years the medical community was relatively uninformed about pain and its treatment. Leading up to the release of OxyContin, though, a new interest in and focus on the treatment of pain arose. In addition to pain specialists around the country, Purdue played a major role in these developments. During this period Purdue contributed heavily to independent patient-advocacy groups such as the National Foundation for the Treatment of Pain and the Chronic Pain Association. It also sponsored many studies and experiments that examined the effectiveness of opioids in the treatment of pain.³⁷ These organizations and studies played a major role in increasing interest in the topic of pain and lessening stigmas associated with its treatment. Purdue, in addition to other pharmaceutical companies, also contributed to the American Pain Foundation, the largest non-profit organization focusing on patients with pain and a major catalyst of the changing perceptions of pain and

³⁵Kleiner, *supra* note 6.

³⁶Tough, *supra* note 16.

³⁷*Id.*

its treatment. In 2000, the foundation received 60 percent of its funds in the form unrestricted grants from several pharmaceutical companies, including Purdue. The group also received funds from nonprofit foundations and many individuals. Their single largest grant was from an individual who died after suffering from serious pain.³⁸

In addition, Purdue's marketing of MsContin, which began in 1984, contributed to the growing acceptance of opioid analgesics in the medical and scientific communities. As time passed, the pills, which were originally used to treat cancer patients, began to be used to treat non-cancer pain as well. Between the years 1990 and 1996 morphine consumption rose in the U.S. by 59 percent (2.2 to 3.5 million grams). To give some perspective, by 1996, the first full year OxyContin was available, only 2 million grams of oxycodone were prescribed each year.³⁹ The nearly two to one prescription ratio of morphine to oxycodone was not to last much longer.

In addition to sponsoring independent studies and advocacy groups, Purdue initiated a campaign of its own. In 1994 it founded "Partners Against Pain" as a public education program. At first the program focused on cancer-related pain, but over time it expanded to cover other forms of chronic pain. The program was publicized in patient pain journals and videos. As the internet grew, the program's website, "partnersagainstpain.com," became the most utilized medium. "Partners Against Pain" promoted three main ideas to patients and their doctors: the extent to which pain was more prevalent than commonly believed, that pain could be treated more effectively and that opioids should be part of that treatment.⁴⁰ The website did

³⁸Food and Drug Administration Center for Drug Evaluation and Research [hereinafter CDER], *Anesthetic and Life Support Drugs Advisory Committee Meeting* (Jan. 30-31, 2002) (statement of John Giglio the Executive Director of the American Pain Foundation), available at www.fda.gov/ohrms/dockets/ac/02/transcripts/3820t1.doc (Jan. 30, 2002) and www.fda.gov/ohrms/dockets/ac/02/transcripts/3820t2.doc (Jan. 31, 2002).

³⁹Joranson et al., *supra* note 21.

⁴⁰Tough, *supra* note 16.

not advertise nor publicize OxyContin or any other Purdue product. Rather, the program was focused on “nonbranded education.” In this way, Purdue sought to create a market for its products by advertising the concept of pain relief rather than the products themselves.⁴¹ A current look at the website reveals a variety of articles, studies and polls, all documenting the extent of pain and its under-treatment. While a variety of forms of treatment are explored, including hypnosis and adjuvant analgesics, so too are very positive reviews of opioid treatment. These resources, included on a page entitled “Information, Tools, and Services for Patients,” do not include any references to Oxycontin.⁴² In addition, other than the small-print copyright information at the bottom of the page, no indication is given that Purdue runs the page. While links to “Partners Against Pain” are common and prevalent on the Purdue company website, the reverse is not the case.⁴³

The lack of full disclosure in the “Partners Against Pain” materials does not mean the information within them is inaccurate. The approach, though, does highlight the manner in which Purdue’s promotion is intimately tied to the growing acceptance and use of opioids in the medical community. Often behind the scenes, Purdue played a significant role in breaking down many of the old taboos regarding opioid medication and in creating an environment where in the year 2000 an opioid could earn more than \$1 billion in sales revenue. As the independent parties and figures show, pain has clearly been traditionally under-treated. In addition, opioid analgesics can be effective, safe and, in some cases, superior to other analgesics. These lessons, though, which needed to be learned by the medical community, were often presented in a very general manner. While a new focus on pain and the use of opioids in treatment had extraordinarily positive possibilities, there were significant risks and complicating factors that needed to be addressed. Over the

⁴¹ See <http://www.partnersagainstpain.com> (last modified Apr. 5, 2002).

⁴² See http://www.partnersagainstpain.com/html/pat_care/pat_care.htm#pkillers (last visited Apr. 27, 2002).

⁴³ See <http://www.purduepharma.com> (last visited Apr. 27, 2002).

past year, though, as OxyContin has made headlines for its negative effects, it has been nearly universally acknowledged that these risks were, in fact, not appropriately addressed early on. The manner in which Purdue sought to create awareness of pain issues, and, in that way, develop a market for its products, offers some insights as to the patterns and state of affairs that made such a lapse possible.

OxyContin was first approved for sale to the public by the Food and Drug Administration (FDA) on December 12, 1995. The drug was approved for the treatment of moderate to severe pain. Pursuant to the Controlled Substances Act, it was classified as a Schedule II narcotic due to the presence of the active ingredient oxycodone. To be approved pursuant to the Federal Food, Drug, and Cosmetics Act a drug must be proven safe and effective under the conditions set forth on its label.⁴⁴ The approval process, though extremely thorough, is sought to be administered in an efficient manner. The approval process acknowledges that no drug is completely safe and that there are an infinite number of variables that are all interwoven and conspire to dictate a drug's effects. As a result, in practice the FDA approval system involves a balancing test between the risks and benefits of a proposed drug. OxyContin was approved on the basis of two clinical trials that showed the drug to be safe and effective in the treatment of moderate to severe pain. As part of the analysis of the risks of the drug, the FDA studied the likelihood of abuse and misuse. In such an analysis, OxyContin's pharmacology, chemistry, clinical manifestations and similarity to other drugs were assessed. In addition, the possibility of public health problems in the general public following approval was reviewed.⁴⁵ After considering these factors, the FDA found OxyContin to have no higher of an abuse or

⁴⁴See generally PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 380-552 (2d ed. 1991).

⁴⁵*Hearing on OxyContin: Balancing Risks and Benefits, Before the Senate Committee on Health, Education, Labor, and Pensions*: 107th Cong. 9 (Feb. 12, 2002) [hereinafter *Senate Hearing*] (statement of John K. Jenkins, Director of the Office of New Drugs, CDER, FDA). See also CDER, *supra* note 38 (testimony of Deborah Leiderman, M.D., Director of the Controlled Substance Staff at the FDA, regarding FDA assessment of the abuse potential of new drugs).

misuse potential than other Schedule II opioids. In fact, the agency felt that OxyContin's abuse potential was less than that of other similar drugs due to its controlled-release mechanism. While the FDA was aware that crushing the drug and intravenously injecting it would defeat the drug's controlled-release mechanism, it did not anticipate such misuse would become widespread. Nevertheless, a warning against this practice was included in the initially approved label. As an controlled-release opioid analgesic, OxyContin shared many similarities with MsContin, which had been available for ten years and had not been widely abused nor misused. The FDA, in part, relied on its experience with MsContin in its evaluation of OxyContin.⁴⁶ The FDA initially approved 10 mg, 20, mg and 40 mg dosages of OxyContin. Later, 80 mg and 160 mg dosages were also approved for "use in the management of pain in opioid tolerant patients stricken with a variety of pain syndromes."⁴⁷ At no point during these approvals did the FDA reveal any special concern for the potential of OxyContin to be abused.

Whatever the causes, it is hard to over-emphasize the commercial success that OxyContin has enjoyed. As described, the 1990's witnessed a considerable change in the medical community's perception of and willingness to utilize opioid analgesics. This change in attitude is borne out by the statistics. Between 1996 and 2000 there was a 23 percent increase in prescriptions for all common opioid analgesics, such as codeine, hydrocodone, morphine and hydromorphone. More generally, sales of prescription painkillers have tripled since 1996 (the overall market for pharmaceuticals doubled over the same period).⁴⁸ During the same period, though, Oxycontin prescriptions increased by over 1800 percent.⁴⁹ While much of this percentage increase

⁴⁶*Id.*

⁴⁷See CDER, APPROVAL PACKAGE FOR OXYCONTIN 80 MG, Application Number: NDA 20-553/S-002 (Dec. 9, 1996) (the 160 mg dosages were made available in 2000).

⁴⁸Kalb et al., *supra* note 15.

⁴⁹OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, WORKING TO PREVENT THE DIVERSION AND ABUSE OF OXYCONTIN (June 12, 2001).

is attributable to the fact that OxyContin was only released in late 1995 and, therefore, large percentage growth was mathematically unavoidable, the number, regardless, is still staggering, significant and relevant. This proposition is supported by the fact that OxyContin sales grew at very high annual rates, even four years after it was released. Between 1999 and 2000, sales increased by 74 percent.⁵⁰ In the year 2000 alone, 6.5 million prescriptions for OxyContin were written, making it the 18th best-selling prescription drug overall and the top-selling prescription opioid.⁵¹ All of these sales have added up to a major windfall for Purdue, which took in over \$1 billion in revenue from OxyContin in 2000, a sum equal to 80 percent of the company's total revenue.⁵²

All of these statistics reveal that over the past half-decade the prescription of painkillers has increased relative to other types of prescriptions. In addition, of prescription painkillers, in general, opioid analgesics have grown the most rapidly. Furthermore, of this subset of painkillers, OxyContin has experienced by far the most rapid and significant growth. All of this is not to say that OxyContin, alone, has changed the drug industry, but it does highlight the tremendous impact that the drug and its supporters have had. The effort of Purdue, along with that of many others, to increase awareness of pain and the use of opioids to treat it was rewarded with an increase in the overall market for painkillers and a relative increase in the use of prescription opioids.

The “successes” of the pain treatment advocates can also be seen in shifts in the types of doctors treating

⁵⁰White, *supra* note 32.

⁵¹Tough, *supra* note 16.

⁵²Maurice Timothy Reidy & Eric Rich, *Painkiller Make Fights Back; As Its Most Lucrative Drug – OxyContin – Came Under Siege, A Family-Owned Company Lost Its Publicity Shyness*, THE HARTFORD COURANT, July 18, 2001, at A8.

pain. Whereas in 1996, the most common use of opioid analgesics was in the treatment of cancer pain, by 2001 oncologists only accounted for 3 percent of the overall prescriptions of OxyContin. By that year, family doctors were the largest prescribers of OxyContin, providing 21 percent of the total.⁵³ In many ways, this statistic represents the most important shift in the medical community's approach to pain and is the key to understanding the tremendous problems that have arisen concerning OxyContin. As examined earlier, a majority of doctors felt under-prepared to diagnose and treat pain. The educational and outreach programs of the pain-treatment movement, though, have made significant headway in publicizing the problem. As a result, pain and its treatment are no longer confined to particular medical specialties or doctors. Rather, as the statistics show, family doctors have greatly surpassed oncologists in prescribing OxyContin. This suggests not only an increased awareness of pain, but also a new comfort with using opioids to treat it. Nevertheless, though, these increases were not complemented by more thorough training about the use of opioids nor their addictive potential. Rather, while the benefits of the drugs, particularly OxyContin, were emphasized and widely publicized, their risks were generally underestimated. In the course of barely a decade, then, opioid analgesics have evolved from taboo, misunderstood, and underutilized medication, into what OxyContin became in the late 1990's: a billion dollar drug, most commonly prescribed by family doctors.

III. The Problems

For the first years it appeared that OxyContin was the wonder drug many felt it could and would be. The number of prescriptions grew exponentially and more and more patients were receiving effective treatment for their pain. For many, OxyContin represented a true change in quality of life. A typical story was reported

⁵³*Id.*

by *Newsday* in New York. Barry Tuttle, who suffered from severe pain twenty-four hours a day for six years had exhausted what he thought were the treatment possibilities. He had undergone surgery, acupuncture, physical rehabilitation and taken thousands of pills without any relief. On the verge of suicide he came upon a description of OxyContin on the website for the American Society for Action on Pain, an independent pain patients advocacy group. Eight months after seeking out the drug, Tuttle's pain had greatly diminished and he said, "I'm free to do a lot more things. I'll never be pain free. Most people never will be pain free if they're chronic pain sufferers. But I can get out and work in the yard. I can mow the front and back yard in the same day."⁵⁴

As millions of pain sufferers were finding relief through OxyContin, the pill spread across the country and became familiar to patients and doctors alike. As had been the case with MsContin, Purdue did not get any worrisome reports of abuse. That all changed early in the year 2000. In February, U.S. Attorney Jay McCloskey of Maine sent a letter to the state's physicians detailing reports of problems with OxyContin abuse in certain communities. As more attention was paid to the issue over the next year, Maine would be identified as one of the hardest hit states. A copy of this letter was forwarded to Purdue, which it claims was the first notice it received that OxyContin was potentially being widely misused.⁵⁵ Soon after, the first media report on OxyContin abuse appeared in the state. The April, 2000 story in the *Bangor Daily News* was also the first media report on the problem in the country. It explained that OxyContin "is producing a growing number of opiate addicts throughout the state, leading to increased crime and, sometimes, violence."⁵⁶ Soon after, the story of Maine's growing problem was picked up by a major metropolitan paper. The *Boston Globe* highlighted the OxyContin abuse and the crime associated with it, noting that Maine had become the second highest user of OxyContin in the nation.⁵⁷ Behind these early media reports was a rapidly growing

⁵⁴Tina Susman, *Good Drug, Bad Drug; OxyContin Eases Pain, Lures Addicts*, *Newsday*, July 29, 2001, at A6.

⁵⁵*House Hearing*, *supra* note 14, at 82 (testimony of Paul Goldenheim, Executive Vice President, Research and Development, Purdue Pharma).

⁵⁶Reidy & Rich, *supra* note 52.

⁵⁷Donna Gold, *A Prescription for Crime; Abuse of 2 Painkillers Blamed for Rise in Violence in Maine's Poorest County*,

story. While newspapers, lawmakers and Purdue were just beginning to take notice, tens of thousands of people had already learned about OxyContin's power.

As described, neither the FDA nor Purdue expected OxyContin to be abused. One of the principle reasons for this belief was the controlled-release mechanism. This mechanism could be defeated by crushing the pill, though, and thereafter one could inject, snort or swallow the powder to produce an immediate euphoric high, comparably powerful and addictive as heroin. While a similar effect could be had by manipulating MsContin in a similar fashion, before it had never widely been done. What made a disabled controlled-release opioid so attractive was the relatively high dosages of the opioid that would be immediately absorbed.⁵⁸ Much like heroin, abusing OxyContin in this way results in almost immediate addiction.⁵⁹

Before one can analyze accurately the misuse and abuse of OxyContin, though, one must put it in the wider context of prescription drug abuse in general. While the reports of death, addiction and crime associated with OxyContin are alarming, in many ways they pale in comparison to the broader statistics. According to the most recent "National Household Survey on Drug Abuse", sponsored by the federal government, it is estimated that in the year 2000, 3.8 million people over the age of 11 used prescription medicine (e.g. pain relievers, sedatives and stimulants) non-medically. Of this number, 2.8 million specifically misused prescription pain medication. To put the number in perspective, during the same period 14 million Americans over the age of 11 reported using illegal drugs.⁶⁰

B. GLOBE, May 21, 2000, at D22.

⁵⁸Chevlen, *supra* note 29.

⁵⁹See Debra Rosenberg, *How One Town Got Hooked*, NEWSWEEK, Apr. 9, 2001 (describing the process and power of OxyContin addiction).

⁶⁰OFFICE OF APPLIED STUD., SAMHSA, SUMMARY OF FINDINGS FROM THE 2000 NATIONAL HOUSEHOLD SURVEY ON DRUG

Abuse of prescription medication is nothing new. OxyContin is certainly not the first prescription medication that has become known for its misuse. The casual and social use of sedatives has been common throughout the century. Thirty years ago, Quaaludes were the prescription drug of the moment. The depressant, officially known as methaqualone, quickly became the rage among abusers who sought the relaxed and hazy high that they offered. Their abuse, and the availability of substitutes with less addictive qualities, lead to Quaaludes being pulled from the market in 1984.⁶¹ More recently, Americans have become familiar with the painkillers Vicodin and Percocet as news stories detailing profiling abusers, such as Melanie Griffith and Matthew Perry, have become common.⁶² Perhaps more noteworthy has been the growing abuse of the drug Ritalin, or Methylphenidate, which is used to treat attention deficit hyperactivity disorder. Millions of children (3 to 5 percent of children in the U.S.) have been prescribed the drug, and in recent years it has become a frequently abused stimulant. Similarly to OxyContin, abusers crush or dissolve the pill and then snort or inject it in order to produce a high.⁶³

While the aforementioned cases of commonly abused prescription drugs were frequently clustered in relatively affluent areas, urban areas and along the coasts, prescription drug abuse was in no way unfamiliar to the more rural parts of the country. In the past, these areas, which have been the hardest hit by OxyContin abuse, have had experience with other painkillers, such as Tylox. Like OxyContin, Tylox contains oxycodone. Unlike OxyContin, Tylox only contains 5 mg of the drug, in addition to 500 mg of acetaminophen. Nevertheless, abusers in many rural areas would recreationally swallow or snort the drug and found it to be somewhat euphoric and not strongly addictive.⁶⁴ As explained by Captain Richard Hall of the West Virginia State Police, “[s]omebody asked a while ago if this [OxyContin abuse] was the first wave. Well this is actually the second wave. In Appalachia, in southern West Virginia, there was another wave earlier called Tylox... In

ABUSE, DHHS Publication No. (SMA) 01-3549.

⁶¹Susman, *supra* note 54.

⁶²Kalb et al. *supra* note 15.

⁶³NAGEL & GOOD, *supra* note 19.

⁶⁴Tough, *supra* note 16.

the mid 1980s, we had a Tylox epidemic.”⁶⁵ Oxycodone, then, while relatively infrequently abused in other parts of the country, had a history of being abused in certain areas. That in later years a drug containing a far more concentrated amount of oxycodone would be abused by the same population perhaps should not have come as such a surprise.

Overall, then, no area of the country has been immune to prescription drug abuse. Furthermore, it is not OxyContin alone that has seen significant increases in abuse in recent years. While prescription drugs have always been abused, the trend lately has nonetheless been dramatic. Last year, while announcing the start of a new and aggressive campaign against the non-medical use of prescription drugs, the head of the National Institute of Drug Abuse, Alan Leshner, called the problem, “a dangerous new drug abuse trend.”⁶⁶ At the same announcement the vice president of the National Community Pharmacists Association, Calvin Anthony, estimated that prescription drug abuse was now costing the country about \$100 billion annual in health care costs. OxyContin, released around the same time this recent trend was developing, was quickly swept up in it. The country was familiar with and susceptible to the abuse of prescription medication and rural areas, in particular, knew the power and dangers of opioids like oxycodone. While there are few consistent patterns to prescription drug abuse (e.g. MsContin was never widely abused) and, over time, a broad range of drugs have been abused, there was nevertheless an established and growing national problem into which OxyContin was released.

There is no question that OxyContin has become a highly abused prescription drug that has devastated many lives. While the figures and statistics do not lie, the media has played a significant role in developing and presenting the contours of the problem. The media’s focus on and role in exposing OxyContin abuse

⁶⁵ *House Hearing*, *supra* note 14, at 34 (statement of Captain Richard Hall, West Virginia State Police).

⁶⁶ John A. MacDonald, *Rise in Abuse of Prescribed Drugs; Institute Calls for Awareness of Medication Hazards*, THE HARTFORD COURANT, Apr. 11, 2001, at A10.

must be acknowledged in any examination of the problem, for one must know what the problem actually is before its causes and potential solutions can be considered. While in many ways the stories covering OxyContin are the most fascinating aspect of the problem, the statistics and anecdotes of law enforcement and health care services speak for themselves.

As described earlier, to date OxyContin abuse has tended to be concentrated in rural areas, particularly in the East. Among the hardest hit states are Kentucky, Maine, Maryland, Ohio, Pennsylvania and West Virginia. This geographic pattern and the drug's opioid lineage has led many to dub OxyContin "hillbilly heroin."⁶⁷ In a written response to the question of what evidence it has that OxyContin is being abused to the extent reported in the media, the DEA, in 2001, cited a number of developments. As described, since 1996 prescriptions for OxyContin increased nearly twenty-fold. In addition, during the same time and contrary to the predictions of the scientific studies, drug treatment centers, emergency rooms, law enforcement personnel and pharmacists all reported a substantial increase in abuse of the drug. In addition, the Drug Abuse Warning Network (DAWN) indicated that emergency room episodes and medical examiner reports involving oxycodone have increased significantly since 1996. Reports from 21 metropolitan areas revealed that oxycodone-related deaths increased 400 percent over the period, while emergency room events increased more than 100 percent.⁶⁸ In 1996 there were 3,190 oxycodone mentions in emergency room visits, while in 1999 there were 6,429.⁶⁹ By 2000 that figure reached 10,825.

These statistics have both strengths and weaknesses. They have particular resonance because they are compromised largely by hospitals outside of the aforementioned rural areas in which OxyContin abuse has

⁶⁷Elizabeth Mehren, *Hooks of 'Hillbilly Heroin'; Abuse of Prescription Painkiller OxyContin Ravages Poor Areas in the East. 'We've Gone Far Beyond a Problem, Far Beyond a Crisis,' Official Says of Synthetic Opiate*, L.A. TIMES, Oct. 4, 2001, at A1.

⁶⁸NAGEL & GOOD, *supra* note 17.

⁶⁹Francis X. Clines with Barry Meier, *Cancer Painkillers Pose New Abuse Threat*, N.Y. TIMES, Feb. 9, 2001, at A1.

been most heavily documented by the media. These figures, then, show that OxyContin abuse is more than just a small, localized problem that the media has over-blown. At the same time, though, the DAWN statistics, which are widely quoted and referred to in many of these media reports as well as government publications, have serious limitations. Rather than measuring the prevalence of drug use and abuse in society, the DAWN survey measures the results of the underlying abuse, i.e. visits to the emergency room. In addition, DAWN simply reports the drugs mentioned upon admission to the emergency room, regardless of the reason for their ingestion or role in the emergency.⁷⁰ For example, a legitimate OxyContin patient, who, contrary to the directions drinks himself to illness, will have both “drugs” reported in the survey.⁷¹ In addition, the DAWN survey does not report OxyContin use specifically. Rather, any mention of a drug containing oxycodone is reported as oxycodone. Hence, while provocative and suggestive, the DAWN survey statistics do not on their own definitively reveal the extent, or even existence, of a problem with OxyContin.

While statistics as to the scope of OxyContin abuse are ambiguous, reports from drug treatment centers have emphasized the significant and growing nature of the problem. Programs in some of the hardest hit areas, such as West Virginia, Pennsylvania, Kentucky and Virginia, have reported that between 50 and 90 percent of newly admitted patients identified OxyContin as their most abused drug.⁷² It is in these hardest hit areas that abuse of the drug has been most dramatic, even before one factors in the personal stories and human interest pieces most prevalent in the media. For example, already by early 2001, the Kentucky State Police identified OxyContin as the drug of choice in the eastern part of the state. In West Virginia, the Gilbert Police Department described OxyContin as the “worst” drug the department had ever encountered.

⁷⁰OFFICE OF APPLIED STUD., *supra* note 28.

⁷¹The 2000 survey reported alcohol-in-combination as the most mentioned emergency room drug, with 204,524 mentions. In comparison, cocaine was mentioned 174,896 times, acetaminophen 33,613 times, ibuprofen 17,923 times, aspirin 15,657 times, and oxycodone 10,825 times (overall ranked 14th).

⁷²NAGEL & GOOD, *supra* note 17.

Abuse of OxyContin there surpassed marijuana use. The Maryland Drug Early Warning System, which monitors drug abuse in real-time, identified OxyContin as a leading emerging drug of abuse in the state. Already by 1999, the DEA reported that 85 percent of arrests for false prescriptions in Maryland were for OxyContin and other oxycodone products.⁷³ In Maine, the U.S. Attorney, in the wake of his warning letter to physicians a year earlier, singled out OxyContin as the most significant drug threat in the state. A report issued by the Maine Substance Abuse Services Commission in January 2002 reported that opioid addiction in treatment programs had increased from 2 percent in 1995 to 12 percent in 2001. That change was described as “unprecedented.”⁷⁴

Over time, as the problem received more attention, more accurate and thorough statistics began to be released. In October 2001, the DEA released the findings of its most comprehensive study to date, which garnered extensive attention from the national media. In the prior 19 months, it was reported, OxyContin was suspected of playing a role in 282 overdose deaths.⁷⁵ The federal study reviewed autopsy data from around the country. In April of 2002, an expanded DEA review of autopsy data reported that OxyContin “might” have played a role in 464 overdose deaths in the past two years.⁷⁶ The initial study also revealed a new and potentially troubling twist to the story. All but 10 of the suspected OxyContin overdoses involved abusers ingesting the drug orally. While this point is most significant in consideration of the potential solutions to the abuse, it is important to note here that previously experts and journalists had assumed that, among abusers, the drug was most frequently snorted or injected. Such studies have numerous faults and critics (as will be reviewed later), but, nevertheless, demonstrate the existence of a problem as well as

⁷³NAT'L. DRUG INTELLIGENCE CTR., U.S. DEP'T. OF JUST., INFORMATION BULLETIN: OXYCONTIN DIVERSION AND ABUSE (2001).

⁷⁴*Senate Hearing*, *supra* note 45, at 6 (statement of Senator Susan Collins of Maine).

⁷⁵Meier, *supra* note 82.

⁷⁶Barry Meier, *OxyContin Deaths May Top Early Count*, N.Y. TIMES, APR. 15, 2002, at A14.

how the exact contours of that problem can be misrepresented by the media. These studies marked the first time the DEA targeted a specific prescription drug, rather than just an active ingredient.⁷⁷ While the FDA carries the responsibility for approving drugs for medical use and regulating their marketing, the DEA also has a role, which in the case of OxyContin has become more and more visible. Specifically, part of the DEA's mandate is to monitor and prevent the diversion of prescription drugs. For example, while the FDA is directly responsible for regulating the marketing of prescription drugs, the DEA has a role to play when marketing or advertising programs may make diversion more likely.⁷⁸ The DEA's involvement with OxyContin has grown dramatically. In 1999 the agency had a dozen OxyContin cases. In 2000, they had 27 cases and through August 2001, they already had 168 more.⁷⁹ This increase in agency attention reveals both the real problems involving OxyContin, in addition to the political pressures and interests at play.

While the statistics are significant and speak for themselves, the extent to which they have been publicized and focused on is not necessarily proportionate. As described, deaths associated with over-the-counter NSAIDs, such as Aleve and Advil, numbered 16,000 in 2000. While there are certainly differences between over-the-counter drugs and Schedule II prescriptions that make such comparisons of limited value, the point many commentators have made is that, in many ways, the fears of an OxyContin epidemic are a media creation.⁸⁰ There is a certain amount of truth to this. Though a rapidly growing problem, OxyContin abuse has to date been relatively limited in scope and geography. Furthermore, the areas facing the most abuse have also suffered from significant alcohol and substance abuse in the past, with much less media fanfare. In a Senate hearing, Senator Collins of Maine identified a characteristic of OxyContin abuse that has made it different, and arguably more compelling, than other drugs. She said, "These statistics, however shocking, do not fully convey the destruction of human life caused by the abuse of OxyContin. When talking

⁷⁷Maurice Timothy Reidy, *Maker Acts on Controversial Painkiller Tablets; 160-mg Tablets of OxyContin Drew DEA Attention*, THE HARTFORD COURANT, May 11, 2001, at A12.

⁷⁸NAGEL & GOOD, *supra* note 17.

⁷⁹House Hearing, *supra* note 14, at 14 (testimony of Asa Hutchinson, Administrator, Drug Enforcement Administration).

⁸⁰Chevlan, *supra* note 29.

to people on the front lines in Maine, I have heard stories of lost jobs, broken families, and young people who naively thought that a legal drug, available at a local pharmacy, could not possibly do them any real harm...”⁸¹ It is these types of stories that have proliferated throughout the national media in the last year and a half. While drug abuse has always garnered a significant amount of press, similarly focused on stories of lives destroyed and families torn apart, never before had they been written about a prescription drug. Prescription drug abuse, though, had never before involved such an addictive and powerful drug. Compared to Vicodin or Quaaludes, OxyContin involved a higher concentration of a more potent drug. While other abused drugs have become widely known, none before OxyContin has so completely grabbed the nation’s attention.⁸² Abuse of other prescription drugs, while very dangerous and destructive to health, did not produce the immediate and all consuming addiction and downward spiral. At the same time, though, all prescription drugs, not just OxyContin were being abused more frequently in recent years. Therefore, the attention grabbing stories on OxyContin provided an excellent segue for the media and politicians to focus on the larger problems and issues at play. It also provided a highly visible and tangible focal point for those that would fight the battle. As a result, OxyContin in many ways became the ideal poster child for a new war on prescription drug abuse in general.

As both a story in itself and as a symbol for a larger problem, OxyContin abuse was an natural headline grabber. The story of “hillbilly heroin” was picked up by media outlets around the country even before the full extent of the problem was known. By December of 2001 the story of the drug, still predominantly abused in rural areas, made it to the big-time of national media. In the same week, both CBS’s critically acclaimed program “48 Hours” and MTV’s reality-based program “True Life” featured vivid and disturbing stories

⁸¹*Senate Hearing, supra* note 45, at 6 (statement of Senator Susan Collins of Maine).

⁸²Barry Meier, *Overdoses of Painkiller Are Linked to 282 Deaths*, N.Y. TIMES, Oct. 28, 2001, at A20.

of OxyContin abusers and their addiction.⁸³ After appearing in rural Maine, reports of OxyContin abuse traveled through western Pennsylvania, eastern Ohio, and Appalachia, specifically rural areas of Tennessee, Kentucky, Virginia and West Virginia.⁸⁴ These areas have a fair amount in common. They are all home to large populations of chronic pain sufferers and disabled people in need of relief. The areas are also defined by poverty and little economic opportunity, far from the cities that offer such attractions, in addition to supplies of more traditionally abused substances like cocaine or heroin.⁸⁵ Finally, as described earlier, these areas had had experience with substance abuse in general, with some of the highest rates of alcoholism in the country and a documented bout with Tylox abuse. This combination offers a good explanation as to why OxyContin abuse would first arise in these areas. While no one had ever seen anything like OxyContin abuse before, the populations of these areas were certainly ripe for it.

As the newspaper accounts of the story spread, certain patterns emerged within them. Rural towns and their sheriffs were nearly always featured. A typical story was featured in *Newsweek* magazine, profiling the town of Hazard, Kentucky and its battle with OxyContin.⁸⁶ The story described the hopelessness of the sleepy rural town and then focused on the story of one of its young, Joshua Coots, who succumbed to the drug. Describing its draw he says, “I don’t know how to describe the buzz. It’s just this utopic feeling. You feel like you can conquer the world... It’s a better high than anything else.” Joshua had previously experimented with pills and marijuana, finding them to be only a “mild distraction.” Joshua’s story encompassed the classic components of the majority of other news reports. He became severely addicted to the drug, which was never prescribed to him, dramatically losing weight and spending all of his money on it. As sources began to dry up he would fake back pain and gain a prescription from a “shady” local doctor or steal them from his grandfather, who was prescribed them for a fractured spine. The story of Joshua Coots and his

⁸³Liz Matson, *Television Reviews; Shows Examine Use, Abuse of OxyContin*, B. HERALD, Dec. 12, 2001, at 50.

⁸⁴Josh White, *Va. Crackdown Urged on Painkiller’s Abuse; Rural Officials Tell of Drug Plague*, WASH. POST, May 18, 2001, at B4.

⁸⁵White, *supra* note 32.

⁸⁶Rosenberg, *supra* note 60.

father, Pastor Donnie Coots, was so compelling that Pastor Coots was invited to testify at a House hearing on OxyContin abuse.⁸⁷ The fact that the Coots's story made its way to Congress highlights the political nature of the problem. While they were certainly an appropriate choice to provide a first hand story of abuse, their participation also reveals the extent to which many officials were reacting to media reports on the drug. Given the relative lack of concrete information or statistically documented widespread abuse, the role media attention has played in drawing the attention of the government and lawyers cannot be denied. Like OxyContin abuse, the media coverage certainly has not been limited to Joshua Coots and other such isolated stories. In eastern Kentucky alone, a police sting operation named Operation Oxyfest in February 2001, headed by Hazard Police Chief Rod Maggard (who was also one of the 11 individuals invited to testify in the House hearing), resulted in the arrests of 207 OxyContin dealers. These raids drew a swarm of reporters to the tiny town of Hazard (pop. 5,500) and made celebrities out of it and many of its officials and citizens, including Joshua and Pastor Coots. The raid also prompted a torrent of articles across the country detailing the coming plague of OxyContin abuse. Before February of that year, there were very few stories of OxyContin abuse and fewer still focusing exclusively on the drug. In the few months following Oxyfest, though, hundreds of stories appeared across the country, reaching both major newspapers and magazines. In addition to the articles cited thus far, other representative headlines of the time include, "Illicit Use of Painkiller OxyContin 'Exploding'"⁸⁸ and "'Poor Man's Heroin' Expected to Hit: Local Authorities Brace for Worst as Abuse of Synthetic Morphine Painkiller Spreads in U.S."'⁸⁹ The content of the stories continued to focus on the devastating characteristics of OxyContin addiction and the personal devastation caused by the drug. In Prince William County, Maine, a story about Toby Terry documented the incredibly powerful addiction and dependence abusers develop and the difficulties of giving up the drug. Josh White of the

⁸⁷House Hearing, *supra* note 14.

⁸⁸Jonathan D. Silver, *Illicit Use of Painkiller OxyContin 'Exploding,'* THE PITTSBURGH POST-GAZETTE, Apr. 5 2001, at A1.

⁸⁹Bill Brownstein, *'Poor Man's Heroin' Expected to Hit: Local Authorities Brace for Worst as Abuse of Synthetic Morphine Painkiller Spreads in U.S.,* THE GAZETTE (Montreal), Apr. 8, 2001, at A4.

Washington Post writes, “He says he’s addicted and can’t imagine going even 12 hours without the drug... Terry’s eyes well with tears as he talked about the withdrawal – the vomiting, the diarrhea, the uncontrollable tremors. ‘You can try to quit taking it, but you can’t, Terry said.’”⁹⁰

While there certainly was a significant and growing problem of OxyContin abuse, the media attention was still remarkable. This attention was welcomed by many public officials in the hardest hit states, who in seeking to get it often described the problem with dramatic adjectives and less than reliable figures. Chief Maggard of Hazard, Kentucky was not the only public official to gain national attention. Many local officials and U.S. Attorneys enjoyed a new found celebrity. For example, Virginia’s U.S. Attorney, Mark Earley, who at the time was seeking his party’s nomination for governor, convened a meeting of Purdue executives and officials from the hardest hit states soon after Operation Oxyfest.⁹¹ In speaking out against the problem, Earley cited at least 30 deaths attributed to OxyContin over the previous three years in Virginia. Similarly, Joseph Famularo, U.S. Attorney for the Eastern District of Kentucky spoke out frequently against the drug, widely quoted making comments such as, I personally counted 59 deaths since January of last year that local police attributed to addicts using the drug, and I suspect that’s pretty conservative.⁹² While this number was heavily circulated, when asked to confirm the number in May of that year, Mr. Famularo’s office refused, simply stating that the figure was given to them by local law enforcement officials.⁹³ Such claims of widespread OxyContin-induced death were disputed by the executive director of the Kentucky State Medical Examiner’s office. While not every drug related-death is necessarily sent through his office, he reported only 27 oxycodone-related deaths in all of Kentucky in 2000. Furthermore, in only 2 of those

⁹⁰White, *supra* note 32.

⁹¹Josh White, *Abuse Reports Bring Meeting On Painkiller; Manufacturer Wants Education on Drug’s Risks*, WASH. POST, Feb. 16, 2001, at B8.

⁹²Clines, *supra* note 69.

⁹³Sandeep Kaushik, *Anatomy of a Drug Scare*, B. PHOENIX, June 21-28, 2001.

cases was oxycodone the only substance identified in the death. In the remainder, dangerous mixtures of alcohol, other prescription medications and illegal drugs were found in the deceased's blood.⁹⁴ Furthermore, there was no way to identify the precise source of the oxycodone, whether it be OxyContin or Percocet, for example. The DEA, itself, acknowledged many of the same difficulties in assessing the true number of OxyContin deaths. As of November 30, 2001, the DEA reported, "The extreme media reports of 'hundreds of deaths' attributed to OxyContin cannot be verified at this time, but the [medical examiner] reports received thus far suggest such numbers are possible if more detailed confirmations were conducted as part of routine [medical examiner] reporting."⁹⁵ By April, 2002 a more thorough review had indeed produced higher numbers of possible OxyContin-related deaths. Nevertheless, the statistics, though more comprehensive, were still limited by the same shortcomings.⁹⁶

These facts highlight many of the complications involved with identifying the precise contours of the OxyContin problem, although they were conspicuously absent from the news reports. This is not to suggest that OxyContin abuse was not a major problem at the time, but rather that media reports and national attention in many ways preceded accurate and complete information. While the job of the media and public officials is often to identify potentially great problems and spur the information gathering process, in this case the story seems to have taken on a life of its own. OxyContin became a national headline based on preliminary and relatively localized information. In a similar manner to the way the media has responded to other "scandals" in recent years, OxyContin abuse received attention beyond what the actual circumstances and facts would seem to have warranted and the reporting revealed a sensationalist tone, often eschewing the full picture and mediating factors. A similar journalistic pattern was seen in the late 1990's, when "black tar heroin," a cheaper form of the drug, left a number of young people dead in the south and was widely

⁹⁴*Id.*

⁹⁵DIVERSION CONTROL PROGRAM, DRUG ENFORCEMENT AGENCY, DRUGS AND CHEMICALS OF CONCERN: SUMMARY OF MEDICAL EXAMINER REPORTS ON OXYCODONE-RELATED DEATHS (2001), *available at* <http://www.health.org/govpubs/dea/oxydeaths.htm> (last visited Apr. 27, 2002).

⁹⁶Meier, *supra* note 76.

reported as the next drug epidemic, a status it never achieved in reality.⁹⁷ In this way, then, the combination of politics and media sensationalism in many ways distorted the realities of the OxyContin problem and must be acknowledged in any examination of it. Even cleared of colorful adjectives and predictions, though, OxyContin abuse and diversion is undeniably a problem (whether it is to become a “plague” or an “epidemic” as some media reports suggested is still up in the air).

Another common aspect of the sustained media coverage during this time were reports of the growing amount of crime associated with the drug. While pharmacy robberies and burglaries were the most dramatic and attention-grabbing of these, a whole host of illegal activities were involved. Some commentators have suggested a link in that the media attention drew addicts to the drug and then, by reporting crimes committed to obtain more of it, gave others the idea.⁹⁸ Regardless of the cause, crimes associated with the drug soon became almost as big of a problem as its abuse. As a legally available drug, the supply of OxyContin did not fit the profile of other abused drugs, such as cocaine or heroin, which are traditionally only available through illegal networks.

The DEA has identified a number of ways abusers have obtained the drug, other than outright pharmacy robberies. People have been documented calling prescriptions into pharmacies posing as physicians. While pharmacies will often find a problem with the call or the prescribing information, abusers will make these calls to a large number of pharmacies and inevitably a few will go through. In addition, there have been numerous reports of individuals gaining access to patients’ information and prescriptions that have been discarded by doctors’ offices, pharmacies or the patients themselves. In this way, addicts can find empty pill bottles with remaining refills, bottles with pills remaining and prescription information that they can

⁹⁷See, e.g. *Drug Abuse. Young, White and Middle-Class*, THE ECONOMIST, Dec. 6, 1997, at 26.

⁹⁸Kaushik, *supra* note 93.

use to obtain their own.⁹⁹ Other approaches include forging prescriptions and what is known as “doctor shopping.”¹⁰⁰ Doctor shopping involves an addict visiting a number of doctors in hopes of getting more prescriptions of a drug. These abusers will not inform the doctors of the other prescribers and few states have systems that would alert the doctors to the problem. As a result, people are free to see a number of doctors for whatever reason and potentially emerge with a prescription for OxyContin from each one.

As OxyContin abuse became more prevalent, unscrupulous doctors and health care workers and traditional drug dealers entered the picture. The business is particularly lucrative. On the streets, OxyContin pills are generally sold for \$1 per milligram or more.¹⁰¹ This means that a prescription of, for example, thirty 20 mg pills, a fifteen day supply by the label’s indications, could be sold on the street for approximately \$600 dollars. This has proven to be a strong temptation to a wide variety of people. Health care workers frequently have unlimited and unsupervised access to pharmaceuticals. Often that temptation is too difficult to resist and these workers either take them for themselves and become hooked or take them to sell to others. In Cincinnati, which closely tracks prescription drug diversion and abuse, 30 percent of arrests in such cases involve medical employees.¹⁰² Another trend was for those with legitimate prescriptions to sell some of their pills. Often, these legitimate patients’ health care plans paid for the drugs, which made their diversion particularly lucrative. Patients on Medicaid, for example, pay \$1 for a \$250 prescription of OxyContin.¹⁰³

Addicts also looked to unscrupulous doctors for their supply. While some doctors were willing to oversubscribe the drug or prescribe it liberally, others would sell the prescriptions outright. These doctors often

⁹⁹NAGEL & GOOD, *supra* note 17.

¹⁰⁰Kalb et al. *supra* note 15.

¹⁰¹See Mehren, *supra* note 67; NAT’L. DRUG INTELLIGENCE CTR., *supra* note 73, at 3; Greg Stone, *West Virginia Authorities See New Sources for Addictive Pain Reliever*, THE CHARLESTON GAZETTE, Feb. 10, 2002.

¹⁰²Kalb et al., *supra* note 15.

¹⁰³Tough, *supra* note 16.

became involved with more extended drug distribution rings. A recent case in Queens, New York involved a network that sold OxyContin and other prescription drugs. The head of the group would pay Dr. Richard Goodin \$60 per prescription and then resell them to abusers.¹⁰⁴ A similar case appeared in Indiana, where a doctor was accused of defrauding Medicaid by illegally prescribing OxyContin to supply a drug ring. In two years the doctor was said to have written over \$1 million in prescriptions, which was six times the dollar value of the next largest prescriber in the state (the doctor had previously been a pain speaker for Purdue at local pain conferences).¹⁰⁵ Other doctors have prescribed OxyContin directly to abusers for a fee. A recent groundbreaking prosecution in Florida charged a doctor with manslaughter for over-prescribing OxyContin, which, it was claimed, directly resulted in the overdose deaths of four patients. Before his arrest, Dr. James Graves was the largest prescriber of OxyContin in all of Florida. Even without charging an additional fee, the standard medical charges associated with prescribing OxyContin to abusers can be quite lucrative. Dr. Graves made \$500,000 a year from prescribing OxyContin in what was described by the prosecutor as a reckless manner to anyone willing to pay the cost of an appointment.¹⁰⁶ Dr. Graves was found guilty and sentenced to 63 years in prison.¹⁰⁷ Criminal charges against doctors who recklessly or illegally prescribe OxyContin and other commonly abused prescription drugs have begun to proliferate.¹⁰⁸ This pattern reflects both a growing problem as well as a reflex of the political and legal system to the heightened media awareness.

Once OxyContin abuse had been identified as a problem, though, the most serious development, as well as

¹⁰⁴Austin Fenner, *Rx Racket Smashed: Doc, Fire Chief in Designer Drug Roundup*, THE DAILY NEWS, Jan. 11, 2002, at S1.

¹⁰⁵Barry Meier, *Doctor to Face U.S. Charges in Drug Case*, N.Y. TIMES, Dec. 23 2001, at A16.

¹⁰⁶Barry Meier, *Doctor Guilty in 4 Deaths Tied to a Drug*, N.Y. TIMES, at Feb. 20, 2002, at A14.

¹⁰⁷*Doctor Given Long Prison Term For 4 Deaths Tied to OxyContin*, N.Y. TIMES, Mar. 23, 2002, at A10.

¹⁰⁸Barry Meier, *OxyContin Prescribers Face Charges in Fatal Overdoses*, N.Y. TIMES, Jan. 19, 2002, at A14. *See generally* James A. Filkins, "With No Evil Intent": *The Criminal Prosecution of Physicians for Medical Negligence*, 22 J. LEGAL MED. 467 (2001) (examining the legal issues involved with prosecuting doctors for harm resulting from negligent practice).

most common topic of new media stories, has been the burglaries and robberies associated with the drug. As described, to buy the drug on the street is expensive and, therefore, both entrepreneurs and addicts often turn to pharmacies to obtain a supply. Demand for the drug is certainly very powerful. Addicts who have not been able to find a source of OxyContin have often turned to heroin as a substitute.¹⁰⁹ Drug store robberies have been documented across the country. In the year and-a-half leading up to October 2001, there were over 700 OxyContin-related burglaries and armed robberies in the U.S.¹¹⁰ In particular, Boston pharmacies have been especially common targets, registering 50 armed robberies and burglaries in the first 10 months of 2001. Despite the fact that OxyContin abuse has not caught on in Boston as much as in other areas, thieves have continually descended on its pharmacies. Investigators believe that the stolen OxyContin is used to supply abusers in Maine. The robberies have also become more organized operations. As opposed to the situation of a desperate addict, such as the story of the injured firefighter with which this paper opened, in recent months investigators are also finding that organized gangs have entered the business. The situation in Massachusetts reached bottom this past summer, when after a string of pharmacy robberies, a nursing home was invaded and its supply of OxyContin stolen.¹¹¹ The robberies highlight many of the biggest challenges presented by OxyContin. As a powerful opioid, the drug is as desirable to an addict or dealer as if heroin were stocked in the local pharmacy. The drug has tremendous potential to be abused and, as a result, the creativity with which people have sought it out is unsurprising. Thieves have even begun to look overseas for a source. In a dramatic robbery, the first of its kind to date, nine armed robbers stole over one million tablets of OxyContin from a Mexico City distribution center. U.S. officials believe the pills were then to be sent to the U.S. for illegal sale.¹¹²

¹⁰⁹Tara H. Arden-Smith and Catherine Holahan, *New Type of OxyContin Crime: Police Say Painkiller Lures Dealer-Junkies*, B. GLOBE, Aug. 21, 2001, at B1.

¹¹⁰James Frederick, *NACDS OxyContin Study Tracks Abuse, Details Preventative Measures*, DRUG STORE NEWS, Oct. 22, 2001, at 11.

¹¹¹Tara H. Arden-Smith, *State Eyes New OxyContin Rules Announcement Follows Invasion at Nursing Home*, B. GLOBE, Aug. 24, 2001, at B1.

¹¹²Josh White, *Oxycontin Abuse Is Increasing, DEA Says*, WASH. POST, Dec. 12, 2001, at A10.

While there is no formal connection between the number of crimes associated with OxyContin and the overall numbers of those abusing it, it is clear that diversion, on its own, is a serious problem associated with OxyContin. While many prescription drugs are abused and obtained in illegal ways, OxyContin is the only one associated with widespread burglaries and armed robberies. In most of the robberies surveyed, the thieves only asked for and made off with OxyContin. This may be a result of doctors clamping down on their prescriptions or simply the highly addictive and powerful properties of the drug. One thing is clear, though, OxyContin is not just another abused prescription drug. These unique aspects of its abuse and diversion must be addressed in any solution to the problems.

IV. The Causes and Responses

As is inevitable when such an intense spotlight is cast on a product, soon Purdue was being scrutinized for its actions in promoting and distributing the pills. By late 2001, the company was even implicated in the type of illegal distribution just described. A pain clinic in Myrtle Beach South Carolina was investigated by the DEA for the high number of OxyContin prescriptions it wrote. Five OxyContin-related overdoses were tied to the clinic and, ultimately, it was closed after six of the doctors who ran it had their narcotics licenses revoked by the DEA. The DEA complained that Purdue “had a moral obligation to alert state and federal authorities to the warnings its sales representatives had received even though it was not legally required to do so.”¹¹³ A *New York Times* investigation found that numerous area doctors and pharmacists had

¹¹³Barry Meier, *At Painkiller Trouble Spot, Signs Seen As Alarming Didn't Alarm Drug's Maker*, N.Y. TIMES, Dec. 10. 2001, at A16.

alerted Purdue sales representatives to potentially illegal and dangerous prescribing patterns at the clinic, but Purdue took no action. In addition, the paper was able to access private company records that showed that first quarter sales in 2001 in the county in question grew by over \$1 million over the previous year. The next largest increase in the country was \$700,000. Nevertheless, while refusing to comment on the specific records, the company explained that there was nothing unusual about such a change due to the benefits of the drug and the makeup of the community.¹¹⁴ Furthermore, in congressional hearings the company vehemently defended its actions in this case, arguing that it does not have investigative capabilities or powers. The company also explained that it does not sell OxyContin directly to pharmacies or particular doctors, but rather to wholesalers who then distribute the drug. Therefore, there were no procedures through which Purdue could have cut off the clinic. The power to prescribe was under the charge of the local pharmacies and the DEA.¹¹⁵

The Purdue representative at the hearing instead emphasized the company's educational programs and materials as its most effective weapon against diversion and illegal prescribers. He said, "[i]f fraud is being committed – if prescriptions are being tampered with – if medicines are being prescribed by criminal physicians, that's a job for law enforcement. Our job is to provide education. Our job is to teach physicians and pharmacists how to avoid abuse and diversion. Our job is to encourage pharmacists to report anything that they're concerned about." While two of the U.S. Representatives at the hearing again called into question the morality of Purdue's approach, there was no allegation of criminal wrongdoing.¹¹⁶ The situation, then,

¹¹⁴*Id.*

¹¹⁵*House Hearing, supra* note 14, at 88 (testimony of Paul Goldenheim, Executive Vice President, Research and Development, Purdue Pharma).

¹¹⁶A similar situation arose two months later when a clinic in North Carolina was shut down after the DEA suspended the narcotics license of the doctor who ran it. Although Purdue was not directly implicated in any wrongdoing, the statements by the sanctioned doctor revealed him to be highly uninformed about the dangers posed by OxyContin. In a *New York Times* article, Dr. Talley (the physician in question) "... makes no bones about his lack of formal training in pain... he jokes that he

exemplifies the tensions and difficulties authorities and journalists have run into when attempting to assess Purdue's culpability for OxyContin abuse. In addition to the powerful qualities of the drug and the crime associated with it, the specter of corporate wrongdoing is another aspect of the story that has brought it so much attention.

As described earlier, Purdue was on the forefront of the movement to increase the awareness and treatment of pain in the U.S.. The company sponsored studies and seminars on the topic long before OxyContin was introduced. Its "Partners Against Pain" program was a great success in alerting both patients and doctors to new information and treatment. Critics have argued, though, that Purdue's promotion of pain relief, and, later OxyContin, under-emphasized the risks of abuse and addiction and, as a result, played a major role in creating the current abuse.

FDA approval of OxyContin marked a new stage in Purdue's marketing program. Successful in rolling back the stigma associated with the use of opioid analgesics for much of the century, Purdue set out to familiarize the medical community with its new product. Significantly, Purdue never sought to market the drug directly to consumers, although it would have been legal to do so.¹¹⁷ Prescription drug advertising is a \$15 billion-a-year business, of which direct-to-consumer marketing has composed a growing amount. The Harvard School of Public Health found that from 1997, when the FDA eased rules for television advertising, to 2001, spending on such direct-to-consumer advertising tripled.¹¹⁸ Although much of its work on behalf of pain awareness was focused on lay consumers, its marketing of OxyContin was directed only at medical

would fail any tough test to certify him as a pain expert because he only uses drugs to treat pain." Dr. Talley, himself, said "If the addict fools me and gets his fix, well at least he got a safe drug to abuse." Barry Meier, *A Small-Town Clinic Looms Large as a Top Source of Disputed Painkillers*, N.Y. TIMES, Feb. 10, 2002, at 22. The case highlights the manner in which many physicians were made to feel comfortable prescribing OxyContin while perhaps underestimating its dangers.

¹¹⁷ *Senate Hearing, supra* note 45, at 17 (testimony of John K. Jenkins, Director of the Office of New Drugs, CDER, FDA).

¹¹⁸ Kim Jiramongkolchai, *Study Shows Rise in Drug Advertising*, HARV. CRIMSON, Feb. 19, 2002, at 3.

professionals. It is the content and zeal of this advertising, though, that has been called into question.

In many ways, criticism of Purdue's promotion of OxyContin also implies a criticism of the FDA. OxyContin was approved in 1995 for the treatment of "moderate to severe" pain. Since its release, the FDA has only once questioned Purdue's promotional materials. In general, the FDA does not regulate advertisements before they are placed. Instead, when an ad is to be published it must be sent to the Division of Drug Marketing, Advertising and Communications. Any review of or action on an ad, then, occurs after it is published and, in most cases, simply requires the ad to be pulled, although the FDA is empowered to order corrective action.¹¹⁹ The FDA's only action against the marketing of OxyContin came on May 11, 2000.¹²⁰ In issue was an advertisement in the May 4, 2000 issue of the *New England Journal of Medicine*, entitled "Proven Effective in Arthritis Pain." The FDA found it to be misleading due to the fact that it suggests that OxyContin has been studied for all types of arthritis and can be used as a first-line treatment for the affliction. Such claims were unsubstantiated and did not include highly relevant information, such as the fact that the participants in the study in question were chosen precisely *because* they were not getting relief from other medication. The FDA also questioned Purdue's claim that any dose of OxyContin can be used to treat moderate to severe osteoarthritis, as well as the fact that the risks particular to the elderly, such as respiratory depression, were not included in the ad. While Purdue discontinued the ad and no subsequent action was taken, the contentions highlight the fine line Purdue was treading by touting and possibly exaggerating the drug's possible uses and benefits while under-emphasizing the potential risks. This was an approach, though, Purdue was otherwise able to pursue virtually unchecked. Due to the change in atmosphere regarding the

¹¹⁹*Senate Hearing, supra* note 45, at 9 (statement of John K. Jenkins, Director of the Office of New Drugs, CDER, FDA), available at <http://www.fda.gov/ola/2002/oxycontin0212.html> (Feb. 12, 2002).

¹²⁰Letter from Spencer Salis, Pharm. D., Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, FDA, to Beth Connelly, R.N., Senior Associate, Regulatory Affairs, Purdue Pharma L.P. (May 11, 2000) (on file with author and with the FDA).

treatment of pain with opioids and, arguably, too little FDA oversight early on, Purdue was able to market its pill more broadly and with fewer warnings than, in retrospect, seem appropriate.

Many of the FDA's initial regulatory moves have now come into question. For example, in his congressional testimony DEA Administrator Asa Hutchinson agreed with the assertions of some of the representatives, that FDA approval of OxyContin for moderate pain may have been too lenient and may have contributed to the widespread problem.¹²¹ While at the time OxyContin was approved the FDA was aware that crushing the pills and injecting them could result in a lethal overdose, and included a warning against the practice, it did not foresee such abuse becoming widespread. Commenting on the situation, Dr. Cynthia McCormick, director of the FDA's Division of Anesthetics, Critical Care and Addiction Drug Products, explained that the FDA is reassessing how it reviews prescription narcotics for potential abuse. She acknowledged that the FDA had failed to research all of the ways in which abusers might tamper with OxyContin, a mistake she said the agency did not want to make again.¹²² The FDA attempted to remedy some of these deficiencies in July, 2001, when the agency, in cooperation with Purdue, significantly strengthened the warning and indications section of the label, adding a "black box" warning which is the strongest for an FDA approved product. Specifically, the new labels warn that OxyContin should be used only for the treatment of moderate to severe pain when a twenty-four hour painkiller is needed for extended periods (previously the indication was "for the management of moderate to severe pain where the use of an opioid analgesic is appropriate for more than a few days"). In addition, the new label highlights that OxyContin has similar abuse potential to

¹²¹*House Hearing*, *supra* note 14, at 25 (exchange between Representative Frank Wolf of Virginia and Asa Hutchinson, Administrator, Drug Enforcement Administration).

¹²²Barry Meier & Melody Petersen, *Sales of Painkiller Grew Rapidly, But Success Brought a High Cost*, N.Y. TIMES, Mar. 5, 2001, at A1. *See generally CDER*, *supra* note 38 (testimony of Deborah Leiderman, M.D., Director of the Controlled Substance Staff at the FDA, on FDA assessment of abuse liability).

other opioids.¹²³ The black box was an attempt to raise awareness about the power and risks of OxyContin that had previously been under-emphasized. In a “Talk Paper” prepared by the FDA to guide personnel to respond consistently and accurately to questions from the public, the FDA revealed a serious shift in its approach to the drug. While still approved and indicated for the treatment of moderate pain, the “Talk Paper” goes on to explain, “[a]n important factor that must be considered in prescribing OxyContin is the *severity* [emphasis added] of the pain that is being treated, not simply the disease causing the painful symptoms. FDA continues to recommend that appropriate pain control be provided to patients who are living with *severe* [emphasis added] pain.”¹²⁴ As part of the reorientation, Purdue sent a “Dear Doc” letter to over 800,000 doctors, informing them of the changes to the label and highlighting OxyContin’s potential for misuse.¹²⁵ This letter, though, was markedly less personal than Purdue’s previous interactions with many of the recipients.

While in the early 1990’s Purdue focused on creating awareness of pain issues, after OxyContin’s release its marketing strategy aggressively sought to create awareness of the drug. Purdue continue to sponsor pain seminars around the country. At these seminars, as was the case before, no specific drugs were mentioned. Nevertheless, a conflict of interest is easily imputed. According to a company consultant, Purdue would pay the transportation and hotel costs for hundreds of doctors to attend pain seminars in Florida, California and Arizona. Later these doctors would be recruited and paid to speak to other doctors at local pain seminars, of which there have been approximately 7,000.¹²⁶ While the seminars filled in many of the gaps regarding the

¹²³Josh White, *More Warnings About OxyContin; FDA, Drugmaker Advise Caution in Prescribing Addictive Painkiller*, WASH. POST, July 26, 2001, at B2.

¹²⁴FDA TALK PAPER, FOOD AND DRUG ADMINISTRATION, FDA STRENGTHENS WARNINGS FOR OXYCONTIN (July 25, 2001), available at <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01091.html> (July 25, 2001).

¹²⁵Letter from Robert F. Reder, MD, Vice President, Medical Affairs and Worldwide Drug Safety, Purdue Pharma L.P., to over 800,000 physicians and health care professionals (July 18, 2001) (on file with the FDA, Purdue and the author).

¹²⁶Meier & Petersen, *supra* note 122.

treatment of pain that most physicians describe in their education, until the recent controversies emerged they did not emphasize the risks of addiction, another area in which doctors were woefully unprepared.

In addition to the seminars, Purdue employed approximately 800 salesmen and representatives around the country who visited doctors individually to encourage them to prescribe OxyContin. While this practice is common in the pharmaceuticals industry, the aggressiveness of Purdue's marketing has been criticized. Not only were the potential risks of the drug under-emphasized, but the benefits were espoused and, arguably, exaggerated at every turn. In 2000 alone, Purdue spent approximately \$200 million on its marketing of OxyContin.¹²⁷ Criticisms of the salesmen were highlighted in a story in the *New York Times*. Dr. Peter Leong, who runs a pain clinic in Bangor, Maine, was told by a salesman that OxyContin was safe enough to treat short-term pain. Believing OxyContin to be too powerful to use for anything but chronic, severe pain, Dr. Leong threw out the salesman, saying, "OxyContin is a good drug. But the problem was, they were pushing it for everything."¹²⁸

Given that large bonuses were offered to those whose areas increased their number of OxyContin prescriptions the, it is unsurprising that the salesmen were aggressive. One OxyContin saleswoman in Florida, who made \$50,000 in 1999, earned a \$100,000 bonus in 2000 for the increase in sales in her territory.¹²⁹ Florida, as described, is one of the areas hardest hit by OxyContin abuse. In addition, Purdue targeted particular areas and physicians that already prescribed large amounts of other analgesics.¹³⁰ While this strategy en-

¹²⁷*Senate Hearing, supra* note 45, at 34 (testimony of Paul Goldenheim, Executive Vice President, Research and Development, Purdue Pharma).

¹²⁸Meier & Petersen, *supra* note 122.

¹²⁹*Senate Hearing, supra* note 45, at 24 (statement of Art Van Zee, Lee Coalition for Health, St. Charles, Virginia).

¹³⁰*House Hearing, supra* note 14, at 16 (testimony of Asa Hutchinson, Administrator, Drug Enforcement Administration).

sured good sales, without proper information and education as to the properties which made OxyContin so different and dangerous, it also likely helped create the problem.

There is no formal evidence that Purdue or its salesmen ever explicitly promoted OxyContin for uses not approved by the FDA. Nevertheless, the marketing approach was aggressive and, according to many observers, inappropriate. Purdue salesmen were highly incentivized and free to make broad and, in retrospect, potentially misleading claims. Not only were doctors instructed about pain and the benefits of using OxyContin to treat it, but they were also sometimes warned about what would happen to them if they didn't. In contrast to the current legal environment in which doctors, like Dr. Graves, are being prosecuted for the manner in which they prescribed the painkiller, just a year or two earlier doctors were being warned that they could be sued for not treating pain. Indeed, a jury in California recently awarded \$1.5 million to a plaintiff against a doctor who was accused of failing to prescribe adequate painkillers to a terminal cancer patient.¹³¹ Other states went so far as to enact pain management laws that, building on the new studies and research of the previous decade, identified the treatment of pain as a patient's right. One such law was enacted in West Virginia in March of 1998. It immunized doctors from criminal or other sanctions for merely over-prescribing the pill, even to addicts.¹³² These laws and the existing legal environment were utilized by Purdue representatives and salesmen in their pitches to doctors. Consistent with the general marketing plan, they suggested that there was nothing to lose and everything to gain by prescribing the drug and that any refusal to do so was something close to malpractice.

More trivial marketing techniques were also employed to reinforce Purdue's message about OxyContin.

One such promotional aid was an OxyContin pen that had a pull-out conversion chart. The chart shows

¹³¹Debra Rosenberg, *Drugs: Profits vs. Pain Relief*, NEWSWEEK, July 2, 2001, at 49.

¹³²*House Hearing, supra* note 14, at 35 (testimony of Captain Richard Hall, West Virginia State Police).

physicians what dosage of OxyContin is equivalent to other medications, such as Tylenol #3, a Schedule III drug.¹³³ The pen has been criticized for suggesting to doctors that any pain treated with one of the other drugs on the conversion chart can be treated OxyContin. Purdue has maintained that such materials are standard in the industry and are even put out by hospitals and, as a result, are teaching materials rather than aggressive promotional pieces. Given the early OxyContin promotion as well as the drug's special characteristics, though, advertising pieces like the pen only served to make doctors more comfortable with the drug and more likely to prescribe it. Nowhere on the pen did it describe the addictive properties of OxyContin relative to other drugs. Another promotional technique that has come under fire was the use of vouchers for a free seven-day supply of the drug that Purdue continued to provide doctors well into 2001.¹³⁴ Like many of the other advertising moves, free trials are common in the industry. Nevertheless, that they were continued to be sent out for a year after Purdue was first alerted to the problems reveals either a serious public relations error, a disconnect with the abuse of their drug, a disinterest in this abuse, or a combination of the three.

The free samples are also consistent with the rest of Purdue's early marketing program in that, in hindsight, they seem inappropriate given the strength and addictive qualities of the drug. At best, the program as a whole simply presented a drug for sale in a manner that reflected an honest industry-wide underappreciation of the risks associated with OxyContin. At worst, the campaign actually influenced physicians' understanding of the medication and led to more liberal prescribing patterns than would have been the case otherwise. While the campaign, as described, does not appear to have been illegal in any way, the evidence suggests that the campaign did play a role in the growing abuse of the drug. This view has been expressed

¹³³*Id.* at 71 (testimony of Paul Goldenheim Executive Vice President, Research and Development, Purdue Pharma).

¹³⁴Meier, *supra* note 82.

by the head of the DEA, Asa Hutchinson, and numerous local officials.¹³⁵

Interestingly, there has not been a serious call to ban OxyContin outright. Here and there an official or other newsworthy figure has called for the drug to be discontinued, but these calls have been isolated and heavily and persuasively countered.¹³⁶ Even in the face of growing public and political pressure, the DEA and twenty-four health advocacy organizations publicly advocated a balanced approach to the problem that will not interfere with the treatment of legitimate patients.¹³⁷ For each of the horror stories about addiction and ruin there are many supporting the tremendous positive effects of the drug.¹³⁸ As described, there was undeniably a lack of focus on and treatment for pain in the U.S. This medical blind-spot left many people with unnecessary and debilitating pain and doctors with too little information or medicine to treat it. Despite its risks, then, OxyContin has done an enormous amount of good. The problem seems not to be the drug itself, but, rather, how it has been prescribed and diverted. The solutions to the problem do not involve limiting legitimate patients' access to the drug. While the pill itself is not to blame, Purdue bears at least some responsibility for the abuse and certainly is the key to many of the solutions.

In addition to suing their doctors, those who have suffered due to OxyContin abuse have also looked to the company for blame and compensation. These suits, perhaps better than administrative actions, reports or comments, highlight Purdue's potential missteps in its marketing and distribution of OxyContin. Principally the suits, which numbered over forty through this February, allege that Purdue mislead doctors and patients

¹³⁵Barry Meier, *Official Faults Drug Company for Marketing of its Painkiller*, N.Y. TIMES, Dec. 12, 2001, at A16.

¹³⁶See, e.g. Chevlan, *supra* note 31; Nagel, *supra* note 31; Kleiner, *supra* note 6 (detailing the back and forth).

¹³⁷Josh White, *DEA backs Medical Use of OxyContin*, WASH. POST, Oct. 24, 2001, at A26.

¹³⁸See, e.g. Ulysses Torassa, *Pain Relief Doesn't Have to Be Addictive*, S.F. CHRONICLE, Mar. 10, 2002, at E3.

about the appropriate uses for OxyContin as well as its addictive nature.¹³⁹ The majority of the specifics are just variations of those charges and are far too individualized and numerous to examine here.¹⁴⁰ Suffice it to say that the prospect of large awards has incentivized plaintiffs and their lawyers to make every possible claim. Purdue, not surprisingly, has vigorously denied any wrongdoing. Robert Hogan, Purdue's executive director of public affairs said, "[t]he marketing of this drug was absolutely within the letter of the law... and Purdue stands by its marketing representatives. Are our salespeople aggressive? Yes. Are they coercive and deceptive? No... [A]s to allegations that our representatives misrepresented the drug or overpromised its benefits, or made statements outside the label— that's not the case."¹⁴¹ Thus far, Purdue has been quite successful in defeating the suits. While none have come close to trial yet, many have faced significant substantive and procedural hurdles (e.g. removal to federal court or failing to be certified as a class) and have dropped the suits, as others have in their wake.¹⁴² The pattern thus far suggests that plaintiffs have yet to build a strong legal case against Purdue.¹⁴³

More recent cases, such as two class-actions filed in New Jersey and Washington D.C. on February 26th of this year allege more concretely that OxyContin did not live up to Purdue's marketing. The complaints claim that Purdue's own studies showed that most patients required "rescue" or "breakthrough" medication, such as OxyFast or OxyIR. Therefore, it is argued that by marketing OxyContin as offering complete 12 hour pain relief, Purdue knowingly mislead consumers.¹⁴⁴ Similar to many of the other suits, the complaints

¹³⁹Naomi Aoki & Jeffrey Krasner, *Plaintiff Drops OxyContin Suit After Transfer to Federal Court*, B. GLOBE, Feb. 6, 2002, at C4;

¹⁴⁰*See, e.g.* Josh White, *VA Class-Action Suit Filed Against OxyContin Firm; Residents Say Company Marketed Painkiller Inappropriately and Didn't Warn of Risks*, WASH. POST, June 19, 2001, at A6.

¹⁴¹Jean Hellwege, *Suits Filed Against OxyContin Maker May Be Mere "Tip of the Iceberg."* TRIAL, Sept., 2001, at 80.

¹⁴²*OxyContin Lawsuit Dismissed in Mississippi*, PR NEWswire, Feb. 4, 2002; *Federal Judge Rules OxyContin Lawsuit Won't Be a Class Action*, ASSOCIATED PRESS, Feb. 14, 2002.

¹⁴³Ian Zack, *Oxy Morons*, FORBES.COM, (Apr. 12, 2002) at http://biz.yahoo.com/fo/020412/oxy_morons.1.html

¹⁴⁴*See* Devoe v. Purdue Pharma et al., No. MERC-653-02 (N.J. Super. Ct. Law Div. filed Feb., 26, 2002).

go on to allege that Purdue downplayed the addictive risks associated with OxyContin.

Moreover, it is not just private parties with which Purdue has to contend. On June 11, 2001, West Virginia Attorney General Darrell V. McGraw, Jr. filed suit (the complaint also names Abbott Laboratories, which was a co-marketer of OxyContin, particularly to hospitals). In addition to claiming civil liability for Purdue's marketing tactics, the case also questions Purdue's failure to market an abuse-resistant form of OxyContin.¹⁴⁵ To legal observers, this case in many ways will determine Purdue's future liability. Similar to tobacco litigation, many states are standing back, waiting to see what the outcome will be.¹⁴⁶ West Virginia is suing for reimbursement of the health care and enforcement costs it claims it has been forced to incur due to OxyContin abuse. Similar to the private civil cases, though, the case will turn on how much Purdue knew about the drug's addictive qualities, and when they knew it. Thus far there does not appear to be any smoking gun. While admittedly aggressive, the marketing campaign has not been shown to be intentionally or recklessly misleading in the face of large and apparent risks. While Purdue's marketing certainly bears blame for the widespread abuse, it is not likely to borne in a legal venue.

In the face of these legal challenges, Purdue's best defense in many ways has been its response since the first reports of OxyContin abuse became public. As described, there does not appear to have been any reason for the company to have suspected that OxyContin might be abused. MsContin had been released with little or no diversion for over fifteen years. While oxycodone was expected to be a better seller due to the negative associations people had with morphine, abusers were not likely deterred by the stigma. In addition, it was over four years after OxyContin was introduced that the first reports of abuse came out, despite already high sales. Therefore, the drug clearly was not unreasonably addictive. Few claims of addiction

¹⁴⁵See *State of West Virginia v. Purdue Pharma et al.*, No. 01-C-137-S (W. Va. filed June 11, 2001).

¹⁴⁶Matt Bean, *Fighting the 'Miracle Drug' That Turned Deadly*, COURT-TV.COM, at http://www.courtstv.com/news/feature/oxycontin_ctv.html (last visited Apr. 27, 2002).

stem from those who were prescribed the pill legitimately and took it according to directions. Rather, the drug has become addictive for those who did not follow the indications or broke the pill and then ingested it. While the acknowledged role of and potential need for the “rescue” medication makes the controlled-release aspect of OxyContin a less powerful tool against abuse, there have been no public reports of abuse of OxyFast or OxyIR. Those drugs would be used as part of a managed pain treatment regime and those are not the patients who became addicted. Furthermore, the role of these medications in the treatment was well documented from the beginning for physicians and pharmacists. There is no denying that OxyContin is a powerful drug with highly addictive properties. Nevertheless, these risks can be controlled with adequate care and supervision. The facts and circumstances of OxyContin abuse indicate that the real fault lies in a lack of education and understanding about addiction and the addictive qualities of the pill, rather than with the pill itself or any intentional deception by Purdue.

Purdue’s response to these problems reveals little initial hesitation and a willingness to acknowledge these problems and work to fix them. For example, the West Virginia suit faults Purdue for failing to formulate OxyContin in an abuse resistant way.

As the facts show, though, there was no reason to suspect that such a formulation would be necessary. Even the FDA admits that it knew that crushing the pill would defeat the controlled-release mechanism, but it did not believe that that would be widely done. Nevertheless, since the reports of abuse came out, Purdue has embarked on an aggressive scientific program to develop an abuse-resistant form of the pill. The program calls for the addition of an antagonist that will block the opioid effects of the pill if it is crushed and ingested. Developing such a compound is complicated and potentially risky. Other drugs have contained a compound called naloxone to combat abuse. For a number of scientific and medical reasons, though, that antagonist is not ideally suited to combination with oxycodone. Rather, researchers have looked to naltrexone, a similar

acting antagonist, with longer acting properties.¹⁴⁷ There are a number of complications involved with such a reformulation. One major issue is that reformulation in this manner will not limit the opioid effects of the drug if crushed and taken orally.¹⁴⁸ This may limit the value of reformulation, for the federal review of autopsies revealed that the great majority of those who died from an overdose connected with oxycodone chewed the pill and took it orally.¹⁴⁹ In addition, reformulating the drug involves adding a second active ingredient that legitimate users do not need. A great amount of care must be taken to ensure that the new formulation is still effective and will not adversely affect patients.¹⁵⁰ Finally, a reformulated drug would have to be approved by the FDA. While the company could submit the drug under an expedited review process for changes to already approved drugs, the process would still take an additional six to ten months.¹⁵¹ Nevertheless, by the end of this year Purdue will have spent \$100 million on researching and developing new forms of abuse resistant painkillers.¹⁵² Purdue began clinical studies on a new formulation of OxyContin in December of 2001, with an aim to file an application with the FDA by the end of this year and have the drug on the market by 2003. The drug under consideration would be made available as a substitute for OxyContin in areas where abuse has been prevalent.¹⁵³ The challenges inherent in reformulating the drug, though, make it clear that there is no magic bullet to stop OxyContin abuse.

Purdue's response to the reports of abuse has not been limited to research and development. In assessing both legal and moral liability for the abuse, a central issue will be whether the company continued to sell the product without additional warnings after it became aware the drug was addictive and being widely

¹⁴⁷Barry Meier, *Maker Chose Not to Use a Drug Abuse Safeguard*, N.Y. TIMES, Aug. 13, 2001, at A11.

¹⁴⁸*Senate Hearing*, *supra* note 45, at 16 (testimony of John K. Jenkins, Director of the Office of New Drugs, CDER, FDA).

¹⁴⁹Meier, *supra* note 82.

¹⁵⁰*Senate Hearing*, *supra* note 45, at 16 (testimony of John K. Jenkins, Director of the Office of New Drugs, CDER, FDA).

¹⁵¹Meier, *supra* note 147.

¹⁵²*House Hearing*, *supra* note 14, at 28 (statement of Paul Goldenheim, Executive Vice President, Research and Development, Purdue Pharma).

¹⁵³Michael Lasalandra, *OxyContin Maker Testing Abuse-Resistant Pill Design*, B. HERALD, Dec. 5, 2001, at 17.

abused. That does not appear to have been the case. Like federal regulators and local law enforcement, Purdue was caught by surprise as the stories began to appear. Though they have certainly made missteps, since the first reports came out their actions overall have been increasingly focused in the right areas and offer a roadmap as to how best to combat OxyContin abuse and diversion. Education has been one of the primary responses. Whether justified or not in their earlier approach, the tone of Purdue's materials and programs on OxyContin have changed significantly. The following exchange between Senator Susan Collins of Maine and Dr. Paul Goldenheim of Purdue, highlights well the educational changes and efforts made by the company in the wake of the reports:

COLLINS: You showed us a number of excellent materials and I've been through them in your submitted packet to the committee, that are designed to alert people to the dangers of abusing prescription drugs. They are excellent materials. I am curious whether they were provided to physicians by your field reps when you first began marketing OxyContin or whether these were only developed later when it became evident that there was a serious problem with abuse of your product.

GOLDENHEIM: The answer is a little bit of both. Some of the materials for example the opioid therapy documentation kit which talks about some of the issues that Dr. Payne raised about assessment and proper documentation and evaluating the patient and in forming an individualized treatment plan that and some of the guidelines were distributed as soon as they were available in 1997... So we disseminated these guidelines as they were developed by the medical community. Some of the other materials to fully respond to your question for example, the brochures on how to avoid abuse and diversion, tamper resistant prescription pads. Those were developed after we were alerted to the problem, typically in cooperation with law enforcement. We spent a great deal of time, the senior executives at Purdue, traveling up and down the northeast corridor, starting in Maine, trying to learn what the problem was, what the sources were that they've been described very nicely and we developed those materials in response to that.¹⁵⁴

While it is clear that the medical community seriously needed information on abuse and diversion from early on, once the problems became visible Purdue altered its marketing program and, over time, helped limit the problem. As was seen in Purdue's initial reluctance to focus on OxyContin's risks, though, its anti-abuse campaign has also taken time to focus on areas that are of the most concern. Such difficulties are to be expected in any similar campaign initiated in the face of a huge amount of publicity and a dearth of reliable

information, and Purdue's approach has evolved in response to the growing understanding of the problem.

Purdue's formal response began in March of 2001 when it introduced its "10-Point Plan to Reduce Prescription Drug Abuse and Diversion, Without Compromising Patient Access to Proper Pain Control." The title highlights the approach Purdue and much of the medical community have taken in addressing the problems, insofar as it makes maintaining access to the pill a top priority. The 10-Point Plan involved a host of initiatives structured to combat diversion and abuse. The initiatives highlighted in the plan have become the basis for Purdue's efforts to reduce OxyContin abuse. The degree to which different aspects have been emphasized, though, has evolved in response to criticism and changing information. A Purdue press release from March, 2001 presented the 10 points. They included improved healthcare professional education, the distribution of tamper-resistant prescription pads, the launch of "Painfully Obvious" (a prescription drug abuse prevention and education program for middle and high school students), the continued distribution of opioid documentation kits and medical guidelines for the prescription of opioids, and the distribution of abuse and diversion brochures. The remaining points of the program were the endorsement of prescription monitoring programs (PMPs), the development of educational programs with the law enforcement community, the establishment of the RADARS system (the Researched Abuse, Diversion, and Addiction-Related Surveillance System is meant to improve on the DAWN statistics), the improvement of efforts to combat international smuggling (Purdue independently began marking pills sent to Canada and Mexico), and increased research into abuse-resistant medication.¹⁵⁵ In addition, in May Purdue suspended shipments of the 160 mg OxyContin, although likely to little effect. The pill was appropriate for only the most opioid tolerant patients and made up only one percent of OxyContin prescriptions. Perhaps in part due to its infrequent

¹⁵⁵ See http://www.purduepharma.com/pressroom/app/news_announc/ss_10ptPlan.asp (last modified Jan. 31, 2002).

prescription, the pill was rarely reported as abused (according to the DEA the 20 mg pills are the most frequently abused).¹⁵⁶

This mix of approaches initially did not satisfy some, particularly in areas hard hit by abuse. Many felt that the program was misdirected and complained that Purdue's efforts did not include support for rehabilitation programs. In addition, others felt that Purdue's efforts with prescription pads and international smuggling were ways for the company to avoid the real problem and would not do much good.¹⁵⁷ While accurate statistics regarding the precise channels of the illegal supply of OxyContin are unavailable, the general belief is that the problems are more local and less high tech in nature. While Purdue's efforts in these areas cannot hurt, more would be gained by focusing on the education of physicians and patients about the dangers of the drug. Public officials, specifically, often spoke out against Purdue's initial focus. For example, at a news conference in Alabama involving the parents of children who had overdosed on OxyContin, Gov. Don Siegelman interrupted a Purdue representative who was going through the 10-Point Plan, saying, "I find this very offensive, and I want you to stop. We've had enough public relations and enough sugar-coating of this issue and quite frankly, as governor, I am fed up."¹⁵⁸ Purdue had a similar problem in its relationship with the Attorney General of West Virginia, who three months after a meeting with Purdue executives that outlined their approach, filed the lawsuit described earlier.

These criticisms highlight a consistent problem Purdue has had with its public relations and campaigns. As described, the company had traditionally been extremely publicity shy and its internal working are highly protected. Nevertheless, in the years leading up to OxyContin's release, the company initiated an ambitious marketing campaign. Since the troubles with OxyContin became public, though, not only have

¹⁵⁶Reidy, *supra* note 77.

¹⁵⁷Tough, *supra* note 16.

¹⁵⁸*Id.*

these older campaigns been criticized, but the company has continued to make missteps. To some degree this is unsurprising given the media frenzy that has descended on the company. Opposite a devastated family in a small town in Appalachia, a billion dollar pharmaceutical company will have a difficult time coming off sympathetically. In addition, the company does have a genuinely difficult balance to maintain between its duty to customers who greatly benefit from the drug and those who have had their lives ruined. The balance reflected in the title and approach of the 10-Point Plan is representative of these challenges, which make it impossible to make everyone happy. In spite of these realities, the company has still seemingly had a hard time defending itself and expressing its intentions and plans to the public. By the summer of 2001 the public tide had turned significantly against it and Purdue initiated a public relations campaign to defend itself and its product. The company assembled a four person public relations team and set out to defend itself in a more aggressive and organized manner.¹⁵⁹ Purdue's public relations missteps are somewhat ironic given the lineage of the company. Though founded by Mortimer and Raymond Sackler, their brother Arthur was also involved with the company. Arthur made his own fortune as owner of the New York medical advertising agency, William Douglas McAdams. He was famous for revolutionizing the way drugs are marketed, modifying the dry, catalogue approach of the 1950's and 60's into one which used flashy color images. He also introduced the idea of direct-to-consumer advertising to the industry. In 1997 he was posthumously elected into the Medical Advertising Hall of Fame.¹⁶⁰ While Arthur's brothers likely could use his talents and expertise to help their company weather the current storm, in many ways it is precisely the tactics he was famous for that has left them in such a lurch.

These early setbacks, though, helped the anti-abuse program evolve and, over time, different areas of the

¹⁵⁹Reidy & Rich, *supra* note 52.

¹⁶⁰Wong, *supra* note 2.

10-Point Plan have received more attention and funding. Specifically, research and development, education and PMPs have received the most attention in Purdue's recent statements and actions. While there are numerous challenges to reformulating OxyContin, the growing focus on education and PMPs is hopeful. Purdue's informational response is focused on both the healthcare community and patients, particularly those in high risk groups and areas. To healthcare workers Purdue has stressed appropriate patient assessment and selection, prevention of diversion and abuse, as well as the recognition of addictive behaviors. In addition, as described, in cooperation with the FDA Purdue voluntarily modified OxyContin's physician prescribing information, adding a "black box" warning to the label and sending out letters to over 800,000 health care workers. These types of educational efforts seem to be the most effective way for Purdue to combat abuse. In addition to distributing materials regarding abuse and diversion, Purdue has sponsored Continuing Medical Education programs in at-risk areas in order to emphasize doctors' roles in preventing such behavior.¹⁶¹ In addition, sales representatives, particularly those who operate in areas of high abuse, have been retrained to highlight the risks of abuse and diversion using input from the DEA. 180 representatives have gone through the training and their "primary" responsibility in these high risk areas is now to educate healthcare professionals on how to combat abuse and diversion. In addition, any visit anywhere by a sales representative now highlights the information included in the July 2001 "Dear Dr." letters, as well as the changes to the prescribing information and label.¹⁶² Furthermore, Purdue has continued to send out, and emphasized more, the Federation of State Medical Boards' "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." The guidelines, published in May of 1998, have received wide support, including from the DEA, and serve as an excellent reference for doctors generally unfamiliar with the treatment of pain and the prevention of abuse and diversion.¹⁶³ Though developed during the upswing of interest in and

¹⁶¹Alex Otto, *Oxycodone Abuse Creating Problems for Pharmacists, Patients*, 7 PHARMACY TODAY 4 (2001).

¹⁶²*House Hearing*, *supra* note 14, at 75 (testimony of Paul Goldenheim, Executive Vice President, Research and Development, Purdue Pharma).

¹⁶³NAGEL & GOOD, *supra* note 19. See also <http://www.fsmb.org> (posting the guidelines and information about them).

support for the improved treatment of pain and the utilization of opioids, the guidelines offer a balanced approach to the practice and are independent of corporate sponsorships.

V. The Lessons and Solutions

Increasingly, education has come to the forefront of Purdue's program. It is these sorts of efforts that will be most effective in curbing the diversion and abuse of OxyContin. While Purdue has limited control over the monitoring and enforcement of how its drug is abused, it can have a positive influence on how and why it is prescribed. As described, doctors acknowledged a real ignorance as to issues regarding both pain and addiction. This lack of training was a recipe for disaster and has to be considered one of the primary causes of the problems with OxyContin. As the statistics show, millions of people are abusing prescription drugs. This is a problem independent of OxyContin. Nevertheless, OxyContin is a particularly strong and addictive medication. Doctors felt too comfortable prescribing the drug for too many people in too many circumstances with too little information and oversight. One of the unique aspects of OxyContin is that it is an opioid that general practitioners have felt comfortable prescribing. The drug had truly remarkable positive properties and, without much experience or training, doctors saw no reason not to use it to relieve their patients' chronic pain. There is no doubt doctors are highly trained professionals who knew the drug was different than other pain relievers and bear individual responsibility for any liberal prescribing of the drug. Nevertheless, though, better formal training in the areas of pain diagnosis and treatment, as well as the recognition and prevention of addiction, would clearly have made a difference. This was not entirely Purdue's responsibility as it initially released OxyContin. While prescription drug abuse was a known problem and

OxyContin's characteristics might have suggested that special precautions be taken, there was no formal sense, either from regulations, clinical trials or experiences with similar drugs, that Purdue should provide special education over and above what it did at the time. As the problem has emerged, though, so has an important part of the solution. By better educating medical professionals as to the issues involved with prescribing OxyContin, a significant amount of diversion and abuse can be eliminated. As described, very few people have claimed to become addicted to the drug by taking it according to instructions. Rather, the drug has come to be abused by those who have been prescribed the drug improperly or have taken it improperly after receiving a prescription. In this way, then, doctors and healthcare workers are the first line of defense against abuse. As the suppliers of the drug, they are in an excellent position to help limit its abuse. Purdue's educational efforts are a big step towards achieving this goal.¹⁶⁴

In addition, medical schools and professional associations must also highlight these issues. While particularly relevant to OxyContin abuse, prescription drug abuse in general could be reduced by such programs. Finally, patients and abusers also need to be educated. Once again, medical professionals are the first and best resource here. When prescribing a drug doctors must stress the risks and dangers as well as the appropriate ways it should be taken. In support of these efforts Purdue has produced a number of public service announcements regarding the dangers of prescription drug abuse. These ads have targeted adolescents and young adults. The "Painfully Obvious" campaign, unveiled as part of the 10-Point Plan, included a website and has been the focal point for many of these efforts.¹⁶⁵ In August, Purdue launched a poster campaign in community centers, schools and other areas where teens congregate. The posters highlight the negative effects of prescription drug abuse. For example, one reads, "Rubbing tuna fish in your armpits does not make a good deodorant. And itchy red skin splotches caused by abusing prescription drugs look nasty."¹⁶⁶

¹⁶⁴See generally *Drawing the Line Between Pain Management and Addiction*, 9 PSYCHOPHARMACOLOGY UPDATE 1 (2001) (examining the need for physician training in pain management and addiction).

¹⁶⁵See generally <http://www.painfullyobvious.com> (last visited Apr. 27, 2002).

¹⁶⁶Kristen Rountree, *Time for a Change*, ADWEEK, Aug. 20, 2001.

This fall the company initiated a series of radio ads that also played up the side effects of prescription drug abuse, but did not mention OxyContin specifically. The ads were to run in the areas hardest hit by OxyContin abuse.¹⁶⁷ In addition, somewhat controversially, Purdue hired many of their most vocal critics in government and law enforcement to work as consultants in formulating ways to combat prescription drug abuse as well as to speak and educate on its behalf. Notable hires included U.S. Attorneys Joseph Famularo and Jay McCloskey, of Kentucky and Maine, respectively.¹⁶⁸ A tension arose, though, for although one would seemingly want to have the best and most experienced people working to combat the problem, hiring their critics gives the impression that Purdue was trying to silence them. In addition, some attorneys have argued that these hirings are also meant to give Purdue an advantage in the lawsuits against it. Regardless of their propriety, the hirings offer another example of, both, the aggressive manner in which Purdue has sought to fight OxyContin abuse, as well as its difficulties with public relations.

The public service announcements, in addition to providing valuable information, also represented an effort by Purdue to improve its battered public image. The company, hoping to build up some goodwill around the country and perhaps dampen some of its nearly constant and uniformly bad press, sought to emphasize its commitment to, and efforts on behalf of, reducing prescription drug abuse. If there was any doubt as to the matter, a six month campaign begun this February laid it to rest. In ads placed in newspapers around the country, Purdue, without mentioning OxyContin, highlighted the large problem of prescription drug abuse as well as its efforts to fight it. In regard to the campaign, Purdue spokesman Robin Hogen said, “[t]here’s been too little recognition in the media for what we have been doing. We could bury our heads in the sand the way the industry has.”¹⁶⁹ It is still unclear whether or not this most recent campaign will have the

¹⁶⁷ *OxyContin Maker to Run Drug Abuse Ads*, L.A. TIMES, Nov. 9, 2002, at A33.

¹⁶⁸ Laurence Hammack, *Lawyer: Purdue Pharma Co-Opts Critics*, THE ROANOKE TIMES, Mar. 2, 2002.

¹⁶⁹ *Purdue Pharma Ads Discuss Painkiller*, MILWAUKEE J. SENTINEL, Feb. 21, 2002, at D1.

desired effect. One can note already, though, that since the start of 2002 there has been a noticeable decline in the amount of media attention focused on OxyContin and Purdue. While this may simply be a product of the fickleness of the modern media or an acknowledgment that the problem was not as large as portrayed, Purdue has benefited. Nevertheless, one of the few recent articles that focuses at all on the company, reveals that the company still finds itself in a bind. In March the company donated \$3 million to Massachusetts General Hospital to open the Purdue Pharma Pain Center.¹⁷⁰ The donation reveals that Purdue intends to continue promoting issues regarding pain despite the OxyContin crisis. Unfortunately for Purdue, though, the article covering the gift was one of the few in recent months that once again examined the problems surrounding OxyContin and Purdue. It appears, then, that for the time being, if it wishes to avoid negative press, the company can do so by limiting its own public actions.

In general, then, any reasonable blame Purdue is to receive seems to come more from its inaction than anything it affirmatively did. While Purdue's actions certainly did contribute to the pills' popularity and availability, none have been shown to be illegal or even more than potentially inappropriate. Rather, OxyContin abuse stems from a complicated mixture of factors. Lack of medical training in important areas, widespread abuse of prescription drugs in general, and OxyContin's unique qualities all made for a potential problem. No one predicted the problem, nor did it arise until nearly four years after the drug was released. While the drug had remarkable sales figures which grew by significant amounts each year, that is unsurprising given the widely documented benefits it brought to the millions who suffer from chronic pain. In retrospect, the drug's risks and dangers should have been made clearer by Purdue and the medical community should have taken them more seriously. The problem, though, was one of information and education, rather than any concerted effort to encourage or engage in the mis-prescription and misuse of the drug.¹⁷¹ Given this

¹⁷⁰Raja Mishra, *Deal May Tie MGH to Furor on Pain Pill; OxyContin Maker Funds New Center*, B. GLOBE, Mar. 14, 2002, at A1.

¹⁷¹*See generally Purdue Pharma Not Responsible for OxyContin Abuse, Expert Panelists Say*, REUTERS HEALTH INFO., Feb. 7, 2002 (detailing a conference sponsored by the American Enterprise Institute where a vast majority found Purdue not to be responsible for the recent abuse of OxyContin).

understanding, Purdue's efforts in education are a big step in solving the problem. Purdue, though, cannot tackle it all by itself. Even with a renewed focus on the issues surrounding the treatment of pain and addiction by all parties in the medical field, education alone is not the whole solution. There is also a significant role to be played by enforcement and monitoring. In the early days of the problems, when people's fears were at their highest, proposals in this area went so far as to call for the drug to be banned. Over time, though, as the scope of the problem has been clarified and put into perspective, and the value of the pills has been acknowledged, new approaches have been identified.

No matter how much education and training doctors and patients receive, there will still inevitably be those who want to divert the drug. Therefore, there must be a system in place that utilizes other means and incentives to prevent such diversion and to catch and punish it when it does occur. All of the efforts in this area, though, must be evaluated against the important goal of maintaining access to the drug for legitimate patients.¹⁷² Neither the FDA nor the DEA (which puts in place manufacturing quotas for the drug) has formally expressed any interest in reducing legitimate patients' access to the drug.¹⁷³ Some have proposed limiting prescribing power for the drug to pain specialists. Such a proposal is unfeasible, though, for there are only about 3,000 such specialists in the country.¹⁷⁴ Limiting prescribing power in this way would unnecessarily restrict patient access to the drug. Furthermore, there is no assurance that all pain specialists will prescribe the drug perfectly or spot every potential abuse. While OxyContin is a powerful drug and pain a largely misunderstood condition, other physicians can be trained to administer the drug responsibly. That is by far the more sensible solution.

In a similar vein, some have argued that OxyContin only be administered from central pharmacies. This measure is in large part a response to the numerous reports of pharmacy robberies in conjunction with the

¹⁷²See generally Hilary Waldman, *Saved by OxyContin; Chronic Pain Sufferers Get Their Lives Back But Worry That War Against Abuse Could Restrict Access*, THE HARTFORD COURANT, Aug. 14, 2001, at D3 (highlighting the unique positive effects of the drug and the fears of those who have benefitted from it).

¹⁷³White, *supra* note 137.

¹⁷⁴Chevlan, *supra* note 29.

pill. The hope is that a centralized pharmacy would be more prepared and able to deter and protect against such robberies. In addition, a centralized distribution system would limit some of methods of diversion by which illegitimate patients seek out the drug. While this approach is aimed at achieving worthwhile goals, it is an unrealistic and inappropriate way of approaching them. Once again, this solution would result in limiting legitimate patients' access to the drug. Even in Massachusetts, the state hardest hit by OxyContin-related pharmacy crime, such a proposal was rejected by the state pharmacy board, which mandates that pharmacies stock a broad assortment of medically essential drugs.¹⁷⁵ Especially given the fact that OxyContin patients are often in extremely poor health, increasing the distance they must travel to get the drug would be prohibitive. In addition, security concerns can be addressed amply at the local pharmacies. For example, OxyContin can be locked in a safe after closing, when most robberies take place, or pharmacies can be allowed to carry lower inventories of the drug to deter thieves. Finally, the goals of deterring and catching those abusers who illegitimately obtain prescriptions can be better achieved by improving the nation's PMPs, which is the most promising approach on the enforcement side of the effort and will be discussed shortly. Overall, then, limiting the production, prescription and distribution of the drug is an inefficient and inappropriate means to limit diversion and abuse. Rather, measures should be focused on limiting diversion and abuse, directly, while leaving legitimate patients with local access to the drug.

One area in which this approach is complicated, though, is the extent to which governments ought to cover OxyContin under public insurance and prescription plans. Already, six states have developed systems to prevent Medicaid recipients from receiving the drug so easily.¹⁷⁶ In July of 2001, Vermont became the first state to refuse welfare coverage for OxyContin.¹⁷⁷ In March, Governor Swift of Massachusetts also cut OxyContin from the list of medicines covered by the state's prescription drug plan.¹⁷⁸ As described, welfare fraud is

¹⁷⁵Arden-Smith, *supra* note 111.

¹⁷⁶Bean, *supra* note 146.

¹⁷⁷Carey Goldberg, *Vermont: State Won't Cover Painkiller*, N.Y. TIMES, July 21, 2001, at A11.

¹⁷⁸Steve Marantz, *Swift Plan to Cut Coverage for Nine Brand-Name Drugs*, B. HERALD, Mar. 15, 2002, at 10.

common in the diversion of OxyContin and the estimated costs run into the millions of dollars, leading some to describe covering the drug as “federally financed drug abuse.”¹⁷⁹ Limiting coverage under these programs, then, offers a way to hinder diversion of the drug, while still keeping it available. While traditional economic theory has little relevance when dealing with addiction, nevertheless one would still expect that as the price of a drug rises, its demand will decrease. At the least, early stage abusers might be deterred from attempting to get the drug in the first place if they must pay full price. As described, a Medicaid patient, for example, will pay \$1 for a prescription of OxyContin that would cost \$250 retail. Furthermore, to obtain a similar quantity of the drug on the street one would have to pay approximately \$2000. These price discrepancies not only lower a barrier to abuse by making it virtually costless for illegitimate patients in these programs to obtain the drug, but also offer a ripe opportunity for huge profits through fraud and diversion. Certainly poor patients suffer from pain just like other patients, but the costs of making the pill available through welfare programs suggest that this is one area where it might make sense to lessen the drug’s availability, either by cutting it out completely or by raising its price to a point where obtaining it is not basically free. Another approach to limiting diversion of the drug is occurring “naturally.” Lawsuits, both criminal and civil, have a role to play in reducing OxyContin abuse. As described earlier, numerous suits have been leveled at both physicians and Purdue. These suits and the threat of more will also serve as a deterrent to irresponsible marketing, distribution and prescribing of the drug. As in all aspects of combating OxyContin abuse, care must be taken not to chill doctors and other healthcare professionals from administering the drug to appropriate patients. Frivolous suits should be discouraged, because the fear of suit, when combined with the sensationally negative publicity the drug has received, may lead doctors to simply not prescribe OxyContin and instead continue prescribing other less effective medication. To date, as reviewed earlier, the legal environment seems to be adapting well and appropriately to the problem. Honest and responsible

¹⁷⁹Melody Petersen & Barry Meier, *Few States Track Prescriptions As Way to Prevent Overdoses*, N.Y. TIMES, Dec. 21, 2001, at A1.

doctors are not being tried nor going to jail and frivolous suits against Purdue are not going forward nor being settled.¹⁸⁰

Enforcement must also play a role in deterring the addicts, themselves, from obtaining and abusing the drug. Arresting and prosecuting prescription drug abusers involves unique challenges, though, even compared to traditional illegal drug enforcement. A state prosecutor in Maine said of one aspect the problem, “[i]f you have probable cause to think somebody has 30 bags of heroin and they are dealing it, you can get a search warrant. If you have probable cause to believe that somebody has 30 OxyContin tablets and they are selling them out of their house, it would be hard to get a warrant.”¹⁸¹ State and federal law enforcement agencies should work to develop new approaches to combat prescription drug abuse. One approach would be to give harsher penalties and sentences to those found in possession of prescription drugs without a prescription. It has been repeatedly documented, as seen in the personal stories described earlier, that many people are more comfortable abusing prescription drugs because they are seen as safe and *legal*. Measures must be put in place that change that impression. As we have seen, OxyContin abuse can be every bit as destructive and dangerous as cocaine or heroin abuse. Therefore, the penalties and perceptions regarding the drugs must be modified accordingly.¹⁸² Perhaps most importantly, though, measures must be adopted that make supervising and catching such abuse much easier. Because these drugs are available in every pharmacy and legitimately prescribed millions of times, catching illegal users will always be difficult. All the penalties in the world will not make a difference if an addict does not believe he or she will ever be caught. Therefore, the greatest potential for improvement in this areas involves PMPs.

¹⁸⁰Zack, *supra* note 143.

¹⁸¹Mehren, *supra* note 67.

¹⁸²*See, e.g.* Steve Ritea, *Toughened Regulations for OxyContin Proposed*, THE TIMES-PICAYUNE (New Orleans), Apr. 10, 2002, at 5 (reviewing new proposals in Louisiana to combat rising OxyContin abuse, including stronger penalties for abusers and doctors who prescribe the drug illegally).

PMPs, prescription monitoring programs, are what their name implies. The programs, usually through electronic databases, record and track who prescribes and who gets certain medicines.¹⁸³ Although they differ as to the drugs that they track and the logistics of the databases, as of this year, fifteen states had implemented programs fitting the general description.¹⁸⁴ Traditionally, the programs have been heavily opposed by both the medical community and pharmaceutical companies, both of which fear doctors being deterred from prescribing necessary medication.¹⁸⁵ Nevertheless, in recent years, given the rapid increase of prescription drug abuse in general, more and more states have begun to look seriously at the programs. The publicity given OxyContin diversion and abuse has brought the issue to a head and eight more states, including Connecticut, Florida and New Jersey, are close to implementing PMPs.¹⁸⁶ PMPs offer the most effective and efficient means to enforce the laws against the diversion and abuse of both OxyContin and other prescription drugs. The value of the programs has become clearer and clearer as the problems have become more prevalent. As described, even Purdue has made supporting PMPs part of its efforts in this area. The statistics show that the support is well placed. For example, the five states with the lowest per capita levels of OxyContin abuse all have PMPs in place, while the majority of states that report significant abuse do not.¹⁸⁷ Without these programs there is no way other than calling up each and every relevant pharmacy to track the amount of drugs being prescribed by any doctor or purchased by any patient. Therefore, it is very easy for drugs to be illegally prescribed or obtained through “doctor shopping.” Once a PMP is in place, though, a central database tracks such information and illegal diversion can be more effectively combated.

¹⁸³See generally DIVERSION CONTROL PROGRAM, DRUG ENFORCEMENT AGENCY, PROGRAM REPORT: A CLOSER LOOK AT STATE PRESCRIPTION MONITORING PROGRAMS (2000) (reporting the results of a detailed in-depth study conducted by the DEA into PMPs across the country as well as their costs and benefits, finding the benefits to greatly outweigh the costs), available at http://www.deadiversion.usdoj.gov/pubs/program/rx_monitor/index.html (last visited Apr. 27, 2002).

¹⁸⁴*Pharmacy Practice: State Monitoring Programs Seen As Key to Tackling OxyContin Abuse*, DRUG WEEK, Feb. 22 - Mar. 1, 2002, at 15.

¹⁸⁵Petersen & Meier, *supra* note 179.

¹⁸⁶Bean, *supra* note 146.

¹⁸⁷*House Hearing*, *supra* note 14, at 8 (statement of Asa Hutchinson, Administrator, Drug Enforcement Administration).

There are few legitimate drawbacks to the system. As stated, doctors and pharmaceutical companies fear that not only illegal prescriptions, but also legitimate prescriptions, will be chilled. A study by the DEA, though, has found no such effect in those states already using PMPs.¹⁸⁸ Furthermore, the programs are focused on deterring abusers from seeking out numerous doctors for prescriptions, rather than on individual doctors' prescribing habits. Purdue's simultaneous support for both PMPs and easy access to medication for legitimate patients reveals that the programs can be tailored to inhibit only illegitimate prescribing. Critics have also raised fears about the loss of patient confidentiality. PMPs, though, do not make any more information available than already is under controlled substance regulations. The programs merely centralize the information and make it more useful. In addition, every state with a monitoring system as of 2000 had put in place safeguards to protect confidentiality and no breaches have been reported.¹⁸⁹ The most significant drawback of the programs, then, seems to be their costs. For example, Kentucky instituted a program in 1999 that has received wide acclaim. The program cost about \$415,000 to start and \$600,000 thereafter to operate.¹⁹⁰ Though not too expensive, states' resources are stretched and often it is difficult to find funding for PMPs. In addition, it is critical to their effectiveness that once established, PMPs receive adequate funding. One of the reasons Kentucky's PMP failed to catch the growing OxyContin problem early on was that the three pharmacists who ran it were overwhelmed by routine work.¹⁹¹ To help alleviate these strains this year Congress appropriated \$2 million to fund grants to help states establish PMPs.¹⁹²

Federal intervention in the establishment of PMPs is needed for more than just fiscal reasons. In many ways, a state independently setting up a program can be somewhat futile. In areas with a number nearby

¹⁸⁸ DIVERSION CONTROL PROGRAM, *supra* note 183.

¹⁸⁹ *Id.*

¹⁹⁰ *Pharmacy Practice: State Monitoring Programs Seen As Key to Tackling OxyContin Abuse*, *supra* note 184.

¹⁹¹ Petersen & Meier, *supra* note 179.

¹⁹² *Id.*

borders, prescription abusers can easily cross state lines to evade the system and get their fix.¹⁹³ This has been commonly reported in the Appalachian areas hardest hit by abuse. For example, although Kentucky recently instituted a PMP, its effectiveness is limited by the fact that states next door do not have them. Therefore, more federal funding and coordination would be very valuable in establishing the PMPs and making them as effective as possible. Given the human and financial devastation that prescription drug abuse has wrought, the costs hardly seem prohibitive.

By combining these types of educational and enforcement initiatives OxyContin's full potential may be realized. As has been seen, there is a tremendous amount of good that OxyContin can do. The medical community for the first time has made the treatment of chronic pain a top priority. Until recently, a lack of focus on the issue and a dearth of treatment options left tens of millions of Americans to suffer without much hope. Unfortunately, though, the enthusiasm with which the medical community embraced the treatment of pain was not tempered by complete and formal training. OxyContin, in retrospect, was far too powerful of a drug to be released casually into this environment.

Although a Schedule II narcotic, it quickly became a billion dollar product. What was needed was much more information and education. Behind the sensational headlines lies that simple fact. While a number of other factors and circumstances certainly contributed to the abuse and diversion of the drug, their significance is largely determined by their effect on people's understandings of and approach to the use of the drug. There is nothing inherently wrong with OxyContin. That it is extremely powerful and potentially addictive does not mean it should not be available. Rather, these special qualities show why the drug is different from typical prescription drugs, and prescription drug abuse, and why it deserves special attention. Going forward, the

¹⁹³Rosenberg, *supra* note 59.

experiences with OxyContin have not only revealed some solutions to the problems at hand, but have also exposed weaknesses in the general system that will help prevent similar situations in the future. While both Purdue governmental and agencies made mistakes along the way, none were so clear at the time or easily avoidable as to warrant individual reprimand. Rather, the story of OxyContin is in many ways that of a drug slightly ahead of its time. There will always be those who will misuse prescription drugs, but they need not go unchecked. As educational and enforcement initiatives evolve so too will the full potential of the drug.