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# NOTES

## No Pain No Gain?! Who Will Make the Greatest Sacrifices in Curbing Opioid Analgesic Diversion and Abuse?

BY KENT DURNING\*

### I. INTRODUCTION

The Substance Abuse and Mental Health Services Agency (“SAMHSA”) estimates that nine million people currently abuse prescription drugs in the United States.<sup>1</sup> Prescription drugs contribute to twenty-five percent of all United States drug overdose deaths,<sup>2</sup> this trend parallels an increase in legal prescription drug use throughout the nation.<sup>3</sup>

The prescription drug abuse problem is particularly acute in Kentucky. For example, in 2001 Kentucky’s rate of hydrocodone<sup>4</sup>

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<sup>1</sup> Alexandra Marks, *Steep Rise in Abuse of Legal Drugs*, CHRISTIAN SCIENCE MONITOR, Oct. 1, 2003, at 1, available at <http://www.csmonitor.com/2003/1001/p01s01-ussc.htm>. Abuse is defined as use “for non-medical and often recreational purposes.” *Id.* An estimated one-third of those abusers are children between twelve and seventeen years old. SAMHSA reported a 163% increase in emergency room visits for injuries related to prescription drug abuse between 1995 and 2002. *Id.*

<sup>2</sup> *Id.* Although these statistics are alarming, it is important to note the possibility for overlap, where the contribution of prescription drugs in a specific death may be uncertain because of the contemporaneous use of other illicit or non-pharmaceutical substances. See *infra* part III.C on the inadequacy of drug reporting systems.

<sup>3</sup> See Marks, *supra* note 1 (noting the parallel between a four-fold increase in prescriptions for Ritalin, a stimulant used to treat attention deficit disorder, and its increase in popularity as a recreational drug among teenagers).

<sup>4</sup> Hydrocodone is “one of the most often-diverted pharmaceutical drugs.” DRUG ENFORCEMENT ADMIN., DRUGS AND DRUG ABUSE, STATE FACTSHEET, KENTUCKY, at

distribution per 100,000 residents was almost twice the national average; it is now the second highest in the nation.<sup>5</sup> Further, Kentucky's rate is at least twenty percent higher than that of Tennessee or West Virginia.<sup>6</sup> The eastern part of the state is home to the majority of Kentucky's prescription drug abuse problems; nine of the state's top ten counties in per capita hydrocodone use in 2001 are located in this economically depressed region.<sup>7</sup> Eastern Kentucky also has an exceptionally high percentage of per capita prescription drug use relative to the rest of the nation,<sup>8</sup> and several Eastern Kentucky counties are among the nation's leaders in the distribution of opioid analgesics, commonly known as "painkillers."<sup>9</sup> The repercussions of this trend permeate all aspects of life for residents of these areas.<sup>10</sup>

Several factors contribute to the alarmingly high levels of prescription drug use and abuse in Eastern Kentucky. One factor may be that the Appalachian region is home to very high rates of cancer,<sup>11</sup> and opioid analgesics are widely prescribed to treat severe cancer pain.<sup>12</sup> Another possible factor is the prevalence of coal mining and logging in Eastern Kentucky; both industries present dangers that can lead to serious debilitating injuries for which opioid analgesics are a common treatment.<sup>13</sup>

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<http://www.usdoj.gov/dea/pubs/states/kentucky2003p.html> (last visited Aug. 16, 2004) [hereinafter DEA KENTUCKY FACTSHEET]. Hydrocodone is "the generic name for a family of drugs including Vicodin, Lorcet, and Lortab." Jerry Adler, *In the Grip of a Deeper Pain*, NEWSWEEK, Oct. 20, 2003, at 48.

<sup>5</sup> DEA KENTUCKY FACTSHEET, *supra* note 4.

<sup>6</sup> *Id.*

<sup>7</sup> Gideon Gil, *Prescription for Abuse, Five Doctors at Clinic Allegedly Fed Addictions*, COURIER-JOURNAL (Louisville), Oct. 20, 2002, at A1.

<sup>8</sup> DEA KENTUCKY FACTSHEET, *supra* note 4.

<sup>9</sup> *Id.* "Opioid analgesics [narcotics], the most powerful analgesics, are the mainstay for treatment of severe acute pain and chronic pain . . . . Opioids are all chemically related to morphine, a natural substance extracted from poppies, although some opioids are extracted from other plants and other opioids are produced in a laboratory." MERCK MANUAL OF MEDICAL INFORMATION 450 (Mark H. Beers ed., 2d home ed., 2003) [hereinafter MERCK MANUAL], available at <http://www.merck.com/mrkshared>.

<sup>10</sup> DEA KENTUCKY FACTSHEET, *supra* note 4. Assistant Commonwealth's Attorney Lori Daniels describes changes in vote-buying practices in Eastern Kentucky in a way that illustrates the reach of this problem: "What it takes to get the attention of some voters now is no longer a case of beer or \$10 or \$15. Now it's a handful of OxyContin." *Id.*

<sup>11</sup> Joseph Gerth, *UK to Study Cancer in Appalachia, Region's Death Rate is Higher than Nation's*, COURIER-JOURNAL, Aug. 8, 2000, at B1 (noting that Kentucky, Tennessee, Virginia, and West Virginia, all rank above the national average in various forms of cancer, and that individuals' failure to get cancer screening is likely one reason).

<sup>12</sup> James A. Inciardi & Jennifer L. Goode, *OxyContin and Prescription Drug Abuse*, CONSUMERS' RESEARCH MAGAZINE, July 2003, at 17.

<sup>13</sup> *Id.* at 19.

Some also assert that pharmaceutical abuse is not stigmatized in Eastern Kentucky because prescription drug use is so widespread.<sup>14</sup> Another reason for pharmaceutical abuse not unique to Kentucky is “a misconception among abusers and others that prescription drugs are safer than illicit narcotics.”<sup>15</sup> Others point to the region’s struggling economy as a likely cause of high levels of painkiller abuse.<sup>16</sup> Additionally, Eastern Kentucky’s proximity to other state borders enables drug-seeking Kentucky residents to visit doctors and fill prescriptions in multiple states, thereby avoiding detection by Kentucky’s prescription monitoring systems.<sup>17</sup>

#### A. Law Enforcement Difficulties in Curbing Prescription Drug Abuse

Prescription drug abuse is especially difficult to combat because medications do not become illegal until they are inappropriately prescribed or distributed.<sup>18</sup> Pharmaceutical controlled substances legally travel through commercial channels in great quantities, and only upon diversion late in the distribution process do they become law

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<sup>14</sup> DEA KENTUCKY FACTSHEET, *supra* note 4 (“Whole families [in the region] have grown up abusing these drugs and these individuals see nothing wrong with using them.”); *see also* Vanita Gowda, *Not What the Doctor Ordered*, GOVERNING, Jan. 2003, at 34 (describing the Appalachian region of Kentucky as having a history of recreational drug use involving illegal and legal drugs).

<sup>15</sup> Laura Bauer, *Overdose Deaths Rise in Jefferson, Police Recruit Pharmacists, Physicians, to Help Recognize and Prevent Prescription Drug Fraud*, COURIER-JOURNAL, Oct. 11, 2003, at A1.

<sup>16</sup> Gil, *supra* note 7. In regions suffering from unemployment and low income, Medicaid fraud “presents an inexpensive mechanism for abusing drugs and oftentimes an easy rout to a lucrative enterprise. For example, a Medicaid patient may pay only \$3 for a bottle of one hundred 80-milligram OxyContin tablets . . . [which] can net the patient up to \$8,000 on the illegal market.” Inciardi & Goode, *supra* note 12, at 18.

<sup>17</sup> Gideon Gil, *Prescription For Abuse, Prescription-Monitoring System Has Gaps, Few Neighboring States Operate Similar Programs*, COURIER-JOURNAL, Oct. 21, 2002, at A1. “Most of the seven states bordering Kentucky do not have prescription-drug monitoring systems so doctor-shoppers can avoid detection by crossing state lines . . . Indiana and Illinois are the only states adjacent to Kentucky that track sales of controlled substances, but they monitor only the most addictive drugs.” *Id.* *See also* Gideon Gil, *Bill Adds Drug-Monitoring Funds, U.S. Rep Hal Rogers’ Program Helps States Curb Widespread Abuse of Prescription Medications*, COURIER-JOURNAL, Jan. 12, 2003, at B1; *See discussion infra* Part III.B.2 for a discussion of the Kentucky All-Schedules Prescription Electronic Reporting system (KASPER).

<sup>18</sup> Bauer, *supra* note 15 (explaining the practical difficulties encountered in trying to monitor substances that may be used illegally by some, but are necessary as legal pharmaceuticals for others).

enforcement concerns.<sup>19</sup> Deceptive patients, dubbed “doctor shoppers,”<sup>20</sup> are the most likely culprits.<sup>21</sup> On the other hand, “[d]ishonest doctors are the least likely source of diversion, accounting for less than two percent of all pharmaceutical diversion.”<sup>22</sup> Pharmacies are also becoming a source of diverted pharmaceuticals.<sup>23</sup>

Local and federal law enforcement agencies have achieved some success combating the prescription drug abuse problem in Kentucky. Doctors with suspicious prescribing practices have faced both disciplinary penalties<sup>24</sup> and criminal action.<sup>25</sup> In Ashland, Kentucky, authorities shut down one doctor’s clinic that generated cash profits between \$4,000 and \$5,000 per day by prescribing controlled substances to drug seekers.<sup>26</sup> Along with physician convictions and discipline, eight hundred OxyContin abusers and traffickers were arrested by Kentucky law enforcement personnel between January 2001 and November 2002.<sup>27</sup>

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<sup>19</sup> Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55, 63 (2003). Conceptualizing prescription drug abuse, as compared to abuse of more traditional illicit drugs, is difficult because of the need to balance restricted access with availability in drug control policy. *Id.*

<sup>20</sup> Gil, *supra* note 7. “Doctor shoppers” obtain opioid analgesics by feigning pain and visiting multiple doctors. *Id.*

<sup>21</sup> Stephen J. Zeigler & Nicholas P. Lovrich, Jr., *Pain Relief, Prescription Drugs, and Prosecution: A Four-State Survey of Chief Prosecutors*, 31 J.L. MED. & ETHICS 75, 76 (2003). Other methods some drug abusers and traffickers use to obtain opioid analgesics include robbery, assault, and even pharmacy robberies and thefts. Incidence of the latter has increased dramatically in Eastern Kentucky in recent years. DEA KENTUCKY FACTSHEET, *supra* note 4.

<sup>22</sup> Ziegler & Lovrich, *supra* note 21, at 76. The next two most common sources of diverted pharmaceuticals are older doctors with outmoded prescribing practices and chemically impaired doctors. *Id.*

<sup>23</sup> DEA KENTUCKY FACTSHEET, *supra* note 4. *See infra* Part IV (discussing pharmacies).

<sup>24</sup> *See, e.g.*, Gregory A. Hall, *State Board Suspends Doctor’s License, His Prescriptions for Pain Medicine Set off Inquiry*, COURIER-JOURNAL, Oct. 31, 2003, at B7. One notable example involved the emergency suspension of a Louisville, Kentucky doctor in October 2003. Kentucky’s Board of Medical Licensure issued the suspension after the physician prescribed Methadone to an undercover Metro narcotics agent complaining of a stiff back and then later offered a refill despite the officer’s report of no continuing pain. *Id.*

<sup>25</sup> *See, e.g.*, Gideon Gil, *Doctor Pleads Guilty in Drug Case, E. Kentucky Physician Served Addicts, Was Sometimes Paid in Sex*, COURIER-JOURNAL, Apr. 29, 2003, at A1. Seven Eastern Kentucky doctors, five of whom were connected to one clinic in South Shore, Kentucky, were convicted or pled guilty for illegally prescribing opioid analgesics. Physicians working in the South Shore Clinic saw as many as eighty patients each day and prescribed narcotics with little or no medical inspection. *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> Alan Maimon, *Governor: Financial Crisis Hurts Drug Fight, Patton Urges Agencies to Boost Programs Despite Limited Funds*, COURIER-JOURNAL, Nov. 23, 2002,

Law enforcement's crackdown on unscrupulous doctors and other players in the prescription drug black market has had significant ramifications throughout the prescription drug-abusing community. As drug availability has fallen,<sup>28</sup> the street value of OxyContin has skyrocketed from \$1.00 per milligram to as much as \$2.50 per milligram.<sup>29</sup> Even drug treatment facilities are feeling the strain of the area's drug abuse problems, evidenced by extraordinarily long waiting periods for admission.<sup>30</sup>

Law enforcement and civil legal remedies play very important roles in protecting the public from the potential dangers of pharmaceutical opioid analgesics. The heightened law enforcement mobilization against prescription drug abuse in Eastern Kentucky appears to be affecting both illegal users' drug abusing patterns and the doctors' prescribing practices.<sup>31</sup> Further, manufacturers of opioid analgesics increasingly face civil suits for harm suffered by individuals because of their contact with or use of manufactured pharmaceuticals. These methods of addressing the prescription drug problem are the most visible and address certain aspects of the overall issue. However, often lost in the debate over how to curb the problem is the vital need for effective treatment of patients suffering from chronic pain. The danger exists that effective pain

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at A1. "Operation OxyFest 2001" was a coordinated effort involving more than 100 officers from different jurisdictions that resulted in the arrest of 207 illegal OxyContin users and dealers in Kentucky. Inciardi & Goode, *supra* note 12, at 20.

<sup>28</sup> DEA KENTUCKY FACTSHEET, *supra* note 4. There is some information indicating that drug abusers are switching to heroin and methadone as the availability of OxyContin decreases and its price increases. The diminishing supply of OxyContin is also thought to have contributed to a sharp increase in pharmacy robberies—sixty-nine of Kentucky's 1000 pharmacies were robbed for OxyContin between January 1, 2000, and June 30, 2001. *Id.*

<sup>29</sup> *Id.* See also *infra* Part I.C (discussing OxyContin).

<sup>30</sup> Maimon, *supra* note 27. Kentucky's budget crisis frustrates the efforts to address the state's prescription drug abuse problem, and drug treatment facilities suffer from the shortage of resources. In November 2002 there was a minimum six-week wait to get into a Kentucky treatment program. *Id.*

<sup>31</sup> The DEA KENTUCKY FACTSHEET, *supra* note 4, states:

The availability of OxyContin appears to be diminishing in Kentucky, as evidenced by the recent rise in the street price from \$1.00 to approximately \$2.00 per milligram . . . . Anecdotal information . . . suggests that OxyContin abusers may switch to heroin and/or methadone in response to a diminished availability of OxyContin in a given region. This trend is beginning to manifest itself in Kentucky, with regional doctors increasingly prescribing methadone in lieu of OxyContin for pain management.

*Id.*

treatment will be overlooked or even hindered by policies and legal doctrines intended to remedy the prescription drug abuse problems.<sup>32</sup>

This note focuses on the law and policy meant to regulate the manufacturer and distribution of opioid analgesics and the effect (or potential effect) on the quality and availability of pain management medication. Of special concern is the manner in which the needs of pain patients tend to yield to law enforcement policies, since the most efficient and frequently employed responses to the problem involve limiting or complicating access to pain medications.

Section II describes the role played by the FDA and the DEA in approving and regulating the manufacturer and distribution of prescription opioid analgesics and highlights the degree to which law enforcement policies tend to override medical health policies.<sup>33</sup> Section III focuses on the role played by state medical and pharmaceutical licensing bodies in establishing standards for prescribing and dispensing opioid analgesics, and outlines steps taken by Kentucky to address the problems of abuse and pain undertreatment.<sup>34</sup> Section IV addresses the special problem of pharmacies.<sup>35</sup> Section V discusses proposed changes in the tort doctrines used against the manufacturers of opioid analgesics and the detrimental effect these proposals could have on patient access to and progressive developments in pain management technology.<sup>36</sup> The remainder of this section provides a framework in which to address some of the problems unique to prescription drug abuse which are necessary to a full understanding of this sensitive issue.<sup>37</sup>

### B. *OxyContin*

*OxyContin* is an appropriate illustration for much of the law and policy discussed herein because it is both condemned as too prone to abuse and applauded as a breakthrough in pain management. Purdue Pharma, *OxyContin*'s manufacturer, has been criticized for aggressively marketing such an addictive substance and for recommending its use to treat lower levels of pain.<sup>38</sup> At the same time, Purdue Pharma defends

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<sup>32</sup> See *infra* Part III.A.1-2.

<sup>33</sup> See *infra* notes 61-97 and accompanying text.

<sup>34</sup> See *infra* notes 98-173 and accompanying text.

<sup>35</sup> See *infra* notes 174-196 and accompanying text.

<sup>36</sup> See *infra* notes 197-252 and accompanying text.

<sup>37</sup> See *infra* notes 38-60 and accompanying text.

<sup>38</sup> Gowda, *supra* note 14, at 35. Jody Collins, Florida's Senior Assistant Attorney General, asserts that *OxyContin*'s marketing went "above and beyond the marketing of other drugs." *Id.*

itself saying that it has appropriately disseminated information about a valuable new development in pain management.<sup>39</sup> OxyContin's development and marketing thus illustrate most of the issues of law and policy addressed in this note.

### 1. *Historical Background of OxyContin*

After its release in 1996, OxyContin rapidly became the most widely prescribed opioid analgesic, recording sales in excess of \$1 billion in 2002.<sup>40</sup> OxyContin is similar to morphine, but with fewer side effects.<sup>41</sup> The synthetic opioid in OxyContin is oxycodone hydrochloride, the same one featured in other Schedule II painkillers.<sup>42</sup> However, OxyContin is unique because its tablets are not accompanied by some form of nonsteroidal anti-inflammatory drug ("NSAID"),<sup>43</sup> and it is manufactured for sustained pain relief over a period of twelve hours.<sup>44</sup>

The specific advantages of OxyContin are difficult to quantify, but anecdotal evidence coupled with the sheer volume of physician prescriptions suggests that it satisfies an otherwise unmet need.<sup>45</sup> It

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<sup>39</sup> *Id.*

<sup>40</sup> Noah, *supra* note 19, at 62. See also Marks, *supra* note 1 (noting that prescriptions for OxyContin have increased twenty-fold between 1996 and 2000); Inciardi & Goode, *supra* note 12, at 18 (citing retail sales of more than \$1.45 billion in 2001 and \$1.59 billion in 2002).

<sup>41</sup> Dianne E. Hoffman & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J.L. MED. & ETHICS 21, 23 (2003).

<sup>42</sup> See Noah, *supra* note 19, at 61–62.

<sup>43</sup> See PURDUE PHARMA L.P., OXYCONTIN PACKAGE INSERT: CLINICAL PHARMACOLOGY (2003), <http://www.purduepharma.com/PI/Prescription/Oxycontin.pdf>. "Most nonopioid analgesics are classified as nonsteroidal anti-inflammatory drugs (NSAIDs) . . . and may be combined with opioids to treat moderate to severe pain." MERCK MANUAL, *supra* note 9, at 452.

<sup>44</sup> Noah, *supra* note 19, at 62. The name "OxyContin" was chosen in part to convey the distinguishing characteristic: "Oxy—" for oxycodone HCl, and "–contin" for controlled-release. See PURDUE PHARMA L.P., OXYCONTIN PACKAGE INSERT: CLINICAL PHARMACOLOGY (2003), <http://www.purduepharma.com/PI/Prescription/Oxycontin.pdf>.

<sup>45</sup> Noah, *supra* note 19, at 67. Noah explains that while anecdotal evidence "give[s] no sense for the drug's aggregate utility," the more than six million prescriptions written each year suggest an increased medical efficacy relative to other opioid narcotics. *Id.* The number of prescriptions seems to be a good indicator of efficacy because it is unlikely that unethical prescribing practices could inflate the number of OxyContin prescriptions into the millions. Presumably, the majority of these prescriptions are legitimate, and that number reflects the drug's benefits. *Id.* See Hoffman & Tarzian, *supra* note 41, at 25 (noting that increased volume of prescriptions is not always proof of diversion).



provides an additional pain relief benefit over other oxycodone and hydrocodone products because these other medications offer uneven relief for only three to four hours.<sup>46</sup> Furthermore, the presence of NSAIDs in many other opioid painkillers can have significant deleterious effects that do not occur with OxyContin.<sup>47</sup>

OxyContin's time-release design provides a benefit when used according to instructions, enabling a more stable administration of oxycodone than competing products.<sup>48</sup> Considered alone, this feature would seem to decrease the drug's attractiveness to abusers because it does not produce the quick, euphoric high that competing opioid narcotics produce.<sup>49</sup> However, OxyContin's time-release design can be bypassed by scraping or sucking the coating off, crushing the pill, and swallowing, snorting, or injecting the pure oxycodone.<sup>50</sup> Bypassing the time-release feature makes the drug more attractive to abusers than competing tablets because the entire twelve-hour dosage can be ingested immediately, without the undesirable NSAIDs contained in other opioid analgesics.<sup>51</sup>

## 2. *Is OxyContin the Problem?*

Overdose deaths from OxyContin are usually the result of acute pulmonary edema.<sup>52</sup> Combining opioids with other depressant drugs, a common practice among drug abusers, increases the risk of death by compounding the respiratory depressant effects of opioids.<sup>53</sup>

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<sup>46</sup> Noah, *supra* note 19, at 62.

<sup>47</sup> MERCK MANUAL, *supra* note 9, at 453. "Regular use of NSAIDs may . . . increase the risk of developing a kidney disorder, sometimes resulting in renal failure (a disorder called analgesic nephropathy)." *Id.* "NSAIDs tend to irritate the stomach's lining and cause digestive upset . . . , peptic ulcers, and bleeding in the digestive tract." *Id.* at 452. "For older people, the risk of side effects due to NSAIDs is increased." *Id.*

<sup>48</sup> Noah, *supra* note 19, at 62.

<sup>49</sup> *Id.* In fact, "Purdue Pharma and Abbot Labs promoted [OxyContin] to a broader group of physicians and as presenting a lower risk of abuse and diversion." *Id.*

<sup>50</sup> *Id.* See also Adler, *supra* note 4, at 49 (discussing drug abusers' methods).

<sup>51</sup> Noah, *supra* note 19, at 62; Adler, *supra* note 4, at 49 (noting that the side effects of opioid analgesics accompanied by NSAIDs may act as a disincentive to abuse).

<sup>52</sup> Noah, *supra* note 19, at 62.

<sup>53</sup> Edward J. Cone et al., *Oxycodone Involvement in Drug Abuse Deaths: A DAWN-Based Classification Scheme Applied to an Oxycodone Postmortem Database Containing over 1000 Cases*, 27 J. ANALYTICAL TOXICOLOGY 57, 59 (2003) ("Concomitant co-administration of other depressant drugs . . . is common practice among opioid abusers. This practice substantially increases the likelihood of a fatal outcome because of potentiation of the respiratory depressant effects of opioids."); see also Part III.C *infra* (discussing reporting system inadequacies).

OxyContin has been held publicly responsible for varying numbers of deaths in Kentucky since its introduction. Yet, there is some debate over the actual number of deaths that can fairly be attributed to OxyContin alone.<sup>54</sup> Some characterize the surge of news attention as a media frenzy that has unnecessarily vilified a beneficial drug.<sup>55</sup>

Though OxyContin deaths have received considerable attention, it is worth noting that the lawful use of nonopioid drugs causes considerably more deaths than the illegal use of OxyContin.<sup>56</sup> For example, NSAIDs may be a much more serious public health problems, contributing to the deaths of thousands of patients annually.<sup>57</sup> The FDA and the DEA's preference for NSAIDs over opioid analgesics may be a misplaced federal policy. One commentator phrases the question as follows: "[s]hould injuries to third parties who misuse prescription drugs attract greater concern from public officials than injuries suffered by legitimate patients?"<sup>58</sup>

The issue of effective pain management must also be considered in light of the recent media attention, which has triggered widespread concern about the abuse of OxyContin. There is a great risk that aggressive policies intended to limit the use and abuse of the drug could be enforced without consideration of their destructive effects on pain management therapies. Public health policy in general, and physicians in particular, have become more focused on the needs of suffering patients as more is learned about the prevalence of untreated pain. Although positive steps have been taken, measures that are designed to counteract the abuse of opioid analgesics could interfere with recent advances in pain management.<sup>59</sup> One example of that risk was seen in July 2000, when Purdue Pharma introduced a 160-milligram dosage of OxyContin. The dosage was designed for patients who had developed opioid tolerance. However, it was quickly withdrawn from the market after controversy arose over its abuse.<sup>60</sup>

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<sup>54</sup> See *infra* Part III.C and accompanying text.

<sup>55</sup> See generally Inciardi & Goode, *supra* note 12, at 17, 20–21; Sandeep Kaushik, *OxyCon Job: The Media-Made OxyContin Drug Scare*, CLEVELAND FREE TIMES, May 2–8, 2001, at 14, available at <http://www.altnet.org/module/printversion/10933>.

<sup>56</sup> See *infra* notes 50, 72 and accompanying text.

<sup>57</sup> Noah, *supra* note 19, at 71 n.142 (citing a 1998 article estimating 16,500 annual deaths caused by NSAIDs annually among arthritis patients alone).

<sup>58</sup> *Id.* at 62.

<sup>59</sup> See generally Inciardi & Goode, *supra* note 12.

<sup>60</sup> *Id.* at 17.

## II. FEDERAL REGULATION OF CONTROLLED SUBSTANCES

Federal regulation of pharmaceutical controlled substances is not conducted by a single federal agency; the Food and Drug Administration (“FDA”) and the Drug Enforcement Administration (“DEA”) are both involved. The FDA is primarily concerned with ensuring that pharmaceuticals are deemed safe for human consumption, and the DEA is primarily concerned with enforcing drug laws. Because each agency’s objectives differ, their policies are also divergent in many instances. The following section presents the contours of each agency’s duties regarding pharmaceutical controlled substances and discusses the results when their policies collide.

### A. *The FDA and the DEA*

Pursuant to the Federal Food, Drug, and Cosmetic Act (“FFDCA”),<sup>61</sup> the FDA approves opioid analgesics once they are determined to be safe and effective for medical use and commercial marketing.<sup>62</sup> The FFDCA establishes no limits to physician prescribing practices; the regulation of such practices is traditionally within the scope of state power.<sup>63</sup>

Accordingly:

Once [an approved] new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.<sup>64</sup>

In addition to verifying the safety of pharmaceuticals, the FDA regulates how they are marketed.<sup>65</sup> When a drug manufacturer’s

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<sup>61</sup> 21 U.S.C. §§ 301–399 (2005).

<sup>62</sup> Aaron M. Gilson & David E. Joranson, *U.S. Policies Relevant to the Prescribing of Opioid Analgesics for the Treatment of Pain in Patients with Addictive Disease*, 18 *CLINICAL J. PAIN*, July–Aug. 2002, Supplement, at S91, S92, available at [http://www.medsch.wisc.edu/painpolicy/publicat/02cjp/Tx\\_addicts.pdf](http://www.medsch.wisc.edu/painpolicy/publicat/02cjp/Tx_addicts.pdf).

<sup>63</sup> *Id.* at S92 (“Throughout the debate leading to the [passage of the FFDCA], there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and the patient.”) (citing *United States v. Evers*, 643 F.3d 1043, 1048 n.14 (5th Cir. 1981)).

<sup>64</sup> *Evers*, 643 F.3d at 1048 n.14.

<sup>65</sup> Noah, *supra* note 19, at 62–63. However, despite its lack of regulatory authority, the DEA criticized Purdue Pharma’s aggressive marketing of OxyContin. *Id.*

marketing decisions are in question, the FDA often issues letters requesting that the responsible company cease its deceptive marketing. In essence, these letters form a foundation for possible future legal action against the company.<sup>66</sup> The FDA may pursue criminal prosecutions against firms whose marketing harms public health.<sup>67</sup>

Opioid analgesics are subject to greater FDA scrutiny than other drugs because of the rubric under which the FDA approves medications. The first step in the approval process is demonstrating that the drug has valid therapeutic value that outweighs any hazardous side effects.<sup>68</sup> A consequence of this process is that the FDA places a greater emphasis on the value of medications that target treatable diseases.<sup>69</sup> Since opioid analgesics provide only symptomatic relief, or “palliative care,” they must overcome a greater burden in the approval process.<sup>70</sup> Further, palliative care is not only undervalued in the approval process, but opioid analgesics receive even more scrutiny because of their perceived hazardous potential.<sup>71</sup>

Opioid analgesics, the most significant medications for pain management, are classified as “controlled substances” under the Controlled Substances Act (“CSA”).<sup>72</sup> The DEA, a division of the

<sup>66</sup> Christiane Truelove, *An Aggressive Enforcement Strategy*, *News from Rockville*, MED AD NEWS, Aug. 1, 2003, at 62. The FDA issued a warning letter to Purdue Pharma requiring them to place a prominent magazine ad to replace previous ads the FDA regarded as deceptive. *Id.*

<sup>67</sup> *See id.*

<sup>68</sup> *See* Noah, *supra* note 19, at 56–57. “[F]irms seeking to market pain management technologies shoulder a particularly challenging evidentiary burden given the pronounced placebo effect that researchers encounter in this context.” *Id.* This evidentiary struggle is compounded by the difficulty in measuring a condition as subjective as pain and by the variability in patient response to certain treatments. *Id.*

<sup>69</sup> *See id.*

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

<sup>71</sup> *See id.*

<sup>72</sup> 21 U.S.C. §§ 801–904 (2005). The Controlled Substances Act establishes five schedules of controlled substances. 21 U.S.C. § 812 (2005). These schedules classify controlled substances according to the following findings:

(1) SCHEDULE I.

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.

(A) The drug or other substance has a high potential for abuse.

Department of Justice, is responsible for regulating controlled substances.<sup>73</sup> As a result, substances like opioid analgesics fall under the regulatory scope of both the FDA and the DEA.<sup>74</sup>

The CSA imposes a series of registration, security, and monitoring requirements on all individuals and businesses involved in the legal distribution of controlled substances.<sup>75</sup> As evidenced by its scheduling decisions, it appears that Congress recognizes the necessity of accommodating substances with legitimate medical applications while still protecting the public from the potential dangers of controlled substances.<sup>76</sup> The CSA also empowers the DEA to impose requirements on manufacturers and distributors of legal narcotics that vary depending on the schedule rating of the drug involved.<sup>77</sup>

(B) The drug or other substance has currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substance may lead to severe psychological or physical dependence.

(3) SCHEDULE III.

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

*Id.*

<sup>73</sup> Noah, *supra* note 19, at 58.

<sup>74</sup> See Gilson & Joranson, *supra* note 62, at S92.

<sup>75</sup> Noah, *supra* note 19, at 58.

<sup>76</sup> *Id.* This recognition by congress helps to "explain[] the central role, for purposes of distinguishing Schedule I from all other controlled substances, of the criterion that asks whether the drug has 'a currently accepted medical use in treatment in the United States.'" *Id.* (citation omitted).

<sup>77</sup> *Id.* Production quotas, precise inventory systems, registration procedures, and secure production and transportation facilities are among the requirements imposed upon manufacturers of Schedule II medications. *Id.*

### B. *The Interaction of FDA and DEA Regulation*

The CSA and the FFDCRA are independent statutory schemes. As a result, the CSA has no role in defining the appropriate medical uses of controlled substances.<sup>78</sup> This does not mean, however, that the FDA's health concerns always assume primary importance with regard to decisions about the use of controlled substances. Generally, the FDA prefers simply to approve substances with some medical applications, leaving judgments concerning the comparative efficacy of medications to practitioners and patients.<sup>79</sup> However, Congress may preempt the FDA's conclusions regarding the accepted medical use of an approved drug due to law enforcement concerns.<sup>80</sup> Such instances demonstrate that drug control policies may supersede the goal of promoting and improving medical science.<sup>81</sup>

As pharmaceuticals that pose a heightened risk of abuse, opioid analgesics face greater scrutiny throughout the FDA's approval process, despite posing fewer risks to patients than some non-narcotic alternatives. Not surprisingly, non-narcotics may be approved with significantly less scrutiny than their opioid counterparts. For example, two separate NSAIDs, Zomax and Duract, were approved by the FDA despite suspected risks to patient health.<sup>82</sup> The approval of each drug was

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<sup>78</sup> Gilson & Joranson, *supra* note 62, at S92 ("The CSA has the clear purpose of controlling the abuse and diversion of controlled substances, while not interfering with appropriate prescribing for medical and scientific purposes.").

<sup>79</sup> Noah, *supra* note 19, at 56.

<sup>80</sup> Noah, *supra* note 19, at 59–60. One example of Congress preempting the FDA involved the approval of methaqualone ("Quaalude") as an accepted medical treatment for insomnia. Congress required the FDA to withdraw its approval and mandated rescheduling it as a Schedule I controlled substance. Congress justified the reclassification with its conclusion that methaqualone did not offer advantages over other products with less risk of abuse—a law enforcement concern.

<sup>81</sup> Another example of the primacy of drug control policies may be seen in the FDA's approval of Marinol. Marinol contains the synthetic form of tetrahydrocannabinol ("THC"), which is the principal psychoactive ingredient in marijuana. Although the FDA and DEA both deny the existence of any accepted medical use for marijuana, Marinol was not only approved as a Schedule II controlled substance, but was subsequently rescheduled as Schedule III at the insistence of its corporate sponsor. *See id.* at 60; Marsha N. Cohen, *Breaking the Federal/State Impasse Over Medical Marijuana: A Proposal*, 11 HASTINGS WOMEN'S L.J. 59, 60–62.

<sup>82</sup> The FDA approved the NSAID Zomax, despite knowledge that it was a potential human carcinogen, because it was considered a non-narcotic alternative for treating severe pain. Zomax met its commercial demise when patients began dying mysteriously

at least partially based on the agency's preference for non-narcotic pain treatment alternatives that are not prone to drug abuse.<sup>83</sup> In both instances, however, these drugs were subsequently removed from the market after serious health risks were observed.<sup>84</sup>

### C. *Patient's Interests Suffer When Policies Collide*

The FDA's preference for certain classes of drugs over others, dubbed the "one size fits all approach," is criticized for its failure "to account for the possibility that [the contested] drug might provide some unique benefit to a small group of patients who are refractory to the drug of choice."<sup>85</sup> This approach is problematic because the FDA has ignored the experiences and needs of patients exhibiting abnormal responses to generally-prescribed, normally effective drugs. It is clear that "[i]f aggregate risk-benefit balancing [embodying the one size fits all approach] becomes the standard for future scheduling decisions, then the needs of individual patients will compete against the consequences of the irresponsible behavior of abusers, and the DEA may opt to sacrifice products that offer insufficiently dramatic advantages over existing alternative treatments."<sup>86</sup>

Great tension exists between drug enforcement policies implemented to protect society from the destructive effects of drug abuse, and medical health policies adopted to protect an individual patient's right to the most effective medical treatment. As one scholar notes:

It makes little sense to protect irresponsible physicians and illegitimate users from their own bad judgment if it means sacrificing the welfare of those in genuine need. . . . [A]gency initiatives that attempt to restrict

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from anaphylactic reactions. Similarly, the FDA approved Duract, another NSAID valued as an alternative to narcotic analgesics, despite reviewers' concerns that it might cause liver damage. The manufacturer of Duract removed it from the market within a year of its release after correlations developed between Duract use and liver toxicity, which "resulted in at least four deaths and eight liver transplants." Noah, *supra* note 19, at 56-57.

<sup>83</sup> *Id.*

<sup>84</sup> *Id.* It is interesting to note that overuse or abuse of antibiotics also poses a great public health hazard, although they are not considered to be as substantial a public health risk as opioid analgesics because they are not targets of diversion. A failure to follow indications when using antibiotics can give rise to drug-resistant bacterial strains, estimated by some to contribute to 70,000 deaths annually. The media does not publicize this threat in the same way it does the threat of opioid diversion, though it is potentially further reaching. *Id.* at 73 n.167.

<sup>85</sup> *Id.* at 59.

<sup>86</sup> *Id.* at 59-60.

access by limiting supplies or channels of distribution would reflect an unfortunate pursuit of administrative expediency or a response to the failure of more precisely targeted law enforcement efforts.<sup>87</sup>

This policy collusion can produce alarming results. Specifically, the medications with acknowledged health risks for a few legitimately-prescribed patients are preferable to lower-risk medications with a higher potential for criminal abuse. In other words, a higher likelihood of side effects to an already suffering patient is preferred to a heightened risk of illegal diversion.<sup>88</sup> “[T]he long-running ‘war on drugs’” upsets the intended balance “between the extent to which control decisions should be based upon law enforcement criteria, and the extent to which such decisions should be based on medical and scientific determinations.”<sup>89</sup>

No area of medical treatment is affected by this imbalance as much as pain management. A different approach is required in this field because practitioners treat symptoms, not diseases. Further complicating the “one size fits all approach” is that pain is subjective and unquantifiable, and patient reaction to medical treatment is highly variable.<sup>90</sup> In this context, dividing regulatory authority between a law enforcement agency and an agency focused on patient health can generate incongruities:

In some instances, the DEA’s desire to facilitate prosecution of drug abusers by placing a substance into Schedule I or II conflicts with the FDA’s effort to promote the development of a drug potentially valuable in the treatment of a legitimate class of users. . . . In other instances, . . . the FDA has done little more than ‘rubber stamp’ DEA scheduling recommendations.<sup>91</sup>

A shift in the government’s perception of drug abuse occurred during the Reagan era. Drug abuse was once considered a public health issue, but came to be perceived as an issue of politics, morals, and law

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<sup>87</sup> *Id.* at 63.

<sup>88</sup> *See supra* Part II.C.

<sup>89</sup> Noah, *supra* note 19, at 60.

<sup>90</sup> *See id.* at 59–60.

<sup>91</sup> *Id.* at 61. These scheduling incongruities are especially problematic in light of the necessary studies required for FDA approval once a substance is placed in Schedule I. Merely obtaining approval to test Schedule I substances is exceedingly difficult. *See id.*



enforcement.<sup>92</sup> When applied to the prescription drug abuse problem, this shift poses several dangers. Eastern Kentucky, where there are many people with pain management needs, provides a good example: there is a great risk that Reagan era law enforcement policies aimed at restricting access to opioid analgesics could undermine patient health policies in that region and perpetuate the problem of pain undertreatment.<sup>93</sup>

In 2003, the DEA announced an increase in controlled substance fees paid by pharmacies—\$210 every three years, to \$393 every three years.<sup>94</sup> The DEA said these controlled substance fees “would raise \$134 million for the [Diversion Control Program] in fiscal year 2004, \$15 million of which by law must go to the U.S. treasury.”<sup>95</sup> DEA officials said the primary reason for the increase was to fight OxyContin diversion and inappropriate Internet opioid analgesic prescriptions.<sup>96</sup> Some pharmacist and physician groups see this as simply another exercise of federal power that prioritizes law enforcement policies above those of public health by “capitalizing on public concern over OxyContin and other often-abused [prescription] drugs to expand the diversion program at the expense of healthcare providers.”<sup>97</sup>

### III. STATE REGULATION OF PHARMACEUTICAL CONTROLLED SUBSTANCE PRESCRIPTION AND DISTRIBUTION

Medical and pharmacy practice is governed by state rather than federal agencies. Because pharmaceutical controlled substance diversion and abuse involves physicians and pharmacists, their involvement “along with the bodies responsible for their oversight, is crucial in addressing diversion and abuse. The following section discusses the pain undertreatment problem brought on by the mounting concerns about pharmaceutical abuse. Undertreatment of pain experiences by patients occurs when their pain is not properly controlled despite the technology and resources to do so. It is a very real danger because of a combination

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<sup>92</sup> Hoffmann & Tarzian, *supra* note 41, at 22.

<sup>93</sup> *See id.*

<sup>94</sup> Todd Zwillich, *Feds Propose to Raise Rx Diversion Enforcement Fees*, DRUG TOPICS, March 17, 2003, at 51.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* (“[T]he diversion control program has led to frosty relations between DEA and pharmacists.”). In fact, general counsel for the National Community Pharmacists Association has advised pharmacists to oppose forced fees by refusing to cooperate with DEA agents. Physicians have also expressed some displeasure with the fees. As one AMA spokesman asserted, “We’re opposed to user fees for needs that should be borne by all of society.” *Id.*

of factors. Reluctance of physicians to prescribe opioid analgesics out of fear of running afoul of regulations or of encouraging patient addiction and refusal of pharmacies to even supply these drugs are two main reasons discussed in this section. The responses taken by some state bodies and an analysis of those measures with respect to the pain undertreatment problem are also discussed.

#### A. *The Pain Undertreatment Problem*

##### 1. *Pain Undertreatment: Physician Prescribing Practices*

During the last two decades, the United States medical community has largely come to accept both the pervasiveness of pain undertreatment and the minimal risks of addiction for pain patients without a history of drug abuse.<sup>98</sup> Despite this fact, estimates of the number of Americans suffering from chronic pain exceed 50 million, and “more than 40% to 50% of patients in routine practice settings fail to receive adequate relief” for chronic pain.<sup>99</sup> As a result, many physicians and governmental agencies have become more attentive to the needs of chronic pain patients.<sup>100</sup>

Although there is no single reason for the widespread undertreatment of pain, one factor is physicians’ reluctance to prescribe narcotic pain medications. Many physicians attribute their reluctance to prescribe opioid analgesics to concerns about “closer regulatory scrutiny, criminal investigation, or even criminal prosecution.”<sup>101</sup> Studies also indicate that

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<sup>98</sup> Hoffmann & Tarzian, *supra* note 41, at 21.

<sup>99</sup> Tammy Chernin, *Painkillers and Pill Popping: Profession Mounts Counter-offensive Against the Growing Problem of Opioid Abuse*, DRUG TOPICS, Aug. 6, 2001, at 31. The financial costs resulting from chronic pain are high. It is estimated that the annual cost of medical expenses, lost income, and lost productivity owing to chronic pain is \$100 billion. *Id.*

<sup>100</sup> Hoffmann & Tarzian, *supra* note 41, at 21. Hoffmann and Tarzian note that many “physicians began to prescribe greater amounts of pain medication” and that “[m]any state legislatures also passed ‘intractable pain statutes . . . designed to provide physicians with some assurances by reducing both the real and perceived risks of being subjected to regulatory sanctions for treating pain with controlled substances.’” (citations omitted).

<sup>101</sup> Ziegler & Lovrich, *supra* note 21, at 75. Physicians treating the terminally ill have the additional concern “that their actions could be misconstrued as physician-assisted suicide or euthanasia” in the event of patient death “during the course of aggressive palliative care.” *Id.* at 76. *See also* Hoffmann & Tarzian, *supra* note 41, at 21 (noting physician confusion about acceptable opioid prescribing practices and their scope of potential liability).

physicians are slow to prescribe narcotics because they are “concerned that their prescribing practices will raise suspicions of pharmaceutical diversion,” and because “of [a] fear of iatrogenic addiction.”<sup>102</sup> However, evidence suggests that health care professionals often have great misconceptions regarding the level of regulatory scrutiny to which they are actually subject. In fact, the degree of perceived regulatory risk usually far exceeds the actual risk.<sup>103</sup>

Another factor contributing to the undertreatment of pain is the comparative likelihood that state medical boards will discipline for over prescription rather than under prescription. A survey of state medical board executives in thirty-six states revealed that a higher threshold of harm was likely to be applied in evaluating complaints of pain undertreatment.<sup>104</sup> This problem appears to be exacerbated by the fact that most state medical board efforts to educate physicians about pain management issues tend to focus “on what physicians who prescribe opioids for pain must do to avoid board scrutiny.”<sup>105</sup> This approach does not adequately address the problems of pain undertreatment.

Additionally, federal regulatory agencies’ heightened attention to pharmaceutical abuse and diversion contributes to the concerns voiced by many doctors. State medical boards feel pressure to closely monitor and discipline physicians because of “concerns about Medicare and Medicaid fraud and abuse and the government’s ‘war on drugs.’”<sup>106</sup> Some commentators trace this pressure to state medical boards

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<sup>102</sup> Ziegler & Lovrich, *supra* note 21, at 75–76. An addiction is iatrogenic when it is “induced inadvertently by a physician or surgeon or by medical treatment or diagnostic procedures.” MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY 572 (10th ed. 2002).

<sup>103</sup> Ziegler & Lovrich, *supra* note 21, at 75–76; see also News Release, Drug Enforcement Administration, *The Myth of the “Chilling Effect”* (Oct. 30, 2003), <http://www.usdoj.gov/dea/pubs/pressrel/pr103003p.html>. The DEA states that the chilling effect enforcement of the CSA has on physicians is a myth. During the first through third quarters of 2003, a mere .05% of the 963,385 DEA-registered physicians prescribing controlled substances actually had legal action taken against them. Similarly, in each year between 1999–2002, fewer than 1% of physicians were subject to any action by the DEA. An inquiry into the types of action taken against physicians might also allay any concerns they may have. For the first through third quarters of 2003, the DEA’s diversion investigations took the following action against doctors: 7.79% had their registrations revoked; 1.36% suffered civil fines; 4.76% received administrative hearings; 4.99% received letters of admonition; 7.71% were arrested; and 73.47%, the vast majority, were “surrenders for cause.” *Id.*

<sup>104</sup> Hoffmann & Tarzian, *supra* note 41, at 38 (noting that state medical boards more often consider over-prescribing “a clear violation of standard care and a clear example of patient harm,” as compared to under-prescribing).

<sup>105</sup> *Id.* at 38–39.

<sup>106</sup> *Id.* at 22.

disciplining physicians for over prescribing opioids.<sup>107</sup> In turn, these disciplinary measures reinforce physicians' fears that their own prescribing, however appropriate, may make them susceptible to sanctions.<sup>108</sup>

## 2. Pain Undertreatment: Pharmacy Refusal to Fill, Sell, or Stock

Physicians, as the administrators of therapy and treatment, play a key role in addressing the pain management problem. Pharmacists, as the primary dispensers of opioid analgesics, also play an integral role. Addressing the problems of opioid abuse and diversion, while protecting patients' needs, requires pharmacists to be just as involved as physicians.

Due to the public health dangers created by unsupervised use of controlled substances and other potentially harmful medications, pharmacy practice is essentially a "socially sanctioned monopoly."<sup>109</sup> Pharmacists are subject to extensive civil, criminal, and regulatory monitoring and liability for improper professional conduct.<sup>110</sup> Because of this heavy responsibility, pharmacists are understandably cautious when dispensing substances that may present a risk of liability.

Some authors assert that pharmacists have a duty to dispense opioid analgesics when presented with a legally valid prescription that is therapeutically appropriate for the patient.<sup>111</sup> Pharmacists can contribute to the problem of untreated pain when they refuse to fill such prescriptions.<sup>112</sup> It should be noted that a pharmacist's refusal to fill such valid and appropriate prescriptions is generally unintentional. Many refusals are caused by the difficulty in determining when prescriptions satisfy validity and appropriateness requirements.<sup>113</sup>

The DEA's Corresponding Responsibility Rule ("DEA Rule") attempts to distinguish between a prescription and a purported

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<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> David Brushwood, *The Pharmacist's Duty to Dispense Legally Prescribed and Therapeutically Appropriate Opioid Analgesics*, PHARMACY TIMES, Jan. 2002, at 55–56.

<sup>110</sup> *Id.* at 56.

<sup>111</sup> *Id.* at 55–56.

<sup>112</sup> *Id.* "[P]harmacists have at times sought to oversimplify their diversion prevention activities." *Id.* Generally, while pharmacists are mindful of the effect that filling invalid or inappropriate prescriptions can have on substance abuse, they give less thought to the risk of pain undertreatment caused by refusing a valid and appropriate prescription. *Id.* at 56.

<sup>113</sup> *See id.* at 56.

prescription.<sup>114</sup> Under the DEA Rule, it is “unlawful for a pharmacist to knowingly fill a purported prescription.”<sup>115</sup> However, “[a]n innocent filling of a purported prescription by a pharmacist who could not know that the order is not legitimate does not violate the regulation.”<sup>116</sup> Under this rule, if a prescription should have prompted inquiry but the pharmacist ignores “obvious indicators of invalidity,” that pharmacist has breached a legal requirement.<sup>117</sup> The DEA Rule combats substance abuse by limiting pharmaceutical diversion. However, many pharmacists lack an understanding of the fine distinctions between addiction,<sup>118</sup> physical dependence,<sup>119</sup> analgesic tolerance,<sup>120</sup> pseudo-addiction,<sup>121</sup> and substance abuse.<sup>122</sup> This can lead pharmacists to overscrutinize valid prescriptions in the shadow of DEA-imposed regulation. The difficulty is that symptoms and behaviors of substance abuse, which should trigger higher scrutiny in evaluating the validity and appropriateness of a prescription, can easily be mistaken for the predictable symptoms of a patient with legitimate pain treatment needs.<sup>123</sup>

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<sup>114</sup> *Id.* “A prescription is an order for medication that has been issued for a legitimate medical purpose by an authorized prescriber . . . acting in the usual course of professional medical practice.” In contrast, a purported prescription is an order “issued for other reasons, such as the support of addictive habits.” *Id.*

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

<sup>116</sup> *Id.* at 57. The DEA Rule thus takes into account the inevitability of mistakes and inadvertent fillings of purported prescriptions.

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

<sup>118</sup> Addiction is defined as “a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm.” *Id.* at 59. (quoting MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN (Federation of State Medical Boards 1998)).

<sup>119</sup> “Physical dependence on a controlled substance is a physiologic state of neuroadaptation . . . characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use . . . [which], by itself, does not equate with addiction.” *Id.*

<sup>120</sup> “Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.” *Id.*

<sup>121</sup> Pseudo-addiction is a “[p]attern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.” *Id.*

<sup>122</sup> “Substance abuse is the use of any substance(s) for nontherapeutic purposes; or use of medication for purposes other than those for which it is prescribed.” *Id.*

<sup>123</sup> *See id.* at 56. For example, a patient who has been taking opioid analgesics to treat a medical condition may become physically addicted to the medication. Analgesic tolerance will develop after continued treatment, and increasing dosages of opioid analgesics will be required to maintain the efficacy of the treatment. The manifestations of physical dependence and analgesic tolerance in patient conduct, such as requesting

Another factor contributing to the excessive scrutiny of opioid analgesic prescriptions by pharmacists is the lack of clear guidance from case law,<sup>124</sup> because “court cases do not always function well in the establishment of clearly defined standards for the profession.”<sup>125</sup> Case law provides guideposts only for the most egregious deviations from accepted practice.<sup>126</sup> This lack of clarity about liability, combined with the mindset engendered by the war on drugs, has led many pharmacists to err on the side of restricted distribution, which can be a barrier to proper pain management.<sup>127</sup>

A related way that pharmacists can contribute to the undertreatment of pain is by refusing to carry opioid analgesics due to the recent outbreak of pharmacy robberies. Between January 2000 and June 2001, sixty-nine of the one thousand pharmacies located in Kentucky and West Virginia were robbed for OxyContin.<sup>128</sup> Some pharmacies have responded to the rising incidence of pharmacy robberies by refusing to stock OxyContin.<sup>129</sup> The problem became so serious that Purdue Pharma, in an effort to temper economic losses, announced early in 2003 that it would replace all uninsured quantities of OxyContin stolen from pharmacies after July 1, 2001.<sup>130</sup> While the economic losses to pharmacies are unfortunate, perhaps a farther-reaching effect of the pharmacy robbery trend is the potential for a greater restriction of access to a valuable pain medication.

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higher dosages or showing withdrawal symptoms, are very similar to the drug-seeking behavior of the addicted substance abuser. *Id.*

<sup>124</sup> *Cf. id.* at 58–59 (noting that case law fails to provide a comprehensive guide for professional conduct and that many turn to model standards for guidance).

<sup>125</sup> *Id.* (discussing four cases “instructive in an important way for those who must establish decision-making rules for pharmacists in day-to-day practice,” but noting that case law alone is inadequate for that purpose).

<sup>126</sup> *See id.*

<sup>127</sup> *See id.* at 60.

<sup>128</sup> DEA KENTUCKY FACTSHEET, *supra* note 4.

<sup>129</sup> *See, e.g.,* Bauer, *supra* note 15 (discussing a pharmacy in Louisville, Kentucky, that posted a conspicuous sign warning customers that they no longer stocked OxyContin in response to an armed robbery for the drug); Mark Hamstra, *Shaw's Removes OxyContin from Pharmacy Shelves*, SUPERMARKET NEWS, July 16, 2001, at 45 (discussing decisions by pharmacies in Massachusetts and Maine to stop carrying OxyContin in response to store thefts, offering instead to order it for patients with prescriptions); Stephanie Loughran, *Stop & Shop Plays it Safe, Pulls OxyContin*, SUPERMARKET NEWS, May 6, 2002, at 125 (detailing the decision of New England's Stop & Shop stores to stop selling OxyContin in all 226 of its pharmacies in response to a rash of robberies for the drug).

<sup>130</sup> *Purdue to Replace Stolen OxyContin*, DRUG TOPICS, Feb. 3, 2003, at 5.

## B. *Kentucky Responses to Pharmaceutical Abuse and Diversion*

Medical professionals and the state bodies responsible for their oversight have become more sensitive to the needs of pain patients by developing measures to counter prescription drug abuse. Some of these measures are discussed below.

### 1. *State Medical Board Guidelines*

In response to the pain undertreatment problem, the Federation of State Medical Boards ("FSMB") developed guidelines for proper oversight of opioid use in pain management.<sup>131</sup> These FSMB guidelines provide definitions to aid physicians and pharmacists in the effective use of pain medication so that concern for opioid diversion does not undermine the proper treatment of pain.<sup>132</sup> Further, the FSMB guidelines provide pharmacists with a more workable legal standard to judge whether a prescription is valid and therapeutically appropriate. The guidelines help clarify the difference between the pseudo-addictive behavior of a legitimate patient and the similar drug-seeking behavior of an addict—the former is not a sound reason to conclude a prescription is not therapeutically sound.<sup>133</sup> The FSMB guidelines are an important step in providing clear rules for pharmacists that help guarantee proper patient pain management while remaining mindful of the substance abuse issue.

The Kentucky Board of Medical Licensure ("KBML") developed its own *Guidelines for the Use of Controlled Substances in Pain Treatment*, which are largely based on those created by the FSMB, but with more specific attention given to avoiding diversion.<sup>134</sup> The KBML guidelines represent a positive step in addressing opioid diversion while also protecting pain management patients.<sup>135</sup>

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<sup>131</sup> MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN (Federation of State Medical Boards 1998), <http://www.medsch.wisc.edu/painpolicy/domestic/model.htm>.

<sup>132</sup> Brushwood, *supra* note 109, at 59.

<sup>133</sup> *See id.* (noting that under the FSMB guidelines, physical dependence is not equated with addiction, and "the volume and frequency of pain medication use are far less relevant than is the quality of care being provided for the patient").

<sup>134</sup> Kentucky Board of Medical Licensure, *Guidelines for the Use of Controlled Substances in Pain Treatment* (adopted Mar. 22, 2001), available at <http://www.state.ky.us/agencies/kbml/painmanageguide.pdf> (modified Sept. 18, 2003).

<sup>135</sup> Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2001 Annual Review of State Pain Policies: A Question of Balance (2002), <http://www.medsch.wisc.edu/painpolicy/publicat/01annrev/ar-ky.htm>.

While generally considered an advancement for pain management, the KBML guidelines have received some criticism. The University of Wisconsin's Pain & Policy Studies Group ("UWPPSG") notes two potential deficiencies in the language of the new KBML guidelines.<sup>136</sup> The first area of concern involves language that implies opioid treatment is a last resort, appropriate only when nonaddictive measures are exhausted.<sup>137</sup> Since treating pain with opioid medications is recognized as the most effective treatment under some circumstances, reserving such treatment as a last resort is troubling because it may prolong suffering.<sup>138</sup> As a result, patients may suffer needlessly if doctors are required to try potentially less effective treatments first. The implication arising from this approach in the KBML guidelines is that easing patient suffering is not the top priority.

The second area of concern is language in the guidelines suggesting a hiatus from opioid treatment if the patient does not progress toward treatment goals.<sup>139</sup> The UWPPSG commentary explains that this practice is no longer considered appropriate in pain management.<sup>140</sup> Aside from these two areas of concern, the KBML guidelines represent a great step toward addressing pharmaceutical diversion and abuse while still protecting the patient in need.

There are indications that a physician's risk of prosecution correlates to a small degree with the local prosecutor's perception of the medical profession's ability to monitor its doctors.<sup>141</sup> As a result, the KBML guidelines help restore Kentucky prosecutors' faith in the state medical board measures designed to reduce diversion and abuse of narcotic pain medications. In turn, this may lead to more appropriate physician conduct in prescribing opioid analgesics by reducing the fear of prosecution that prompts many physicians to curb their prescription practices.<sup>142</sup>

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<sup>136</sup> *Id.*

<sup>137</sup> *Id.* ("The 'Evaluation of the patient' section requires physicians to determine 'that non-addictive' treatments are ineffective or unacceptable prior to beginning treatment with opioid analgesics. This is unique language and appears to imply that opioids are a last resort.")

<sup>138</sup> *Id.*

<sup>139</sup> *Id.* ("The 'periodic review' section . . . includ[es] references to previous board policy that recommends the use of drug holidays. . . . The use of drug holidays is no longer considered to be appropriate pain management practice.")

<sup>140</sup> *Id.*

<sup>141</sup> See Ziegler & Lovrich, *supra* note 21, at 78, 87–88.

<sup>142</sup> See *supra* notes 85–97 and accompanying text.



In this manner, law enforcement policies may be more appropriately balanced with policies that promote adequate pain management.

## 2. KASPER

In 1999, Kentucky established the Kentucky All Schedule Prescription Electronic Reporting System (“KASPER”),<sup>143</sup> a prescription monitoring system designed to help law enforcement officials identify doctor–shoppers more quickly.<sup>144</sup> The system compiles information on pharmacy sales of “every controlled substance sold in Kentucky’s 2100 pharmacies,” as well as “the prescription records of individual patients.”<sup>145</sup> To assist in the compilation of the database, all pharmacists and physicians must report dispensation of controlled substances to KASPER.<sup>146</sup>

The information in KASPER is currently made available to several different groups. Law enforcement officials may access the information after certifying that “it is needed for a specific, criminal investigation.”<sup>147</sup> Additionally, pharmacists and physicians may access KASPER information to assist in the treatment of specific patients.<sup>148</sup>

KASPER represents a promising step toward solving Kentucky’s prescription drug abuse problem.<sup>149</sup> However, its limited range creates a major loophole for drug seekers; because only Kentucky pharmacies and doctors are monitored, drug seekers can evade detection by crossing state lines to obtain or fill prescriptions.<sup>150</sup> This loophole is of particular concern in Eastern Kentucky because of the region’s proximity to the borders of four neighboring states.<sup>151</sup> As proof of this problem and its

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<sup>143</sup> Gil, *supra* note 17.

<sup>144</sup> *Id.*; Gideon Gil, *Improved Drug Monitoring Supported, Prescription Programs May Help More to Fight Abuse*, COURIER–JOURNAL, Aug. 26, 2003, at B1 (noting that KASPER serves as a national model for combating prescription drug abuse).

<sup>145</sup> Gil, *supra* note 144.

<sup>146</sup> *Id.* KASPER has been effective at collecting data on prescriptions: “information on 35 million prescriptions filled at pharmacies in Kentucky since 1999” has been compiled. *Id.*

<sup>147</sup> Deborah Yetter, *Computer Database Aided Drug Investigation*, COURIER–JOURNAL, Feb. 8, 2001, at A8.

<sup>148</sup> *Id.*

<sup>149</sup> *See id.*

<sup>150</sup> Gil, *supra* note 17 (“Most of the seven states bordering Kentucky do not have prescription–drug monitoring systems—so doctor–shoppers can avoid detection by crossing state lines.”).

<sup>151</sup> Ohio, Virginia, West Virginia, and Tennessee all border the Eastern Kentucky region, and neither Tennessee nor Virginia have computer systems to monitor the sale of controlled substances. *Id.*

scope, some physicians, after being convicted for illegally prescribing controlled substances, reportedly instructed patients to fill their prescriptions in nearby states in order to avoid KASPER's detection.<sup>152</sup>

This loophole is being addressed by giving the Secretary of the Cabinet for Health Services the authority to enter reciprocity agreements with parallel agencies in other states so that data from drug monitoring systems can be combined to inhibit doctor-shopping across state lines.<sup>153</sup> Another adjustment to KASPER that should improve its effectiveness allows "designated agents of the Cabinet for Health Services" to access the information<sup>154</sup> in order to analyze data regarding trends in prescribing practices and controlled substance usage.<sup>155</sup> This expanded access may allow state agencies a greater opportunity to take action before prescription drug abuse in a particular area reaches epidemic status.

When these measures were first under consideration, critics complained of the potential for a chilling effect on physician prescribing practices resulting from expansions in Kentucky's prescription-monitoring programs.<sup>156</sup> Meanwhile, proponents of the measures noted that thorough documentation on behalf of prescribing physicians would adequately insulate physicians who prescribed controlled substances appropriately.<sup>157</sup>

From a pain management perspective, expansions to KASPER and any broadening of investigatory action could potentially restrict patients' access to opioid analgesics, largely because of physicians' and pharmacists' misconceptions about the risk of discipline for prescribing opioid analgesics.<sup>158</sup> Were an expansion to KASPER to have this unintended yet foreseeable effect, it would again illustrate law enforcement policies overriding pain management policies.

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<sup>152</sup> *Id.* One pharmacist in Virginia, a state with no prescription monitoring system, admitted to filling over a hundred prescriptions for OxyContin in several hours—all written by the same since-convicted Kentucky physician. *Id.*

<sup>153</sup> KY. REV. STAT. ANN. § 218A.245 (Michie 2004).

<sup>154</sup> *Id.* § 218A.240.

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

<sup>156</sup> Damon Adams, *Kentucky Doctors May Face More Scrutiny on Prescription Habits*, AMERICAN MEDICAL NEWS, Oct. 20, 2003, at 10 (discussing expansions allowing "the Kentucky Board of Medical Licensure to extend investigations of a physician to other doctors in that physician's practice or community").

<sup>157</sup> *Id.*

<sup>158</sup> See *supra* notes 85–127 and accompanying text.

C. *Uniform Reporting System Needed for Drug-Related Deaths*

The alarm connected with prescription drug abuse is based in part on the number of fatalities linked to such abuse. However, the number of deaths attributed to OxyContin or oxycodone overdose varies greatly both in Eastern Kentucky and nationally, depending on the source consulted. One factor that could contribute to these inconsistent numbers is the difficulty in classifying the cause of death when multiple substances are taken contemporaneously.<sup>159</sup> This factor is not reflected in unsystematized medical examiner or coroner cause-of-death (“COD”) reports and has been identified as a contributing factor to the difficulty of accurately reporting drug-related deaths.<sup>160</sup> The executive director of Kentucky’s Medical Examiner’s Office acknowledged the disparity in the published numbers of deaths caused by OxyContin. In fact, the executive director attributes only two Kentucky deaths to oxycodone alone over a twelve-month period.<sup>161</sup> State and federal agencies need consistent information from the sources they refer to in developing new policies. State medical examiners’ and coroners’ reports are such sources, and their reporting practices may have a great impact on policy development.

Methods employed by state medical examiners and coroners for reporting drug overdose deaths can simplify the complexity of ascertaining whether controlled substance interaction causes death.<sup>162</sup> A lack of accuracy in such reporting can contribute to misconceptions about a drug’s safety or patterns of abusers’ behaviors. To illustrate, a data base including 1243 fatal overdose cases was created from data collected by twenty-three states’ medical examiner and coroner offices between August 1999 and January 2002. This database consisted only of cases in which oxycodone was identified as a contributing factor.<sup>163</sup> Of 1014 applicable cases,<sup>164</sup> 90.6% involved drug abuse, and 96.7% of those

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<sup>159</sup> See generally Cone et al., *supra* note 53 (concluding that accurate studies of mortality rates attributable to abuse of narcotic drugs would benefit from standardized methods of classifying and reporting causes of death).

<sup>160</sup> *Id.* at 58–59.

<sup>161</sup> Kaushik, *supra* note 55, at 16–17 (quoting the executive director of Kentucky’s medical examiner’s office as saying, “as far as deaths go, I’ve heard different numbers in different places at different times; I have no idea where these people are getting their facts-and-figures”).

<sup>162</sup> Cone et al., *supra* note 53, at 58–59.

<sup>163</sup> *Id.* at 57.

<sup>164</sup> *Id.* (229 cases were excluded from this study either because they were incomplete or they were submitted without any identified oxycodone involvement).

deaths involved abuse of at least one other drug in addition to oxycodone.<sup>165</sup> Only 3.3% of the compiled cases reported oxycodone as the sole chemical identified.<sup>166</sup> Less than half of the deaths involving only oxycodone were identified as deaths caused by OxyContin—amounting to 1.3% of all drug abuse deaths in the database.<sup>167</sup> Analysis of the database revealed that there is under appreciation among drug abusers of the increased risk of death when opioids and other central nervous system depressants are used contemporaneously.<sup>168</sup>

The following passage best explains why some reports do not present data on cause of death with optimal accuracy in drug-related cases:

Medical Examiners and Coroners (ME/C) frequently rely on toxicology analysis with a focus on drug concentration in the biological fluids as a key determinant of the cause of death. Such practices ignore the contribution of other drugs present at lower concentrations, pharmacological issues such as toxic drug–drug interactions, antemortem development of tolerance to the respiratory depression effects of opioids, and postmortem drug redistribution . . . .<sup>169</sup>

“[F]atalities attributed to overdose are likely to have opioid concentrations no higher than those found in regular opioid abusers, abusers who died from other causes, or patients who have been compliant with therapy and died from other causes.”<sup>170</sup> Therefore, it is possible for reports of deaths resulting from more complex drug interactions (i.e. contemporaneous abuse of multiple controlled substances) to identify oxycodone as the primary contributing factor despite the presence of smaller amounts of other contributing substances.

Data regarding contributing factors and causes of drug abuse deaths influences law enforcement policies and public health policies. Therefore, a classification system that gives due consideration to the significant role that the contemporaneous abuse of multiple drugs may play in the cause of death is an important step toward adequately

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<sup>165</sup> *Id.* at 64 (“There were an average of 3.5 additional drugs that plausibly contributed to the fatal outcome.”).

<sup>166</sup> *Id.* at 57 (“The most prevalent drug combinations were oxycodone in combination with benzodiazepines, alcohol, cocaine, other narcotics, marijuana, or antidepressants.”).

<sup>167</sup> *Id.* (noting that only twelve of the thirty total oxycodone-only deaths reported OxyContin as the source of the oxycodone).

<sup>168</sup> *Id.* at 58.

<sup>169</sup> *Id.* at 58–59.

<sup>170</sup> *Id.* at 59.

protecting the interests of all groups involved.<sup>171</sup> Pharmaceutical manufacturers would benefit from such a system because they are harmed when imprecise reporting leads to misplaced public perceptions regarding the role their products play in drug abuse deaths.<sup>172</sup>

Furthermore, media reports relying on imprecise reporting techniques not only affect the public, they have an undeniable influence on the perceptions of lawmakers, judges, and juries as well. This could lead to legal theories, prosecutions, or verdicts unfavorable to pharmaceutical manufacturers that fail to serve best the needs of society. Pharmaceutical products that fill an unmet need in the pain management field may be unavailable as a result. Further, a legal climate perceived as hostile to opioid medications could deter the research and development of pain management therapies.

If state bodies are to ensure policies and practices that protect the interests of those who rightfully benefit from opioid analgesics, it is vital to have uniform, systematized, and accurate reporting of mortality data in drug overdose deaths.<sup>173</sup> Otherwise, valuable products like OxyContin could suffer from undue vilification and management of chronic pain could become even more challenged.

#### IV. THE SPECIAL PROBLEM OF INTERNET PHARMACIES

Internet pharmacies<sup>174</sup> warrant special concern in addressing prescription drug diversion because traditional regulatory mechanisms are not equipped to monitor this recent technology. As unscrupulous physicians and pharmacies are identified and disciplined and supplies of opioid analgesics in Eastern Kentucky diminish, many doctor-shoppers will likely utilize the Internet as a new source for controlled substances. The following section discusses the regulatory issues surrounding Internet pharmacies.

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<sup>171</sup> See *id.* at 65. The Drug Abuse Warning Network (“DAWN”), currently the most standardized mortality data reporting system in the U.S., was developed by the DEA in the early 1970’s. *Id.* DAWN was the system used in the study referenced *supra* in notes 139–44 and accompanying text.

<sup>172</sup> See *id.*

<sup>173</sup> See Cone et al., *supra* note 53, at 65 (“These data have [a] major impact on public health policies, law enforcement, and pharmaceutical firms whose therapeutic products are misused or abused.”).

<sup>174</sup> “Internet pharmacy” refers to any entity that “sells medications through its web site.” Kerry Toth Rost, Note, *Policing the “Wild West” of Internet Pharmacies*, 76 CHI-KENT L. REV. 1333, 1333 (2000). These internet pharmacies may be legitimate and law-abiding, or may facilitate acquisition of drugs without a prescription. See *id.*

### A. Internet Pharmacies Generally

The problems inherent in trying to regulate Internet pharmacies have not yet been fully addressed. Because Internet pharmacies are difficult to monitor, the danger exists that doctor–shoppers will turn to them for drugs. If efforts to curb diversion are successful, the availability of opioid analgesics will decrease, thus potentially making this danger a reality.

Internet pharmacies are beneficial because of their convenience,<sup>175</sup> the opportunity to obtain lower–cost pharmaceuticals,<sup>176</sup> the facilitation of patients' privacy,<sup>177</sup> and, in some cases, their ability to help "improve patient compliance with drug therapies."<sup>178</sup> Despite their benefits when used responsibly, Internet pharmacies contribute significantly to the problem of opioid analgesic diversion and abuse.<sup>179</sup> Due in part to their ability to close and reopen within hours, the exact number of Internet pharmacies is unknown.<sup>180</sup> Only some types of Internet pharmacies, including those that provide "cyber consultations," or those that require no prescription at all, contribute to the drug diversion and abuse problem.<sup>181</sup> In addition, "many online questionnaires have the answers

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<sup>175</sup> See *id.* at 1337 (emphasizing a convenience benefit for pharmacy customers who may have decreased mobility or live far from a pharmacy); see also Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 136 (2002) (noting that Internet pharmacies offer "better access to prescription drugs for the elderly and those who live in rural areas").

<sup>176</sup> Rost, *supra* note 174, at 1337 (noting that the ability to offer drugs at lower cost may be related to lower fixed costs and increased competition).

<sup>177</sup> *Id.* (noting that internet pharmacies allow patients to avoid the embarrassment of picking up condition–revealing medications in person and to ask questions out of the presence of others if the pharmacy provides access to a pharmacist).

<sup>178</sup> *Id.* at 1338 (noting that some internet pharmacies send e–mail notifications to customers to remind them when refills are required).

<sup>179</sup> See Marks, *supra* note 1.

<sup>180</sup> *Id.* An exact figure on the number of internet pharmacies is also difficult to obtain because of the rapid growth of this particular market segment: the American Medical Association reported an increase in the number of internet pharmacies from thirty to over 400 between January 1999 and July 1999. Rost, *supra* note 174, at 1334.

<sup>181</sup> Rost, *supra* note 174, at 1334–39 ("Essentially, three types of Internet pharmacies exist: (1) pharmacies that only fill prescriptions written by a patient's physician; (2) pharmacies that charge the patient for a physician 'cyber–consultation' (which usually consists of . . . a simple questionnaire) . . . ; (3) pharmacies that dispense prescription drugs without a physician's prescription."). Internet pharmacies pose an additional risk because they allow a patient to self–diagnose and thus bypass important safeguards in the prescription drug distribution procedure. *Id.*

preselected for the patient,” thus facilitating “the patient providing false or incorrect information” in order to obtain a prescription.<sup>182</sup>

### B. *Operating in the Interstices of Established Regulatory Mechanisms*

Internet pharmacies present a host of regulatory and legal issues.<sup>183</sup> According to the FDA, foreign Internet pharmacies pose an additional problem because they are outside the jurisdiction of the United States.<sup>184</sup> Further complicating the issue is that within the United States no single agency is responsible for the regulation of Internet pharmacies. The effectiveness of the current approach, employing both state and federal power, is debatable.<sup>185</sup>

The issue of who can and should regulate Internet pharmacies is complex. “The FDA purports to lack both the resources and staff needed to deal with the issues raised by Internet pharmacies and online prescribing.”<sup>186</sup> Further, FDA prefers to place heightened regulatory responsibility on companies selling drugs, other regulatory bodies, and state regulatory boards.<sup>187</sup> The DEA also claims to lack the proper resources, and its limited number of pharmaceutical diversion agents lack arrest authority; these agents must therefore rely on other DEA departments to make arrests.<sup>188</sup> Further highlighting the lack of clear regulatory authority, the Federal Trade Commission (“FTC”) can take civil action against Internet pharmacies’ fraudulent commercial practices, but cannot file criminal complaints.<sup>189</sup>

<sup>182</sup> *Id.* at 1341.

<sup>183</sup> *Id.* at 1338–44. Because physician regulation is state-based, Internet pharmacies’ use of doctors from other states makes reprimand difficult. Also, choice-of-law problems are heightened when the state of purchase, the state of a physician’s licensing, and the state of the pharmacy’s operations are all different. *Id.* at 1342–43.

<sup>184</sup> Kristin Yoo, *Self-Prescribing Medication: Regulating Prescription Drug Sales on the Internet*, 20 J. MARSHALL J. COMPUTER & INFO. L. 57, 58–59 (2001) (noting that counterfeit medications, medications below United States manufacturing practice standards, and the sale of non-FDA approved products are risks that accompany foreign Internet pharmacies). See also Rost, *supra* note 174, at 1345; *Fake OxyContin Seized*, CHAIN DRUG REVIEW, Jan. 20, 2003, at 11 (detailing the seizure of thousands of counterfeit OxyContin pills at New York and Boston international airports).

<sup>185</sup> See Rost, *supra* note 174, at 1343–45.

<sup>186</sup> *Id.* at 1345.

<sup>187</sup> *Id.* at 1344–45.

<sup>188</sup> Marks, *supra* note 1 (stating that only 400 of the DEA’s 4000 drug agents track pharmaceutical diversion and that their efforts focus mostly on the most deviant doctors and pharmacies).

<sup>189</sup> *Id.* (noting that the FTC files civil suits, but not criminal complaints). The FTC may take action if a website makes false or misleading claims about drug safety or efficacy, or if an Internet pharmacy states falsely its privacy practices. Rost, *supra* note 174, at 1348.

There exists a debate about whether the regulation of Internet pharmacies should be shouldered by the states or by the federal government. “[C]ritics of federal involvement argue that there currently is no need for federal regulation of Internet pharmacies because individual states are regulating the industry and . . . [they] fear that such involvement would lead to federal regulation of the practice of medicine.”<sup>190</sup> It is possible that excessive regulation of Internet pharmacies could eclipse the benefits to patients that Internet technology provides, and it could become another example of law enforcement policies preempting public health policies. While the American Medical Association, the Federation of State Medical Boards, and the National Association of Pharmacy Boards recognize the problem with Internet pharmacies, they prefer a regulatory scheme that does not nullify the potential for Internet technology to provide public health benefits.<sup>191</sup>

While federal regulation of Internet pharmacies raises concerns, there is a problem with the alternative: state-based regulatory bodies encounter many difficulties in efforts to regulate Internet pharmacies.<sup>192</sup>

### C. *Current Law and Internet Pharmacies*

Current law does little to address the burgeoning problem of illegal Internet opioid analgesic sales. The Controlled Substances Act (“CSA”) has the same requirements for drug distribution regardless of whether it is Internet based or goes through more traditional channels.<sup>193</sup> The Internet Pharmacy Consumer Protection Act (“IPCPA”) attempted to amend the FFDCA by requiring Internet pharmacies to post certain information on their websites, but failed to pass the House.<sup>194</sup> While the IPCPA would have been a positive step in the regulation of Internet Pharmacies, website operators often do not register their sites and would therefore have been difficult to prosecute for violation of the IPCPA.<sup>195</sup>

The problems that stem from monitoring pharmacists and physicians that operate out of physical offices are multiplied when these

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<sup>190</sup> Rost, *supra* note 174, at 1353.

<sup>191</sup> *See id.* at 1346–48.

<sup>192</sup> *See supra* note 183.

<sup>193</sup> Yoo, *supra* note 184, at 83.

<sup>194</sup> H.R. 2763, 106th Cong. (1999) (requiring the name, address, and telephone number of the business; name of licensed physicians and pharmacists, as well as states in which they are licensed to practice; and links to this licensing information on each page of the website).

<sup>195</sup> Yoo, *supra* note 184, at 80–81.



practitioners utilize the Internet instead.<sup>196</sup> Typically, the contribution an unscrupulous physician or pharmacist can make to illicit opioid analgesic distribution is limited by the number of patients who can travel to their offices for prescriptions and medications. Internet pharmacies are not bound by such geographical limitations. Just one unscrupulous Internet pharmacy site can provide controlled substances to any drug-seeker, anywhere. Further, since there is no established national prescription monitoring system, drug-seekers are not restricted to using only one Internet pharmacy. The impact these operations have on the black market can only be estimated, and there is no reason this profitable business should not continue growing until a regulatory mechanism proves effective in punishing physicians and pharmacists who work with noncompliant Internet pharmacies.

The complexity of Internet technology makes the onus of addressing Internet pharmaceutical regulation and diversion that much more difficult. Because their products are accessible to all with Internet access, the public health risk posed by Internet pharmacies can be considerable. These characteristics indicate a need for responsive policies selected for their administrative efficiency and justified by the great risk to public health. There is a risk that such policies will have little regard for the benefits Internet pharmacies create for patients, especially those whose movement is restricted by intractable pain. Some response is necessary. However, the best response is one that is sensitive to patients' needs, while still limiting access to irresponsible abusers.

## V. PHARMACEUTICAL MANUFACTURING AND TORT LAW

The regulatory responses to pharmaceutical drug abuse addressed above illustrate the confluence of two distinct concerns: concerns for the deleterious societal effects of drug abuse and concerns for the needs of patients in pain. This same interplay is manifested in the policies behind tort law. Purdue Pharma has been accused of violating various consumer protection and antitrust laws for its conduct in developing and marketing OxyContin.<sup>197</sup> Some complaints filed against Purdue Pharma include proposed changes to existing tort doctrines.<sup>198</sup> Some of these proposed changes are in response to shifts in medical practices that could have an impact on the research and production of opioid analgesics. Purdue

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<sup>196</sup> See generally *id.* at 57–61 (discussing the current difficulties in regulation of internet pharmacies).

<sup>197</sup> Ausness, *supra* note 175, at 133–35.

<sup>198</sup> *Id.* (discussing the potential applicability to prescription drug sales of negligent marketing claims for overpromotion or negligent failure to supervise retail sellers).

Pharma's production and distribution of OxyContin illustrates well how this could occur. The following section analyzes three tort doctrines that affect opioid analgesic manufacturers and discusses the likely effects on developing tort law when concerns for drug abuse take precedence over concerns for the needs of patients in pain.

### A. *The Learned Intermediary Rule*

In general, “products liability law” imposes a duty “to warn the ultimate consumer” of any dangers associated with a product.<sup>199</sup> However, in the case of pharmaceutical manufacturers, this basic duty is supplanted by the learned intermediary rule, under which pharmaceutical manufacturers only have a duty to adequately warn prescribing physicians and pharmacists.<sup>200</sup> This rule is premised on the traditional notion of the physician–patient relationship: “the physician is primarily responsible for deciding what drugs to prescribe, while the patient plays a relatively passive role.”<sup>201</sup> There are exceptions to this rule, such as choices concerning methods of birth control, where the physician is not central to the decision–making process.<sup>202</sup>

Traditionally, pharmaceutical companies limited their marketing only to physicians. This fact helps explain the different treatment pharmaceutical manufacturers receive, as evidenced by the learned intermediary rule.<sup>203</sup> This approach to liability is changing, and multiple forms of negligent marketing liability have been proposed in response to shifts in pharmaceutical firms' marketing practices—especially the advent of direct–to–consumer advertising.<sup>204</sup>

As the traditional physician–patient relationship has given way to increased patient input in deciding which drugs the doctor will prescribe, and pharmaceutical companies have begun marketing their products directly to consumers, some note that the justifications for the learned intermediary rule are becoming weaker.<sup>205</sup> For example, the *Restatement*

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<sup>199</sup> *Id.* at 107.

<sup>200</sup> *Id.* at 106–07.

<sup>201</sup> *Id.* at 108. The idea is that the physician is the decision maker, so warning the patient is unnecessary. *Id.*

<sup>202</sup> *Id.* at 110–13 (discussing exceptions for vaccinations, oral contraceptives, and intrauterine devices).

<sup>203</sup> *Id.* at 97–98.

<sup>204</sup> *Id.* at 98–99.

<sup>205</sup> *Id.* at 113–14. The erosion of the traditional physician–patient relationship is especially prominent in the realm of Internet pharmaceutical sales. See *supra* Part IV.

(Third) of Torts: *Products Liability* stipulates that manufacturers of prescription drugs should warn patients directly if “the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”<sup>206</sup> The comments to the *Restatement* leave to the courts whether an exception to the learned intermediary rule will be allowed.<sup>207</sup> If the learned intermediary rule were abolished altogether, manufacturers would be required to create warnings for both physicians and consumers.<sup>208</sup>

In the case of OxyContin, imposing a requirement on Purdue Pharma to warn both physicians and consumers would likely be nothing but a hollow formality. All opioid analgesic packages warn of potential risks associated with the drug.<sup>209</sup> If abolishing the learned intermediary rule is premised on providing the user with more information, these warnings are already sufficient. More detailed warnings regarding the heightened risks when the pill is crushed, snorted, or injected would likely advance safety objectives little; worse yet, it could actually serve as a suggestion for more effective abuse instead of as a deterrent.

Another problem with abolishing the learned intermediary rule is that doing so would weaken the traditional physician-patient relationship. As noted, the learned intermediary rule took root when physicians, rather than patients, made all treatment decisions.<sup>210</sup> The traditional exceptions to the learned intermediary rule involve drugs and devices that are administered to large segments of the population to address conditions less individualized than the treatment of chronic pain.<sup>211</sup> Unlike the traditional situation, the prescription of opioid analgesics retains a strong need for physician oversight and involvement. As such, the learned intermediary rule maintains an appropriate balance for use in the context of opioid analgesics.

Rather than widening the gap between physicians and patients, general practitioners and pain specialists alike should focus on increased

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<sup>206</sup> RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY § 6(d)(2) (1998).

<sup>207</sup> Ausness, *supra* note 175, at 117 (noting that the court in *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245 (N.J. 1999), recognized an exception for direct-to-consumer advertising).

<sup>208</sup> *Id.* at 136.

<sup>209</sup> *See id.* at 99-100.

<sup>210</sup> *See id.* at 110.

<sup>211</sup> *Id.* at 110-13 (noting recognized exceptions to the learned intermediary rule for vaccine programs, oral contraceptives, and intrauterine devices).

physician–patient communication for treating chronic pain.<sup>212</sup> When viewed from this perspective, abolishing the learned intermediary rule would do little to advance the objectives of those who support its abolition.

### *B. Negligent Marketing*

Negligent marketing is a tort theory “based on the notion that manufacturers should be required to market their products in a way that minimizes the risk that consumers will injure themselves or others.”<sup>213</sup> There are two recognized types of negligent marketing: 1) marketing toward unsuitable consumers,<sup>214</sup> and 2) failure to supervise retail sellers.<sup>215</sup> A third proposed strain of negligent marketing is overpromotion,<sup>216</sup> which “involves the efforts of manufacturers to pressure or bribe doctors to prescribe certain prescription drugs . . . in excessive dosages or to persons who do not really need them.”<sup>217</sup> The latter two types of negligent marketing are potentially of great consequence to pharmaceutical manufacturers and thus to pain therapy patients.<sup>218</sup> Again, the production and promotion of OxyContin serves to illustrate the likely result of these proposals.

Purdue Pharma has been accused of negligent failure to supervise retail sellers for supplying OxyContin to foreign and internet pharmacies with an awareness that people could obtain it without a valid

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<sup>212</sup> It is arguable, at least in instances where harm has resulted from a patient’s use of OxyContin or other opioid analgesics, that a lack of ongoing physician–patient communication actually contributed to the improper use of the medication.

<sup>213</sup> Ausness, *supra* note 175, at 123 (noting that most negligent marketing cases to date have involved handgun manufacturers). See also Richard C. Ausness, *Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing*, 53 S.C. L. REV. 907, 908–09 (2002) (“This theory assumes that . . . manufacturers . . . have a duty to market their products in a manner that will not affirmatively increase a product’s inherent risk to consumers and third parties”).

<sup>214</sup> Ausness, *supra* note 175, at 123–24. This form “focuses on advertising or promotional efforts that are intended to induce unsuitable persons to purchase products that are dangerous to themselves or others.” *Id.*

<sup>215</sup> *Id.* at 124–25. This form “subject[s] manufacturers to liability when they distribute their products in a way that enables unauthorized users to obtain access to them from unscrupulous retail sellers.” *Id.*

<sup>216</sup> *Id.* at 125.

<sup>217</sup> *Id.* at 133.

<sup>218</sup> See *id.* The first type of negligent marketing, marketing toward unsuitable customers, “does not seem relevant to the promotion and sale of prescription drugs.” *Id.*

prescription.<sup>219</sup> Overpromotion is also potentially applicable to Purdue Pharma's marketing of OxyContin, based on fringe benefits purportedly offered to prescribing doctors and indirect off-label marketing.<sup>220</sup>

Negligent marketing is described as a "bonanza for plaintiffs and a nightmare for defendants" for several reasons: a) plaintiff's success does not depend upon proving a product is defective; b) the learned intermediary rule cannot be invoked to defend a claim of negligent marketing; c) the standard for liability is "essentially meaningless" due to the absence of an "objective way to determine when a particular marketing practice is appropriate and when it can be characterized as negligent"; and d) juries will ultimately decide cases because the claims are highly fact specific.<sup>221</sup>

Manufacturer liability for negligent marketing also presupposes that there is no need for dissemination of information regarding new and effective pain management resources like OxyContin. It is thus possible to view Purdue Pharma's purported aggressive marketing of OxyContin as a reasonable and justified approach to increasing physician familiarity with an opioid analgesic that represents a breakthrough in pain management technology. This point of view is supported by the recognition of the widespread undertreatment of pain.<sup>222</sup>

Imposing additional duties on pharmaceutical manufacturers through the abolition of the learned intermediary rule or the ascendancy of negligent marketing doctrines will likely have a negative financial impact on prescription drug companies.<sup>223</sup> One foreseeable result is higher liability costs, which will decrease the availability of opioid analgesics and increase their cost.<sup>224</sup> In light of the widespread undertreatment of pain, this reduction in pharmaceutical availability would primarily harm patients in need. The rapid increase in the number of OxyContin prescriptions following its introduction suggests that pain patients had found an effective treatment for chronic pain.<sup>225</sup> Increased

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<sup>219</sup> *Id.* at 135–36.

<sup>220</sup> *Id.* at 133–35 (listing free plane tickets, hotel accommodations, and seminars among fringe benefits offered by Purdue Pharma).

<sup>221</sup> *Id.* at 138.

<sup>222</sup> See *supra* notes 85–127 and accompanying text (discussing the undertreatment of pain).

<sup>223</sup> Ausness, *supra* note 175. The situation faced by pharmaceutical manufacturers is even more serious because many courts have relieved plaintiffs of the burden to prove cause-in-fact, enabling plaintiffs to overcome otherwise serious problems of causation through the substantial factor test or market share liability. In addition, due to the threat of great expense, class action suits can coerce settlement even when claims are groundless. *Id.*

<sup>224</sup> *Id.* at 139.

<sup>225</sup> See *supra* notes 38–47 and accompanying text.

liability for zealous promotion of a beneficial drug potentially harms the two parties most essential to the transaction: the producers and the intended consumers.

### C. *Off-Label Use and Marketing*

#### 1. *What the FDA Allows*

The FDA requires that drug labels include all approved uses, “warnings, precautions, clinical pharmacology, indications, contraindications, and adverse reactions.”<sup>226</sup> Consequently, any method or manner of use other than that for which a pharmaceutical was approved by the FDA is considered an “off-label use.”<sup>227</sup> “If a manufacturer wishes an off-label use to be added to a drug’s labeling. It must apply to the FDA for approval as it would for a new drug.”<sup>228</sup> This can be an expensive and exhaustive process.<sup>229</sup> Similarly, “off-label prescribing” is simply prescribing medication for an off-label use; this practice is outside the scope of the FDA’s regulatory authority.<sup>230</sup> Likewise, “off-label marketing” is also an issue. It occurs “when the manufacturers of the drugs promote or advertise their products for purposes, to users, in dosages, or in combinations other than the FDA-approved ones.”<sup>231</sup> The FDA attempts to strictly control off-label marketing, but it should be noted that this regulation applies only to manufacturers:

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<sup>226</sup> Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181, 187 (1999) (citing 21 C.F.R. § 201.56(a) (1998) and 21 C.F.R. § 201.56(d) (1998)).

<sup>227</sup> *See id.* at 187–88 (“The most typical off-label uses are use by persons other than those for whom the drug was approved, use in dosages other than the approved dosages, use for conditions other than those indicated in the labeling, and use in unapproved combination with other drugs.”).

<sup>228</sup> *Id.* (noting the lack of incentive for drug manufacturers to obtain FDA approval for off-label uses since it is difficult and does not necessarily increase sales, “especially if off-label applications are already well known and off-label use is already widespread”).

<sup>229</sup> *See id.* at 188 (characterizing the FDA approval process as “tedious and expensive”).

<sup>230</sup> *See id.* at 189–190.

<sup>231</sup> *Id.* at 191; *see also* Ausness, *supra* note 175, at 134. The economic incentives to engage in off-label marketing are clear: more advertised uses means more users, and more users means more sales.

Accordingly, when physicians write freely about off-label applications of prescription drugs, they are not engaging in off-label marketing, and their activities have never been proscribed. Conversely, if the manufacturer of these drugs reproduces or distributes the doctor's writings to other physicians, its activities are considered to fall in what historically has been the highly-controlled arena of off-label marketing.<sup>232</sup>

The two ends of the spectrum, defined by who is disseminating the information regarding an off-label use, are fairly clear. However, a common practice that is more questionable involves manufacturers providing "grants supporting symposia on unapproved uses of drugs, or grants to managed-care organizations to encourage their off-label use or promotion of a product."<sup>233</sup>

It is estimated "that between twenty and sixty percent of all prescriptions are for off-label uses,"<sup>234</sup> and some assert that optimal patient care *requires* such off-label uses.<sup>235</sup> Under this view, FDA monitoring of these uses unnecessarily pulls resources away from the FDA's primary purpose of efficiently assessing new drugs and constrains effective practitioner discretion.<sup>236</sup> Indeed, the General Accounting Office surmises that the FDA would be unable to review and approve drugs under their meticulous approval process at the rate practitioners in the field discover effective off-label uses.<sup>237</sup>

## 2. *Benefits of Broadening Off-Label Marketing Allowances*

High quality scientific research is conducted in various settings.<sup>238</sup> Further, the FDA's monolithic role as holder of the sole approving power should not be interpreted as diminishing the validity of findings of the general scientific community.<sup>239</sup> Some believe that, but for FDA restrictions on off-label promotion, scientifically validated information regarding new and beneficial off-label uses would be more widely shared throughout the community—often for the benefit of the patient.<sup>240</sup>

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<sup>232</sup> Salbu, *supra* note 226, at 191.

<sup>233</sup> *Id.* at 191-92.

<sup>234</sup> *Id.* at 193.

<sup>235</sup> *Id.* at 193-95.

<sup>236</sup> *Id.* at 195-96.

<sup>237</sup> *Id.* at 198.

<sup>238</sup> *Id.*

<sup>239</sup> *See id.*

<sup>240</sup> *Id.* at 198-99.

“Liberalized off-label promotion therefore should yield the most progressive medical practice.”<sup>241</sup>

Opponents of off-label use believe the heightened risk to public health justifies regulatory control<sup>242</sup> and argue that, without such restrictions, patients become test subjects for off-label uses.<sup>243</sup> Yet, while off-label use is a common practice in modern medicine, off-label marketing is not.<sup>244</sup> The distinction is justified by concern that lifting the prohibition on off-label marketing would provide manufacturers with a means of circumventing current regulatory measures by obtaining FDA approval for the narrowest use, then immediately marketing the drug as one with multifarious applications.<sup>245</sup> The risks of off-label marketing are amplified by the conflicting interests of manufacturers seeking profits, doctors who may be receiving gifts from pharmaceutical firms, and scientists who may have undisclosed financial ties to pharmaceutical firms.<sup>246</sup> Federal legislation, passed in 1997,<sup>247</sup> allows off-label promotion and marketing with restrictive conditions.<sup>248</sup> Passage of this legislation was a small victory for proponents of off-label promotion. However, the legislation is largely hampered by many hurdles that frustrate the potential benefits of off-label promotion.<sup>249</sup>

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<sup>241</sup> *Id.* at 199.

<sup>242</sup> *Id.* at 201–02.

<sup>243</sup> *Id.* at 204. A combination of two drugs, each individually approved by the FDA but whose interaction had not been tested or approved, could be no safer than an entirely unapproved compound. The fen-phen crisis shows the potential for a public health tragedy as a result of off-label use in just this way: two FDA approved drugs became widely prescribed in an unapproved combination that was supported by published scientific evidence. As a result, an estimated 285,000 users suffered heart valve damage. *Id.* at 202–03.

<sup>244</sup> *See id.* at 205.

<sup>245</sup> *Id.* at 205–06.

<sup>246</sup> *See id.* at 206–10.

<sup>247</sup> Food and Drug Administration Modernization Act of 1997, 11 Stat. 2296 (codified as amended at 21 U.S.C. §§ 301–399 (1997)).

<sup>248</sup> *See Salbu, supra* note 226, at 211–12. Manufacturers may only disseminate authorized information on off-label uses: “unabridged peer-reviewed articles or qualified reference publications.” *Id.* at 213 (footnotes omitted). Manufacturers must also submit a copy of the information to the Secretary of Health and Human Services sixty days prior to its intended dissemination. *Id.* at 214. Further, any transmission of this information must be accompanied by a disclosure highlighting the lack of FDA approval for the off-label use in question. *Id.* at 215–16. Finally, the legislation also provides a mechanism to discontinue dissemination if problems arise. *Id.* at 216–17.

<sup>249</sup> *Id.* at 217.



### 3. *The Effect of Heightened Liability for Off-Label Uses on Opioid Analgesic Manufacturers*

Imposing heightened liability on Purdue Pharma and other manufacturers of similar opioid analgesics for sponsoring seminars that promote knowledge of a drug's effectiveness, when such education would benefit current pain management, interferes with the established information-sharing tradition of off-label uses. Effective off-label applications may come to light in a variety of scientifically valid tests and through physician experience.<sup>250</sup> Since obtaining FDA approval for a single medical application is exorbitantly expensive, limiting the means by which off-label uses can be shared could increase a manufacturer's costs to a prohibitive level. Some manufacturer practices are rightfully prohibited. However, consideration should be given to the available resources when a certain field of practice, pain management in this case, suffers from a lack of attention. Allowing manufacturers to sponsor seminars in such cases could help those who are active and knowledgeable in a particular field enlighten those who are not.

The autonomy of physicians who participate in these seminars, as well as physicians who ultimately prescribe medications and oversee patients, demands consideration. Although it is undeniable that medical technology necessitates some degree of regulatory paternalism, where esoteric physician knowledge cannot be grasped by the average patient, overly paternalistic policies can lead to restriction without benefit. Unduly restrictive limits on a manufacturer's promotion of appropriate off-label uses exemplifies just such an overly paternalistic policy.

#### D. *Proposed Liability Theories Would Likely Harm Pain Patients' Interests*

It would be naïve to assume that a pharmaceutical firm's marketing decisions are motivated primarily by an altruistic desire to help the suffering patient rather than to protect the firm's profit margin. Protecting patients from harm that could result from these marketing decisions is a strong factor favoring the existing safeguards that protect patients. Even with these safeguards in place, the supply-and-demand rubric ensures that, where there is a demand, even unprotected interests will be served by those who seek a profit. The pain management field exemplifies this principle: Purdue Pharma recognized the inadequacy of

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<sup>250</sup> See *supra* notes 234-41 and accompanying text.

current pain management technology and developed a product that offered benefits competing drugs did not.

Increased dissemination of information about improvements in pain management is imperative to correcting the pervasive undertreatment of pain. Though some risks to patients may accompany such decisions, the physician's role in prescribing controlled substances and participating in seminars is essential to help avoid diversion and abuse and to protect patients from harm. Physicians cannot make these decisions without adequate information about available treatment.

Negative publicity and threats of liability have forced Purdue Pharma to consider producing a chemical reformulation of OxyContin that could reduce abuse by rendering ineffective all known methods of time-release bypass.<sup>251</sup> While a reformulation could address the drug abuse problem, it also might increase the chances of discovering new adverse reactions in some patients.<sup>252</sup> From the patient's perspective, such a new form would not represent an improvement to them; the value of the extended release feature is so substantial relative to other pain treatments that it justifies continued marketing despite emerging patterns of diversion. Should a risk of harm to abusers warrant heightened liability for a manufacturer whose conduct meets the needs of the suffering patient?

## VI. CONCLUSION

Addressing Eastern Kentucky's prescription drug problem is unquestionably a serious issue that has garnered significant attention. Its prevalence demands a coordinated effort by law enforcement, healthcare professionals, pharmaceutical manufacturers, and all others who control the development of policy. Yet, the consequences can be grave for patients with pain management needs when their access to effective opioid analgesics is restricted or eliminated completely as a result of antidiversion and antiabuse measures. Reducing the benefits of opioid therapy to those patients for whom such technology was initially created is an unsound approach to guarding against the conduct of irresponsible third parties for whom these technologies were never intended.

The FDA drug approval process plays a crucial role in the accessibility of opioid analgesics to legitimate patients. By placing a

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<sup>251</sup> See Noah, *supra* note 19, at 62 (describing investigation by Purdue Pharma of the possibility of including naltrexone in OxyContin to stop those attempting to abuse the drug).

<sup>252</sup> See *id.*

higher emphasis on the value of palliative care when balancing a drug's benefits with its risks, and by focusing more on the intended recipients than on unintended third parties, patient interests may be better protected. An FDA approval policy that recognizes the value of more diverse options for the treatment of chronic pain, rather than the current "one size fits all" approach, would also benefit pain management.<sup>253</sup> Likewise, the DEA plays a crucial role in protecting patient interests. By adopting greater deference to medical practice on the state and federal level, the DEA's role as enforcer of drug laws would be less likely to interfere with those bodies whose objectives are separate from law enforcement. Clearly communicating standards of permissible conduct to participants in the pharmaceutical distribution chain would advance these goals.

On the state level, Kentucky's medical and pharmacy boards, through education and policy changes, could help ensure that medical professionals understand appropriate prescribing and prescription-filling practices. Such education could encourage the confident treatment of patients with pain management needs without the misconceived fear of discipline. The KBML guidelines represent a valuable step toward this objective. In time, regulatory oversight conducted in accordance with these guidelines should enable health care professionals to more confidently provide pain treatments with less concern for discipline. An emphasis on close physician-patient communication would also ensure that physicians become aware of suspicious or dangerous patient conduct while at the same time furthering legitimate treatment goals.

Similarly, programs like KASPER, involving coordinated efforts between state law enforcement officers and medical professionals, help address Kentucky's prescription drug abuse and diversion problem.

The problem of internet pharmacies, however, requires a different approach. Specialized regulation of internet pharmacies will most likely occur at the federal level due to the necessity of uniform requirements; it is not clear what steps Kentucky could feasibly take to address this issue. Regardless of who eventually takes on this task, internet pharmacies must become regulated because they will likely help expand the diversion and abuse of opioid analgesics, even as law enforcement makes great strides to reduce other avenues of diversion.

Proposed tort theories pose another potential complication to effective pain management. Implementation of these theories could affect the development of new pain management technologies if manufacturers are subjected to heightened liability. The potential for profits may be outweighed by the risk of liability and could result in a

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<sup>253</sup> See *supra* notes 74-75 and accompanying text.

decrease in the number of producers of opioid analgesics. Purdue Pharma's experience with OxyContin illustrates the degree to which developing and marketing new pain treatment drugs may make a company a target for lawsuits, even though the drug represents a positive breakthrough in pain management technology.

With regard to opioid analgesics, the proposed abolition of the learned intermediary rule is undesirable because it would facilitate less physician–patient involvement where more is needed, especially in reducing diversion and abuse. Likewise, negligent marketing theories have the potential to harm pain patients' interests. As off-label uses become accepted after a drug's approval, the manufacturer is in a position and has the financial incentive to ensure this potentially valuable information is shared with prescribing physicians. Such marketing practices do not compromise the integrity of medical practice because they do not preempt the physician's role in overseeing a patient's treatment. In the final analysis, malpractice liability can and does provide an avenue for redress when physician conduct is egregious and warrants patient recovery for harm. Most importantly, medical malpractice provides an avenue for that redress without harming producers of pain medicines.

In sum, countering opioid analgesic diversion and abuse requires the coordinated effort of various state and federal regulatory, judicial, or law enforcement bodies. These bodies operate on different policies, each valuing medical health concerns to varying degrees. Because opioid analgesics provide pain treatment for suffering patients, often when no other treatment provides relief, legal and regulatory efforts to curb diversion and abuse of these medications must place an emphasis on preserving patient access to needed medications, promoting positive developments in the pain management field, and minimizing any chilling effect that threatened liability might have on practitioners and pharmaceutical manufacturers for reasonable conduct that counters pain undertreatment. Any response to opioid diversion and abuse that restricts patient access to needed medications or dissuades manufacturers from developing newer, more effective pain management technologies would inappropriately contribute to pain undertreatment.

