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# SUIT TO HOLD MANUFACTURER STRICTLY LIABLE FOR ILLEGAL PRODUCT USE SHOULD BE DISMISSED

by

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For almost a decade, debate has surrounded the widespread prescription and use of a class of pain-killing opioids commonly prescribed to treat chronic pain or assist in palliative care for long-term illnesses. In particular, the prescription analgesic OxyContin®, already heavily regulated as a Schedule II narcotic under the federal Controlled Substances Act of 1970 and related regulations,<sup>1</sup> has received a disproportionate share of attention due to that product's high rate of illegal diversion for illicit uses. OxyContin®, as well as similarly formulated oxycodone drugs, can cause euphoria and is "highly attractive to opioid abusers and doctor-shoppers ... and is abused either as intact tablets or by crushing or chewing the tablet and then swallowing, snorting or injecting."<sup>2</sup> Although brand-name OxyContin® did not receive Food and Drug Administration approval until 1995, and did not enter the market until 1996, the abuse of oxycodone has been a problem in the United States since the 1960s.<sup>3</sup>

By 2000, media reports began to surface regarding allegations that the immensely popular drug was being abused and illegally diverted.<sup>4</sup> Federal agencies such as the General Accounting Office ("GAO") began assessing the extent to which OxyContin® manufacturer Purdue Pharma L.P. ("Purdue") was marketing OxyContin® through a large and skilled sales force targeted at physicians.<sup>5</sup> By 2003 over 300 lawsuits in 25 states and the District of Columbia concerning OxyContin® were pending against Purdue.<sup>6</sup> Many of these lawsuits involved

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<sup>1</sup>21 C.F.R. § 1308.12 (2007).

<sup>2</sup>"Drugs and Chemicals of Concern," U.S. Department of Justice Drug Enforcement Administration, Office of Diversion and Control (Sept. 2007 DEA/OD/ODE), available at [http://www.deadiversion.usdoj.gov/drugs\\_concern/oxycodone/summary.htm](http://www.deadiversion.usdoj.gov/drugs_concern/oxycodone/summary.htm).

<sup>3</sup>*Id.*; see also "Intelligence Bulletin: OxyContin Diversion, Availability, and Abuse", National Drug Intelligence Center, 2004-L0424-017 (Aug. 2004), available at <http://www.usdoj.gov/ndic/pubs10/10550/index.htm>.

<sup>4</sup>"OxyContin Abuse and Diversion and Efforts to Address the Problem," GAO-04-110 (Dec. 2003), available at <http://www.gao.gov/new.items/d04110.pdf>.

<sup>5</sup>*Id.*

<sup>6</sup>*Id.* at 10.

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allegations that Purdue used improper sales tactics and over promoted OxyContin®, causing the drug to be inappropriately prescribed by physicians, and that Purdue’s actions to prevent off-label uses of the drug were inadequate.<sup>7</sup>

The GAO eventually concluded that Purdue had conducted an “extensive campaign” to market and promote OxyContin® that focused on physicians, but also found that a combination of OxyContin®’s formulation, wide availability, and predisposition among users in certain geographic areas towards prescription drug abuse all contributed to OxyContin® abuse and diversion as well.<sup>8</sup> In particular, the GAO noted that in Kentucky and other areas of Appalachia, “[h]istorically, oxycodone, manufactured under brand names such as Percocet, Percodan, and Tylox, was among the most diverted prescription drugs ...”<sup>9</sup> Profit was noted as a primary motive for illegal diversion, for “many areas of the Appalachian region are rural and poverty-stricken, and the profit potential resulting from the illicit sale of OxyContin® may have contributed to its diversion and abuse.”<sup>10</sup>

Ultimately, in May of 2007, Purdue agreed to pay more than \$600 million dollars to the FDA’s Office of Criminal Investigations to settle allegations related to what the FDA described as an “extensive, long-term scheme” to generate “the maximum amount of revenues possible from the sale of OxyContin®.”<sup>11</sup> The FDA alleged that “[Purdue] trained its sales force to represent to healthcare providers that OxyContin® did not cause euphoria and was less addictive than immediate-relief opiates; and allowed health care providers to entertain the erroneous belief that OxyContin® was less addictive than morphine.”<sup>12</sup> At the same time, Purdue agreed to pay nearly \$20 million to 26 states and Washington, D.C., to settle claims that the company had promoted OxyContin® for off-label uses. One of the states involved in that settlement was Kentucky.<sup>13</sup>

*The Commonwealth of Kentucky’s 2007 Lawsuit.* The settlements with regards to OxyContin® marketing directed at physicians have done little to stem lawsuits related to the drug, even by the states involved in the settlement. On October 4, 2007, the Commonwealth of Kentucky, along with Pike County, Kentucky, filed suit in state court against Purdue, the Purdue Frederick Company, Inc., and other manufacturers.<sup>14</sup> The suit, which pleads claims under Kentucky statutory and common law, charged that the defendant manufacturers misled medical providers and others through misrepresentations or omissions regarding the appropriate uses, risks and safety of OxyContin®. In particular, the suit asserted in relevant part that, through misrepresentations and/or omissions related to the manufacture, promotion, and marketing of OxyContin®, the Kentucky state Medicaid program and other state benefits programs suffered losses. Therefore, according to the suit, the defendant manufacturers should be required to reimburse all prescription costs the state had incurred related to OxyContin®, all costs incurred by consumers related to OxyContin®, and all costs expended for state health care services and programs.

Taken as a whole, the Commonwealth of Kentucky’s claims in this matter represent an effort to hold OxyContin® manufacturers strictly responsible for the financial and social impacts of citizens of the state’s illegal abuse and diversion of the already highly regulated drug. Although Purdue paid substantial sums of

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<sup>7</sup>*Id.*

<sup>8</sup>*Id.* at 16-25, 29-33.

<sup>9</sup>*Id.* at 32.

<sup>10</sup>*Id.*

<sup>11</sup>“FDA Announces Results of Investigation into Illegal Promotion of OxyContin by The Purdue Frederick Company, Inc.,” P07-85 (May 10, 2007), available at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01632.html>.

<sup>12</sup>*Id.*

<sup>13</sup>“Attorney General Greg Stumbo Announces Settlement with Purdue Pharma Over Labeling and Marketing of Oxycontin” (May 8, 2007), available at <http://ag.ky.gov/news/purduepharmasettlement.htm>.

<sup>14</sup>The suit has since been removed to federal court, and subsequently transferred to the Southern District of New York for inclusion in an ongoing multidistrict litigation involving OxyContin®. See *In re Oxycontin Antitrust Litigation*, 542 F. Supp. 2d 1359, 2008 WL 925534 (U.S.Jud.Pan.Mult.Lit. 2008).

money to settle federal and state claims related to its marketing of the drug towards physicians, nowhere did its settlement or concession obviate the responsibilities of private individuals, both those using the drug and the doctors necessary to prescribe it, to not engage in illegal behavior. If successful, Kentucky's lawsuit would likely represent a sea change in product liability law for drug manufacturers, in effect holding manufacturers strictly liable for the illegal activities of third parties in abusing or diverting federally regulated drugs approved by the FDA and prescribed under FDA-approved warning labels.

***Illegal Diversion and Causation.*** OxyContin®, as a controlled Schedule II narcotic, is not available to the public without a prescription. It has long been established that the OxyContin® abused in the United States is typically “diverted by illegally written or forged prescriptions, ‘doctor shopping’ (when individuals, who may or may not have a legitimate ailment, visit numerous doctors to obtain drugs in excess of what should be prescribed legitimately), and theft.”<sup>15</sup> OxyContin® abusers also “steal or buy OxyContin from friends or family members with legitimate prescriptions.”<sup>16</sup> Nor is every prescribing doctor an innocent player prescribing controlled narcotics in good faith. There are numerous examples of doctors being accused of engaging in illegal diversions of OxyContin® through fraudulent prescriptions.<sup>17</sup>

Kentucky has identified and acknowledged the role that “doctor shopping” and prescription fraud play in OxyContin® abuse and diversion, going so far as to establish the “Kentucky All Schedule Prescription Electronic Reporting” system, or KASPER.<sup>18</sup> Created by statute,<sup>19</sup> KASPER “tracks all schedule II-V drugs dispensed by licensed Kentucky pharmacists” and was developed “to help physicians, pharmacists and law enforcement fight ‘doctor shopping’ . . .”<sup>20</sup> A typical KASPER report on an individual citizen “shows all scheduled prescriptions for [the] individual over a specified time period, the prescriber and the dispenser,” and submission of that information into the KASPER system is mandatory.<sup>21</sup>

The illegal actions taken by users (and possibly by complicit doctors) in diverting prescription OxyContin® for illegal use should raise a nearly insurmountable bar to finding Purdue liable to those private parties for any resulting injuries. Kentucky law, in accord with many other states, holds that “a manufacturer is not liable when the injuries result from the mutilation or alteration of the [product]. Such intervening conduct severs any causal connection between the product and the injury.”<sup>22</sup> Furthermore, “[i]n Kentucky a plaintiff may not recover in a legal or equitable proceeding when the basis for such an action rests on their own illegal conduct.”<sup>23</sup> Thus, many reviewing courts have rejected OxyContin® lawsuits by private users, often invoking reasons similar to those noted by the GAO when analyzing the origin of the abuse and diversion (namely that many users had past histories of drug abuse that indicated a predisposition to drug abuse, and/or intentionally altered prescription drugs).<sup>24</sup>

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<sup>15</sup>“Intelligence Bulletin: OxyContin Diversion, Availability, and Abuse”, National Drug Intelligence Center, 2004-L0424-017 (Aug., 2004), available at <http://www.usdoj.gov/ndic/pubs10/10550/index.htm>.

<sup>16</sup>*Id.*

<sup>17</sup>*See, e.g.*, “Doctor, Nurse Charged with Illegally Prescribing OxyContin,” (Sept. 26, 2003), available at <http://www.wave3.com/Global/story.asp?S=1458779&nav=0RZFICyK>.

<sup>18</sup>*See* <http://chfs.ky.gov/oig/KASPER.htm>.

<sup>19</sup>*See* KRS § 218A.202 (2007).

<sup>20</sup>*See* “CHFS’ Office of Inspector General Touts Improved Prescription Drug Tracking System; A First for Kentucky and the Nation”, (Mar. 16, 2005), available at <http://chfs.ky.gov/news/CHFS031605A.htm>.

<sup>21</sup>*See* <http://chfs.ky.gov/oig/KASPER.htm>; KRS § 218A.202(3)-(4)(2007).

<sup>22</sup>*Foister v. Purdue Pharma, L.P.*, 295 F. Supp.2d 693, 703 (E.D. Ky. 2003) (*citing Monsanto Co. v. Reed*, 950 S.W.2d 811 (Ky. 1997)).

<sup>23</sup>*Id.* at 704 (*citing Miller v. Miller*, 296 S.W.2d 684, 688 (Ky. 1956)).

<sup>24</sup>*Id.* at 705 (collecting cases, and holding that “the seven plaintiffs that procured and used OxyContin illegally may not recover ...[and] are left with the dilemma which they created.”); *see also Price v. Purdue Pharma Co.*, 920 So.2d 479, 486 (Miss. 2006) (collecting cases, and joining other jurisdictions in “holding that the ‘wrongful conduct rule’ in Mississippi prevents a plaintiff from

Moreover, the causation analysis typically incorporates the “learned intermediary” doctrine, which provides that “once a drug manufacturer has warned physicians of the dangers of the drug, the pharmacy’s liability is cut off by the physician’s knowledge.”<sup>25</sup> Part of the rationale for this doctrine is that:

Pharmaceutical companies ... have no direct contacts with patients. Indeed, in many instances, the patients may not be able to read the printed warnings provided by pharmaceutical companies, either because they cannot read English or because they cannot read at all. In sum, the physician is in the best position to pass on the relevant risks. Thus, a pharmaceutical company must simply ensure that the physician is made aware of the known risks. Doing so absolves it of liability for failure to warn.<sup>26</sup>

Consequently, courts have held that package inserts for OxyContin® have clearly warned of both the “potential dangers of the drug and the best manner in which to minimize those dangers. Even if the patients did not read all of the inserts, their physicians had the ultimate responsibility to do so and to pass that information on to the patients when prescribing OxyContin.”<sup>27</sup>

Thus, provided Purdue continues to adequately alert treating physicians to the potential risks of OxyContin® (and many doctors are already aware of the possible risks associated with opioids), individuals engaging in illegal activity and diversion of the drug properly have no recourse at law against Purdue for injuries caused by the individuals’ own conduct. In light of the immense difficulties facing private plaintiffs who seek to hold Purdue liable for injuries suffered as a result of their own illegal activity, it is alarming that the Commonwealth of Kentucky itself would nonetheless try to attribute the societal costs for that same illegal activity to Purdue and, in effect, seek to require Purdue to “make whole” the state and its public health services, following injuries and costs inflicted by the illegal activities of third parties. Extrapolated to its logical conclusion, the eventual consequence of this and other such state-filed suits would be to hold all manufacturers absolutely responsible for any costs incurred by the state related to the illegal alteration and diversion of lawful products by criminals. The underlying premise of Kentucky’s suit that manufacturers are responsible for and must therefore anticipate and halt any illegal actions by the ultimate users of their products should be rejected.

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suing caregivers, pharmacies, and pharmaceutical companies and laboratories for addiction to a controlled substance which he obtained through his own fraud, deception, and subterfuge.”)

<sup>25</sup>*Id.* at 707. Similarly, in *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 555 (N.D. Tex. 2006), the court granted summary judgment for drug manufacturer under the learned intermediary doctrine in part because even if Purdue’s warning labels for OxyContin were inadequate, prescribing doctor was aware of possible addiction risks for opioids and chose to proscribe them anyway. Moreover, even if the doctor had not been fully aware of the risks, there was no evidence full knowledge of the risks would have altered the doctor’s prescription and an “inadequate warning is not a producing cause of a plaintiffs [sic] injury if a different warning would not have changed the prescribing physician’s decision to prescribe the drugs.”

<sup>26</sup>*Id.*; see also *Smith v. Wyeth, Inc.*, 488 F.Supp.2d 625, 630 (W.D. Ky. 2007) (the “learned intermediary” doctrine . . . functions as a protection for manufacturers of prescription drugs from liability for failure to warn the patient once the manufacturer provides [an] adequate warning to the prescribing physician”).

<sup>27</sup>*Id.* at 708 (further noting that the warnings also advised that OxyContin® tablets “cannot be crushed or divided for administration” and warned that the drug is a “common target for both drug abusers and drug addicts”).