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## A PRESCRIPTION FOR DRUG LIABILITY AND REGULATION

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### *I. Introduction*

As recent developments with VIOXX®, childhood anti-depressants, and other prescription drugs have shown, two realities accompany prescription drug use. First, every prescription drug is designed to work miracles for some class of patients. Prescription drugs save patients' lives, enhance their well-being, or provide them with hope where hope was lacking. Second, every prescription drug also has potential side effects, unavoidable negative reactions in a limited number of patients that can be very serious for those who experience them. In a system fraught with winners and losers, fashioning the right balance between regulation and liability involves complicated legal, scientific, and moral issues. Given recent attention to the side effects that patients can experience, now is an appropriate time to revisit the way regulation and liability work within the prescription drug market.

As with all regulatory regimes, the United States Food and Drug Administration (FDA) manages public risk by issuing forward-looking regulations that impose "prescriptive controls on risk-creating conduct

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*before*<sup>1</sup> potential injury can occur. What makes the FDA different from other federal agencies is that it must approve the risk-benefit analysis for each product it regulates; each drug must be individually approved before a drug company can make, market, or sell the drug.<sup>2</sup> This drug-by-drug national risk strategy defines the class of patients who are most likely to benefit from a particular drug and assures that doctors are armed with warnings and instructions so they can have a science-based understanding of the known potential risks that each drug can pose. A doctor then assesses a patient's personal risks and decides whether to issue that patient a prescription for a specific drug.

Liability, on the other hand, is a backwards-looking compensation and enforcement mechanism designed to manage private risks. It looks at an individual incident and requires a culpable party to compensate a person it injures *after* the individual injury occurs, thereby providing strong incentives "to control risky behavior in order to avoid or reduce future liability."<sup>3</sup>

Liability falls short in the prescription drug context, because, as the American Law Institute's *Reporters' Study* (*Reporters' Study*) has pointed out, "the tort system is ill-equipped to handle" public risks, particularly in cases requiring "specialized experience in assessing risks and control measures."<sup>4</sup> In these situations, liability works best when it complements the federal regulatory regime by requiring companies to pay compensation when they cause harm by operating outside of its regulatory structure.

This article discusses the central issue of how liability works when a prescription drug manufacturer fully complies with the FDA's exacting regulation by selling, marketing, and labeling prescription drugs with specific FDA approval, yet, because of the nature of prescription drugs, a certain percentage of patients experience significant foreseen and unforeseen side effects. In these situations, jurists have generally taken one of two paths. Some judges, driven by compassion for a plaintiff or their own sense of "justice," reach their own determination that the alleged side effect is more serious than the drug's potential benefit and allow the plaintiff to pursue compensation by claiming that the drug has a design or a failure to warn

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1. 2 AM. LAW INST., ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY: REPORTERS' STUDY 83 (1991) [hereinafter REPORTERS' STUDY] (stating that the regulatory agencies use their expertise to "determine what risks to control, the level of control, and often the means of control").

2. See 21 U.S.C. § 355(a) (2000) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the Food and Drug Administration] is effective with respect to such drug.").

3. REPORTERS' STUDY, *supra* note 1, at 83.

4. *Id.* at 87.

defect.<sup>5</sup> Other judges, adhering to the fundamental principles of tort law, have concluded that there can be no design or warning defect when the FDA has approved a drug's specific design and warnings.<sup>6</sup> These jurists require the manufacturer to have committed an objective wrongful act in order for there to be a basis for liability.<sup>7</sup> The drafters of both the *Restatement (Second) of Torts* and *Restatement of Torts, Third* have determined that the latter path achieves a more accurate and desirable litigation and public policy outcome.<sup>8</sup>

Part II of this article reviews the development and application of the federal regulatory scheme that controls the prescription drug market. Part III addresses the body of law that has been built over the last half century to complement this regulatory regime. Part IV discusses the appropriate liability regime for prescription drugs in this country. Part V examines the key public policy issues that this liability regime raises. Part VI explains the choices available to courts for implementing this liability regime. Part VII raises causation issues that could undermine rational liability laws. Part VIII briefly concludes the article.

## *II. Federal Regulation of the Prescription Drug Market*

### *A. Development of FDA Authority to Regulate Prescription Drugs*

Until the early twentieth century, the federal government generally left the regulation of medicine and public health to the states.<sup>9</sup> As a result, drugs were generally unregulated, thus, leaving many ineffective and potentially harmful drugs on the market.<sup>10</sup> Individuals often made their own choices as to which

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5. See, e.g., *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000) (holding that the plaintiff could pursue a design defect claim against the makers of Accutane, a prescription acne medication, and stating that comment k will only apply to prescription drugs on a case by case basis and that, among other factors, the court will consider whether the drug's "benefits justify its risks").

6. See, e.g., *Grundberg v. Upjohn Co.*, 813 P.2d 89, 90 (Utah 1991) ("We hold that a drug approved by the [FDA], properly prepared, compounded, packaged, and distributed, cannot as a matter of law be 'defective' in the absence of proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval.").

7. See, e.g., *id.*; *Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988).

8. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) [hereinafter RESTATEMENT (SECOND)]; RESTATEMENT OF TORTS, THIRD: PRODUCTS LIABILITY § 6 (1998) [hereinafter RESTATEMENT THIRD].

9. See John P. Swann, U.S. Food & Drug Admin., History of the FDA, at <http://www.fda.gov/oc/history/historyoffda/default.htm> (last visited Sept. 28, 2005) (adapting sections from A HISTORICAL GUIDE TO THE U.S. GOVERNMENT (George T. Kurian ed., 1998)).

10. States' treatment of drugs varied widely:

States exercised the principal control over domestically produced and distributed foods and drugs in the 19th century, control that was markedly inconsistent from

drugs to take, as relatively few doctors existed at the time to recommend medications.

The federal government began its effort to standardize drug monitoring and analytical research in 1902, when the Chief Chemist of the Department of Agriculture's Bureau of Chemistry formed the Drug Laboratory; it was a one-man operation with half a desk.<sup>11</sup> A few years later, Congress passed the Pure Food and Drugs Act of 1906,<sup>12</sup> which laid the foundation for modern food and drug law by prohibiting the distribution of mislabeled or adulterated drugs and food in interstate commerce.<sup>13</sup> In 1912, Congress strengthened the law by prohibiting false and fraudulent claims of therapeutic value,<sup>14</sup> and in 1930, it formed the Federal Food and Drug Administration as part of the Bureau of Chemistry.<sup>15</sup>

In 1937, a public health disaster provided the impetus for a tidal shift in federal drug oversight.<sup>16</sup> A well-established pharmaceutical company, Massengill, began selling Elixir Sulfanilamide as treatment for diseases, including strep throat and gonorrhea.<sup>17</sup> The product, which was previously sold as a tablet or in powder form, was manufactured in liquid form in order

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state to state. . . . Federal authority was limited mostly to imported foods and drugs. Adulteration and misbranding of foods and drugs had long been a fixture in the American cultural landscape, though the egregiousness of the problems seemed to have increased by the late 19th century (or at least they became more identifiable).

*Id.*

11. See Donna Hamilton, U.S. Food & Drug Admin., A Brief History of the Center for Drug Evaluation and Research, at <http://www.fda.gov/cder/about/history/Histext.htm> (last visited Sept. 28, 2005).

12. Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, repealed by Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040.

13. See Swann, *supra* note 9, at <http://www.fda.gov/oc/history/historyoffda/section1.html>.

14. Shirley Amendment, Pub. L. No. 62-301, 37 Stat. 416 (1912). Congress enacted this amendment after the Supreme Court of the United States ruled that the Division did not have the authority to seize a product that falsely claimed it could treat cancer. See Swann, *supra* note 9, at <http://www.fda.gov/oc/history/historyoffda/section2.html>.

15. U.S. Food & Drug Admin., *FDA Backgrounder: Milestones in U.S. Food and Drug Law History* (Aug. 2005), at <http://www.fda.gov/opacom/backgrounders/miles.html> [hereinafter *FDA Backgrounder*]. The FDA was transferred from the Department of Agriculture to the Federal Security Agency, the predecessor to the Department of Health, Education, and Welfare, and later to the Department of Health and Human Services. *Id.*

16. See Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER, June 1981, available at <http://www.fda.gov/oc/history/elixir.html>.

17. See Paul M. Wax, *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 ANNALS INTERNAL MED. 456, 458 (1995), available at <http://www.annals.org/cgi/content/full/122/6/456>.

to satisfy popular demand by using diethylene glycol as a medium.<sup>18</sup> Massengill did not realize that diethylene glycol was a deadly chemical known today as antifreeze. The drug killed 107 people — mostly children — before the product was recalled.<sup>19</sup> Because Massengill was not required by the 1906 law to test the safety of the product before marketing it, the FDA could only prosecute the tragedy as a case of mislabeling, as Massengill advertised the drug as an elixir, even though it contained no alcohol.<sup>20</sup>

Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 to require a manufacturer of a “new drug” to test the product and notify the FDA before bringing the new drug to market.<sup>21</sup> This law, for the first time, required companies to prove the safety of new drugs before placing them into interstate commerce.<sup>22</sup> The FDCA also established the requirement of adequate labeling<sup>23</sup> and began distinguishing between products that required a physician’s prescription and those that could be adequately labeled for self-medication.<sup>24</sup>

In 1962, a public health tragedy involving thalidomide, a treatment for morning sickness that resulted in stillbirths and birth defects, led Congress to “fundamentally restructure[] the way in which the FDA regulated new medicines, transforming a system of premarket notification into one that requires individual premarket approval of the safety and effectiveness of every new drug.”<sup>25</sup> Specifically, the 1962 Act gave the FDA responsibility for

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18. See Ballentine, *supra* note 16.

19. See *id.* (noting that Harold Cole Watkins, the chemist responsible for developing the drug, committed suicide); *FDA Background*, *supra* note 15.

20. Ballentine, *supra* note 16.

21. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399 (2000)).

22. 21 U.S.C. § 355. The 1938 law, while requiring manufacturers to prove the safety of a drug to the FDA before marketing, did not require an evaluation of its effectiveness.

23. See *id.* (stating that a drug would be considered misbranded if its label was “false or misleading in any particular”).

24. See Michael I. Krauss, *Loosening the FDA’s Drug Certification Monopoly: Implications for Tort Law and Consumer Welfare*, 4 GEO. MASON L. REV. 457, 461 (1996) (stating that the Act included a provision that allowed for discretionary exemptions from labeling requirements, which the FDA interpreted as providing it with the authority to create “a category of ‘ethical drugs’ that could henceforth be sold only by prescription”). In 1951, the Durham-Humphrey Amendment clarified the legal distinction between prescription and nonprescription drugs. Ch. 578, §§ 1-2, 65 Stat. 648, 648-49 (codified as amended at 21 U.S.C. §§ 333, 353 (2000)).

25. PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW CASES AND MATERIALS* 13 (2d ed. 1991) (observing the role of the FDA in preventing the outbreak of thalidomide side effects that occurred in Europe from occurring in the United States); see also Jeffrey E. Shuren, *The Modern Regulatory Administrative State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 301-03 (2001) (stating that the 1962 Act changed

regulating clinical testing of new drugs, inspecting drug manufacturing facilities, promulgating good manufacturing practices,<sup>26</sup> and requiring manufacturers to report adverse reactions to approved drugs.<sup>27</sup> The FDA also was given oversight responsibilities for prescription drug advertising.<sup>28</sup> In short, the FDA had gained full responsibility for prescribing “the standards of safety and, in some instances, the standards of performance particular products must meet before they reach the public.”<sup>29</sup>

Since the 1960s, this framework has remained in place, with Congress making regular improvements as warranted. For example, in response to complaints from patients, doctors, and pharmaceutical companies that the FDA drug approval process was taking too long,<sup>30</sup> Congress enacted the Prescription Drug User Fee Act in 1992, which required manufacturers to pay user fees to the Agency for the evaluation of new drugs.<sup>31</sup> This fee enabled the FDA to hire more reviewers and decreased the wait time for the public to benefit from safe and effective drugs.<sup>32</sup> In fact, the staff at the Center for Drug Evaluation and Research (CDER) increased by over fifty percent between 1980 and 2000.<sup>33</sup>

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the system from pre-market notification to pre-market approval, which effectively “transformed the FDA’s role from a reviewer of data to an active participant in the drug development process”).

26. See Kefauver-Harris Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified at 21 U.S.C. §§ 321-399 (2000)). The FDA had delayed approval of the New Drug Application for thalidomide, but FDA officials had not suspected the drug could cause birth defects. See FDAReview.org, The Independent Institute, History of Federal Regulation: 1902-Present, at <http://www.fda.gov/history> (last visited June 25, 2005). The drug, however, was sold in forty-six other countries prior to discovery of its impact, resulting in thousands of newborns with physical deformities. *Id.*

27. See Arthur H. Hayes, Jr., *Food and Drug Regulation After 75 Years*, 246 JAMA 1223, 1224 (1981) (noting that oversight of drug advertising was previously undertaken by the Federal Trade Commission (FTC)).

28. *Id.*

29. Richard A. Merrill, *Risk-Benefit Decisionmaking by the Food and Drug Administration*, 45 GEO. WASH. L. REV. 994 (1977), reprinted in HUTT & MERRILL, *supra* note 25, at 20.

30. See John Henkel, *User Fees to Fund Faster Reviews*, FDA CONSUMER SPECIAL ISSUE, Jan. 1995, available at <http://www.fda.gov/fdac/special/newdrug/userfees.html>.

31. Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (codified at 21 U.S.C. §§ 379g, 379h (2000)).

32. In reauthorizing the Prescription Drug User Fee Act in 1997, Congress found that the Act “substantially reduc[ed] review times . . .” Food and Drug Modernization Act of 1997, § 101, Pub. L. No. 105-115, 111 Stat. 2296, 2298 (1997). Congress once again reauthorized the Act in 2002. See Public Health Security and Bioterrorism Preparedness Response Act of 2002, tit. V, Pub. L. No. 107-188, 116 Stat. 594.

33. See Daniel Carpenter & A. Mark Fendrick, *Accelerating Approval Times for New Drugs in the U.S.*, 15 REG. AFF. J. 411, 412 (2004) (on file with author) (finding that the number

The FDA today “administers the most comprehensive drug regulatory system in the world.”<sup>34</sup> Its mission is to optimize the risk-benefit tradeoff by only allowing drugs on the market if they are reasonably safe for their intended class of consumers and setting marketing and warning requirements that companies must adhere to in order to sell their products.<sup>35</sup> With a workforce of 9000 people,<sup>36</sup> the Agency regulates more than 150,000 drugs and medical devices.<sup>37</sup> It also conducts more than 16,000 visits per year to facilities that handle FDA-regulated products in order to inspect manufacturers, to review shipments of imported products, and to examine product samples for signs of contamination.<sup>38</sup> CDER, which began as a one-man operation 100 years ago,<sup>39</sup> now employs over 1700 medical doctors, toxicologists, pharmacologists, epidemiologists, chemists, and statisticians.<sup>40</sup>

### *B. The New Drug Approval Process*

The New Drug Application (NDA), the hallmark of the FDA approval process, subjects all prescription drug applications to rigorous formal rule-making review. The NDA enables the FDA to balance carefully the risks and benefits of each prescription drug, to understand the inherent risks, and to determine how to craft warnings for allowing each drug to be used safely and effectively.<sup>41</sup> Where a drug needs to be particularly strong, such as with psychological issues leading to depression, schizophrenia or bi-polar disorder, the FDA may be more tolerant of potentially dangerous side effects, because without those drugs, patients may pose a significant threat to themselves and

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of CDER employees increased from approximately 1100 in 1980 to 1700 in 2000).

34. Bert W. Rein et al., *Addressing the Conflict: FDA vs. Torts*, PHARM. & MED. DEVICE L. BULL., May 2003, at 1, 1, available at [http://www.lawjournalnewsletters.com/pub/ljn\\_pharm/3\\_5/news/141453-1.html](http://www.lawjournalnewsletters.com/pub/ljn_pharm/3_5/news/141453-1.html) (paid access only).

35. “A principal focus of the Food and Drug Administration, apart from safety, is efficacy. Since every drug includes some risks, the Food and Drug Administration regards efficacy as essential — if one is to take risks, he or she should obtain the desired result.” Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139, 1142 (1985) [hereinafter Schwartz, *Comment K*].

36. Jan Elicker, U.S. Food & Drug Admin., *An FDA Overview: Protecting Consumers, Protecting Public Health* (Aug. 2004), at <http://www.fda.gov/oc/opacom/fda101/fda101text.html>.

37. U.S. FOOD & DRUG ADMIN., STRATEGIC ACTION PLAN: PROTECTING AND ADVANCING AMERICA’S HEALTH 9 (2003), available at <http://www.fda.gov/oc/mcClellan/FDAstrategicPlan.pdf> [hereinafter FDA STRATEGIC ACTION PLAN].

38. See Elicker, *supra* note 36. The agency also has signed cooperative arrangements with many state governments to increase the number of facilities that are checked. *Id.*

39. See Hamilton, *supra* note 11.

40. See Carpenter & Fendrick, *supra* note 33, at 412.

41. See generally 21 C.F.R. pt. 314 (2005).

