

# DETERRING INEFFICIENT PHARMACEUTICAL LITIGATION: AN ECONOMIC RATIONALE FOR THE FDA REGULATORY COMPLIANCE DEFENSE†

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## I. INTRODUCTION

This Article examines the interaction between direct regulation of pharmaceuticals under the Federal Food Drug and Cosmetic Act (FDCA) and the indirect regulation of pharmaceuticals provided by common law tort incentives. The Article concludes that tort liability is generally inappropriate in cases where manufacturers have complied with the FDCA.

The Article begins with a description of the FDCA's operation, and provides an overview of the Food and Drug Administration's (FDA) role in the drug approval process and drug labeling. This overview will demonstrate the need for centralized control over drug labeling. Moreover, we will provide an explanation of the costs and benefits of the drug approval process.

Next, we will focus on the regulatory effects of tort law from an economics perspective. The role of tort law in deterring inefficient accidents depends on the extent and stringency of government regulation. We will examine the sufficiency of regulatory deterrence under various regulatory schemes, including the FDCA. This economic analysis will demonstrate that tort law's applicability should be limited to those regulatory schemes that inadequately deter risks. Since the FDCA adequately deters risk, the proper role for tort law should be to provide incentives for ensuring regulatory compliance.

We then provide a critical review of the legal rules applied to

pharmaceutical litigation in American courts. The uncertainty present in current pharmaceutical litigation stems largely from the failure to adopt regulatory compliance in a strict liability world. Examination of labeling litigation suggests that courts have yet to establish meaningful standards. In addition, design defect litigation, by protecting only those drugs without side-effects, leads to untoward consequences. Furthermore, the tort system has a propensity for error. Our current litigation system generates perverse incentives, which we document.

Finally, we conclude that because of the strict nature of the FDCA, the role of tort liability should be limited through federal legislation.

## II. REGULATORY OBJECTIVES OF THE FDCA

The regulatory objectives of the FDCA are to ensure that the manufacturer shares all risk information with the FDA so that the agency may make informed risk-benefit judgments about the utility of a pharmaceutical.<sup>1</sup> These judgments occur throughout the life of the drug.<sup>2</sup> The agency determines which drugs reach the market and the labeling for those that do.

### A. Standardization of Drug Labeling

Drug labeling reduces the risk of drug-induced injury by informing health care professionals of prescription medications' potential adverse effects.<sup>3</sup> Because prescription drugs rarely can be

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<sup>1</sup> The drug approval process is described *infra* at notes 22-38 and accompanying text. The results of extensive clinical studies must be submitted to the FDA, which then balances safety versus efficacy to determine whether the product should be approved. See Dixie Farley, *Benefit vs. Risk: How FDA Approves New Drugs*, in FDA, FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES (1988), reprinted in PLI, BIOTECHNOLOGY: NEW DEVELOPMENTS IN FEDERAL POLICIES AND REGULATIONS 164, 164 (1988).

Likewise, post-approval safety monitoring is described *infra* at notes 39-49 and accompanying text.

<sup>2</sup> The receipt of new safety information can lead the agency, after holding a hearing, to withdraw approval for marketing of a drug. 21 U.S.C. § 355(e)(1) (1988); 21 C.F.R. § 5.82 (1993). The Secretary of Health and Human Services has authority to order the withdrawal of marketing approval without a hearing where there appears to be an "imminent hazard to public health," provided, however, that the manufacturer receives an expedited post-withdrawal hearing. 21 U.S.C. § 355(e) (1988).

<sup>3</sup> "Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk." *United States v. Rutherford*, 442 U.S. 544, 555 (1979). The FDCA defines a prescription drug as follows:

A drug intended for use by man—

... which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use,

said to present no potential risks, accurate and up-to-date information about their risk potential is a critical determinant in the physician's choice of a patient's medication. An effective warnings policy for risks must communicate with some degree of precision the risk *level* presented by the product in general as well as for its specific class of users.

Under the FDCA and its implementing regulations, the FDA possesses virtually total control over the content of the package inserts that accompany all prescription drugs.<sup>4</sup> Because the information contained in the package inserts plays a critical role in physicians' prescribing patterns, the package inserts must portray the drug's safety profile with accuracy, balance, and brevity.<sup>5</sup> Given these goals, the need for standardization is obvious.

An important function of the FDA is to ensure that risk information is appropriately channelled. The FDCA and its implementing regulations allow the FDA to perform this task in a relatively straightforward manner. In particular, before permitting the sale of a pharmaceutical product, the manufacturer is required to generate both safety and efficacy information and must present this information to the FDA in a new drug application (NDA).<sup>6</sup>

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is not safe for use except under the supervision of a practitioner licensed by law to administer such drug [and] . . . shall be dispensed only [upon prescription].

21 U.S.C. § 353(b)(1)(B) (1988).

<sup>4</sup> Former FDA Chief Counsel Richard Cooper observed that, while a review of the applicable law would lead to the conclusion that manufacturers can act contrary to the FDA's will, the "FDA . . . retains, as a practical matter, complete control over package inserts." Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 236 (1986).

<sup>5</sup> In other words, the "statutory scheme for drug labeling is intended to provide physicians, in straightforward and concise terms, with the information they need to prescribe a drug under conditions that maximize the drug's effectiveness and minimize its risks." 44 Fed. Reg. 37,436 (1979).

<sup>6</sup> Under the FDCA, the manufacturer must submit an NDA to the agency and receive pre-marketing approval in order to market a "new drug," i.e., any drug that is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1) (1988). If the manufacturer of a "new drug" wishes to distribute it lawfully, he can submit an NDA in conformance with 21 U.S.C. § 355(b) (1988). Approval for marketing can be obtained only if, *inter alia*, the applicant submits "adequate and well-controlled studies" demonstrating safety and efficacy. *Id.* § 355(d). Alternatively, the manufacturer can claim that the product is not a "new drug" because it is "generally recognized" as being "safe and effective" for its intended uses. *Id.* § 321(p)(1) & (2). Courts have, however, construed such general recognition to be based on the same adequate and well-controlled investigations required for approval of an NDA under 21 U.S.C. § 355(d). *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973).

The NDA process requires the pharmaceutical manufacturer to submit proposed labeling for the drug.<sup>7</sup> The FDA and the manufacturer then generate the drug's initial label based on the manufacturer-supplied information concerning the drug's safety and efficacy.<sup>8</sup> If the FDA approves the NDA and licenses the drug for sale, the manufacturer has a continuing obligation to report safety-related information to the agency.<sup>9</sup> Drug product labeling often changes over time as a result of the FDA receiving information from the manufacturer or other sources about a drug's safety in the marketplace.<sup>10</sup>

The FDA has adopted a standardized warning vocabulary and structure to ensure that safety information is readily accessible to health care professionals.<sup>11</sup> Each section of drug labeling addresses a specific set of issues. The first section of labeling provides a general "description" of the product.<sup>12</sup> The second deals with the drug's "clinical pharmacology," discussing issues about how the pharmaceutical operates.<sup>13</sup> Drug labeling's third component consists of "indications and usage," so that the particular situations in which the medicine has been shown to be effective are summarized.<sup>14</sup> The "contraindications" section addresses situations in which the drug should not be administered because of particularized, severe risks.<sup>15</sup> The "warnings" section is devoted to serious risks that arise both generally and in particularized contexts.<sup>16</sup> Risks that arise less frequently are addressed in the "precautions" section of the label.<sup>17</sup> The potential for untoward reactions that

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<sup>7</sup> 21 U.S.C. § 355(b)(1)(F) (1988).

<sup>8</sup> Although the manufacturer submits proposed initial labeling with the NDA, the actual labeling is often the result of negotiations between the FDA and the manufacturer. The agency's power to disapprove the NDA ensures that it retains practical control over the contents of drug labeling.

<sup>9</sup> The post-marketing requirements are set forth in 21 C.F.R. § 314.80 (1993).

<sup>10</sup> New technology has decreased the amount of time required to inform the physician of changed labeling. In particular, the *Physicians' Desk Reference* (PDR) has for decades provided the medical profession with an annual compendium of current package inserts supplemented with frequent pocket parts. As with legal publishing, the PDR's publisher has gone on-line, thereby reducing the time required for new information to reach the prescribing physician.

<sup>11</sup> The FDA has explicitly recognized the need for uniformity in drug labeling. See, e.g., 50 Fed. Reg. 51,403 (1985) (citing the potential for confusing or misleading consumers, the proposed rule recognized that the "FDA has a well-established policy of promoting uniformity in the area of labeling").

<sup>12</sup> 21 C.F.R. § 201.57(a) (1993).

<sup>13</sup> *Id.* § 201.57(b).

<sup>14</sup> *Id.* § 201.57(c).

<sup>15</sup> *Id.* § 201.57(d).

<sup>16</sup> *Id.* § 201.57(e).

<sup>17</sup> *Id.* § 201.57(f).

may occur on a random basis is addressed in the "adverse reactions" section.<sup>18</sup> Subsequent to receiving this comprehensive collection of risk information, the physician is advised about the appropriate "dosage and administration" of the drug product.<sup>19</sup>

The uniform structure of drug labeling has important implications for the processing of information. This standardized format significantly assists risk information processing. A physician looking for such information will know where to locate it.<sup>20</sup> Likewise, the regulatory process and institutional memory also ensure that the language used in drug labeling is consistent and appropriate to the degree of known risks posed by the drug. The FDA's central control over labeling results in a uniformity of language that could not occur through a more decentralized form of regulation. The result of FDA superintendence is that drug labeling tends to produce its intended impact.<sup>21</sup>

### *B. The Drug Approval Process: Risk-Benefit Analysis*

As noted, to obtain FDA approval for marketing a prescription drug, a pharmaceutical applicant must generate substantial pre-

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<sup>18</sup> *Id.* § 201.57(g).

<sup>19</sup> *Id.* § 201.57(j).

<sup>20</sup> "By adopting such a standardized format the user of the information can develop expertise in processing the labeling information in a systematic manner." W. Kip Viscusi, *Toward a Proper Role for Hazard Warnings in Products Liability Cases*, 13 J. PROD. LIAB. 139, 157 (1991).

<sup>21</sup> In contrast, the confusion engendered by decentralized labeling can be demonstrated by examining the unintended potential effects of the food cancer warning required by California's Proposition 65. See W. Kip Viscusi, *Predicting the Effects of Food Cancer Risk Warnings on Consumers*, 43 FOOD DRUG COSM. L.J. 283, 283 (1988) (explaining that Proposition 65 was a referendum approved by California's voters in 1986 that required, *inter alia*, warnings on food products containing cancer-causing chemicals). Specifically, in all consumer products that pose a lifetime risk of cancer in excess of 1/100,000, California law mandates the following warning:

WARNING: This product contains a chemical known to the State of California to cause cancer.

CAL. CODE REGS. tit. 22, § 12601(b)(4)(A) (1989). In contrast, the federally-mandated saccharin warning, which deals with a 1/2,500 lifetime cancer risk, reads:

Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals.

<sup>21</sup> C.F.R. § 101.11 (1993).

Based on a sample of adult respondents given these warnings, 56% of the individuals who read both labels thought that the saccharin label indicated a product with less risk than California's warning label. Viscusi, *supra*, at 296-97. Obviously, the particular words chosen to convey a warning will affect the *level* of risks perceived by the recipient. Multiple risk information sources create the potential for dissonance and suggest that centralization and standardization are necessary for an effective warnings policy.

marketing safety and efficacy information through human clinical trials. The approval process often commences with an applicant's submission of an investigational new drug application to conduct such trials. The application contains information about the drug's chemistry, pharmacology, and toxicology and includes the results of animal and laboratory testing.<sup>22</sup> If the FDA fails to respond by either requesting more information or seeking modifications to the protocols for the proposed clinical trials, the trials may commence.<sup>23</sup>

The clinical trial process generally consists of three phases. Phase I trials involve tests done with small numbers of healthy adults—twenty to eighty—and are designed to both document a drug's safety and provide information about “the metabolism and pharmacologic actions of the drug in humans, [and] the side effects associated with increasing doses.”<sup>24</sup>

If the Phase I trials are successful, human testing proceeds to Phase II. Phase II trials usually involve 200 to 300 people who are afflicted with a specific condition or disease. These trials are “conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study” and to determine side effects and problems associated with the taking of the drug.<sup>25</sup>

Successful completion of Phase II testing leads the process to Phase III clinical trials. These trials are substantially larger than the Phase I or II trials and often involve 1000 to 3000 patients with a specific condition or disease.<sup>26</sup> As Phase III testing reaches its conclusion, the applicant generally submits the NDA for the drug to the FDA.<sup>27</sup> The NDA is a compendium of all available data on the drug's efficacy for the proposed uses as well as its safety, and includes, among other things, proposed labeling for the drug.<sup>28</sup>

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<sup>22</sup> 21 C.F.R. § 312 (1993).

<sup>23</sup> See generally Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 776 (1990) (explaining the process involved with a new drug application); David A. Kessler, *The Regulation of Investigational Drugs*, 320 NEW ENG. J. MED. 281 (1989) (explaining how the FDA regulates investigational drugs).

<sup>24</sup> 21 C.F.R. § 312.21(a) (1993).

<sup>25</sup> *Id.* § 312.21(b).

<sup>26</sup> *Id.* § 312.21(c).

<sup>27</sup> As noted, the FDA must license any “new drug” before it is marketed in the United States. 21 U.S.C. § 355(a) (1988).

<sup>28</sup> See 21 C.F.R. § 314.50 (1993) (setting forth specific requirements for a new drug application). The FDCA requires new drug applications to include:

(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effec-

The FDA must ensure that the proposed new drug complies with the FDCA mandate that safety be established and that "substantial evidence" of efficacy be demonstrated for the drug's proposed uses.<sup>29</sup> The FDA review process often takes years of evaluation after the NDA's submission.<sup>30</sup> Ultimately, approval by the FDA reflects a risk-benefit judgment that the product will enhance public health.<sup>31</sup> The entire NDA process is a lengthy one, typically taking between five and seven years to complete.<sup>32</sup>

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tive in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug.

21 U.S.C. § 355(b)(1) (1988).

<sup>29</sup> See 21 U.S.C. § 355(d) (1988):

"[S]ubstantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified . . . to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

*Id.*

<sup>30</sup> Frank E. Young, *The Reality Behind the Headlines*, in FDA, FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES (1988), reprinted in PLI, BIOTECHNOLOGY: NEW DEVELOPMENTS IN FEDERAL POLICIES AND REGULATIONS 126-29 (1988). Generally, the FDA requests further information from the applicant before acting on the application. See Kessler, *supra* note 23, at 283 ("A study of 637 NDAs received since 1981 found that the FDA returned two thirds to the sponsor with requests for more information.") (footnote omitted).

A 1987 estimate placed the cost of the NDA process at \$231 million. Joseph A. DiMasi et al., *Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH ECONOMICS 107, 126 (1991); see also *Drug Price Competition and Patent Term Restoration Act of 1984: Hearings on S. 2748 Before the Comm. on Labor and Human Resources*, 98th Cong., 2d Sess. 106 (1984) (statement of Verne Willaman, Member, Executive Committee, Johnson & Johnson) ("On average, the cost of developing a new medicine in this country is now in the \$70 to 85 million range."); STEVEN N. WIGGINS, THE COST OF DEVELOPING A NEW DRUG 16-19 (1987). The cost of drug development has risen much faster than general inflation. Henry G. Grabowski, *The Impact of Regulation on Innovation*, 34 FOOD DRUG COSM. L.J. 555, 555 (1979) (explaining that the cost of developing new drugs is in excess of \$50 million).

NDAs consist of approximately two to fifteen volumes of summary material accompanied by ten to one hundred volumes of raw data concerning the safety and effectiveness of the new drug. Stephen L. Isaacs & Renee Holt, *Drug Regulations, Product Liability and the Contraceptive Crunch*, 8 J. LEGAL MED. 533, 536 (1987).

<sup>31</sup> Bruce N. Kuhlik & Richard F. Kingham, *The Adverse Effects of Standardless Punitive Damage Awards on Pharmaceutical Development and Availability*, 45 FOOD DRUG COSM. L.J. 693, 695 (1990); Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 10 (1973).

<sup>32</sup> Mary T. Griffin, *AIDS Drugs & The Pharmaceutical Industry: A Need for Reform*, 17



Certain critics of the FDA, in fact, have suggested that the effects of the drug licensing provisions of the FDCA and its implementing regulations combine to deprive patients of useful, innovative drugs.<sup>33</sup> In other words, there are measurable human costs incurred in developing the detailed drug safety profile required by this nation's regulatory scheme: "[T]he central point is, [that with the regulatory scheme for approving drugs] you are choosing one set of deaths and suffering and illness and costs against another. That is the only choice open to us."<sup>34</sup> These public health costs, however, are in a sense hidden: although adverse reactions result in identifiable victims, the costs of drug unavailability are often in the realm of the abstract.<sup>35</sup>

In evaluating an NDA, the FDA also pays close attention to the proposed labeling in order to ensure the labeling's reliability.<sup>36</sup>

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AM. J.L. & MED. 363, 378 n.87 (1991) (citing Gordon, *The Drug Development and Approval Process*, in PHARMACEUTICAL MANUFACTURERS ASSOCIATION, *NEW MEDICINES IN REVIEW* 5 (1990)).

<sup>33</sup> The review process has meant that new drug therapies are sometimes not introduced in the United States until one to two years after they have been approved in other western countries. The Comptroller General, *Report to the Subcommittee on Science, Research, and Technology, FDA Drug Approval—A Lengthy Process That Delays the Availability of Important New Drugs* (1980); see also *Jones v. Lederle Lab.*, 785 F. Supp. 1123, 1127 (E.D.N.Y.) ("Requiring strict proof of safety—both to comply with FDA regulations and to avoid tort liability—slows the availability of new products. The result may well be that dangers will be enhanced during the necessarily extended developmental period."), *aff'd*, 982 F.2d 63 (2d Cir. 1992) (per curiam).

<sup>34</sup> *Competitive Problems in the Drug Industry: Hearings Before the Subcommittee on Monopoly of the Select Committee on Small Business*, 93d Cong., 1st Sess., pt. 23 at 9859 (1973); see also SUBCOMM. ON SCIENCE, RESEARCH AND TECH. OF THE COMM. ON SCIENCE AND TECHNOLOGY, 96TH CONG., 2D SESS., *THE FOOD AND DRUG ADMINISTRATION'S PROCESS FOR APPROVING NEW DRUGS* 31 (Comm. Print 1980); Donald Kennedy, *A Calm Look at Drug Lag*, 239 JAMA 423 (1978) ("[C]onsumers are poorly served when they are denied access to safe products.").

<sup>35</sup> The AIDS crisis—in which those who would be injured by any delay in drug marketing have had the ability to organize—has focused some attention on the costs of delay and has produced some regulatory changes. In particular, steps have been taken to shorten the time required for broader availability of drugs for life-threatening diseases. See 21 C.F.R. §§ 312.34 (making investigational new drugs available for treatment), 312.80 to .88 (1993) (setting forth rules, regulations and procedures for expedited approval of new drugs for life-threatening illnesses or diseases).

These reforms suggest that where the outcome of untreated disease is certain death, the risk-benefit calculus may tolerate additional risks and uncertainty.

<sup>36</sup> See generally 44 Fed. Reg. 37,434, 37,441 (1979), which states:

Labeling is not intended to be a dispositive treatise of all possible data and information about a drug. It is intended instead to advise about potential hazards and to convey *documented* statements concerning safety and effectiveness. The act permits labeling statements with respect to safety only if they are supported by scientific evidence . . .

*Id.* (emphasis added). Accord 21 C.F.R. § 201.56(a) (1993) (stating that labeling must be based on "scientific information").

The implementing regulations permit warnings on the labels only when there is significant medical evidence of a possible health hazard.<sup>37</sup> Moreover, the regulations also preclude warning of a drug's unknown or theoretical adverse reactions.<sup>38</sup> In other words, the FDA's labeling policy acknowledges and addresses labeling choices in the face of scientific uncertainty.

### C. *Post-Marketing Labeling Changes*

There are inherent limitations to pre-marketing testing. In particular, animal studies are imperfect predictors of adverse human health consequences.<sup>39</sup> Likewise, pre-market clinical testing cannot and does not uncover all side effects:

Even the most extensive pre-marketing testing can never cover all possible circumstances. Testing perhaps 3,000 people over a period of months or even a few years won't always identify a rare reaction unfolding over a long time, or affecting perhaps just one person in 10,000. Furthermore, drugs are rarely tested in such potentially vulnerable groups as the elderly, and never among pregnant women. Consequently, not every reaction can be foreseen for the entire population . . . .<sup>40</sup>

The clinical trial process itself has inherent limitations and cannot provide a complete safety profile of a product.<sup>41</sup> Thus, under the

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<sup>37</sup> 21 C.F.R. § 1.21 (1993).

<sup>38</sup> *Id.* § 201.57(d). Because reported adverse effects may prove to be coincidental or erroneous, the FDA must determine whether there is a sufficient basis to warrant a change in labeling.

<sup>39</sup> Thalidomide was tested extensively in animals before its use in humans, but the drug did not cause birth defects in laboratory animals. See Max Sherman & Steven Strauss, *Thalidomide: A Twenty-Five Year Perspective*, 41 FOOD DRUG COSM. L.J. 458, 459-62 (1986).

<sup>40</sup> Stephen J. Ackerman, *Watching for Problems That Testing May Have Missed*, in FDA, FROM TEST TUBE TO PATIENT: NEW DRUG DEVELOPMENT IN THE UNITED STATES (1988), reprinted in PLI, BIOTECHNOLOGY: NEW DEVELOPMENTS IN FEDERAL POLICIES AND REGULATIONS 202, 202 (1988).

<sup>41</sup> There has been an increasing trend for the FDA to mandate post-approval research, especially with respect to long-term safety issues. See Nancy Mattison & Barbara W. Richard, *PostApproval Research Requested by the FDA at the Time of NCE Approval, 1970-1984*, 21 DRUG INFO. J. 309, 313 (1987). Because the pre-market NDA process cannot detect adverse reactions that materialize on a delayed basis, the FDA's policy of mandating further "Phase IV" research ensures that the initial risk-benefit judgment made by the agency can be revisited if necessary. This seems to be an appropriate policy inasmuch as further study of an apparently useful drug will generate new risk information that can address any uncertainties that were noted at the time of the drug's initial approval.

The FDCA and its implementing regulations do not provide for Phase IV studies. Nonetheless, the regulated community has consented to the FDA's practices and, in turn, the agency has communicated its policies to the regulated community. See

FDCA and its implementing regulations, there is an inevitable degree of uncertainty about the newly-licensed drug's safety profile. In fact, one-half or more of a newly-marketed drug's adverse reactions are not discovered until after the product has been marketed.<sup>42</sup>

Post-marketing experience generates important information about a drug's safety profile. The FDCA and its implementing regulations ensure that a manufacturer shares risk information with the FDA.<sup>43</sup> Post-marketing surveillance consists of two primary components—reports of individual adverse experiences and epidemiologic studies.<sup>44</sup> Serious reactions must be reported within fifteen working days of receipt of the information.<sup>45</sup> A comprehensive, post-marketing system of reporting and record-keeping requirements ensures that the manufacturer reports adverse drug experiences discovered in clinical, epidemiological, or surveillance studies, through review of the medical literature, or otherwise.<sup>46</sup> Post-marketing developments might require a change in a drug's labeling or, in rare instances, can lead to restrictions on a product's sale, or even its withdrawal.<sup>47</sup>

Thus, the FDCA and its implementing regulations ensure that there is no disparity of information between the FDA and the manufacturer. While the manufacturer is allowed some latitude in making interim labeling changes, the FDA ultimately must approve *all* post-marketing changes in labeling.<sup>48</sup> The FDCA regulatory scheme in the

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Marion J. Finkel, *Phase IV Testing: FDA Viewpoint and Expectations*, 33 FOOD DRUG COSM. L.J. 181 (1978).

<sup>42</sup> See U.S. GENERAL ACCOUNTING OFFICE, FDA DRUG REVIEW: POSTAPPROVAL RISKS 1976-85 at 3 (1990) (stating that 51.5% of all drugs approved between 1976 and 1985 had serious risks that were discovered post-approval).

<sup>43</sup> 21 C.F.R. § 314.80 (1993).

<sup>44</sup> Gerald A. Faich, *Adverse Drug Experience and Product Liability*, 41 FOOD DRUG COSM. L.J. 444, 445 (1986).

<sup>45</sup> 21 C.F.R. § 314.80(c)(1) (1993). The report of an adverse event does not reflect a conclusion that the injury was iatrogenic. *Id.* § 314.80(l). In fact, determining the causation of an adverse event can be difficult and expensive. See, e.g., Claudio A. Naranjo et al., *Idiosyncratic Adverse Drug Reactions: Challenges to Clinical Pharmacologists*, in IDIOSYNCRATIC ADVERSE DRUG REACTIONS: IMPACT ON DRUG DEVELOPMENT AND CLINICAL USE AFTER MARKETING 1-7 (Claudio A. Naranjo & Judith K. Jones eds., 1990).

<sup>46</sup> 21 C.F.R. §§ 310.303(a), 314.80(c) (1993). Post-marketing reporting obligations include the disclosure of data regarding adverse reactions outside the United States. Ellen J. Flannery, *Reporting Foreign ADRs and ADRs in Phase IV Studies, and the Significance of Causality Assessment*, 46 FOOD DRUG COSM. L.J. 43, 50-51 (1991).

<sup>47</sup> Failure to submit post-marketing reports is itself grounds for withdrawal of the NDA approval. See 21 C.F.R. §§ 314.81(d), 314.80(k) (1993).

<sup>48</sup> The manufacturer can, in narrow circumstances, make a change *prior* to FDA approval pursuant to 21 C.F.R. § 314.70(c)(2) (1993). At the same time such a change is made, the manufacturer must seek FDA approval of the unilateral action. *Id.* § 314.70(c). If, however, the FDA disagrees with the manufacturer's unilateral change in labeling, the agency can institute regulatory action. Accordingly, under the

end confers upon the FDA final regulatory authority for a pharmaceutical product's labeling. Due to the FDA's experience and expertise, initial labeling and post-marketing drug labeling determinations are ultimately made by the FDA, an agency with a high degree of institutional competence.<sup>49</sup>

### III. HOW COMMON LAW TORT ACTIONS REGULATE PHARMACEUTICALS

The common law regulates behavior through the imposition of damage awards against tortfeasors. Liability rules alter behavior by requiring the tortfeasor to pay for the injury caused. An idealized tort system can maximize social welfare, but only if certain conditions can be met.

#### A. *The Regulatory Effects of the Common Law*

##### 1. The Unregulated World

Law and economics posits that the tort system should maximize social welfare by creating incentives that deter some, but not all, accidents.<sup>50</sup> An idealized tort system achieves this objective by requiring the tortfeasor to pay damages that fully compensate victims of accidents caused by risks that are cost-effective to eliminate.<sup>51</sup> For accidents with health effects, the award should be

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regulations, any "freedom of action" possessed by a manufacturer exists only until the agency has determined whether the change is appropriate. If the FDA determines that the labeling change was or would be inappropriate, the manufacturer cannot make the change. The practical effect of the regulatory structure and the manufacturer's need to maintain its relationship with the FDA is total FDA control over the contents of the package insert. See Cooper, *supra* note 4, at 235.

<sup>49</sup> See, e.g., Pennington P. Landen, *Federal Preemption and the Drug Industry: Can Courts Co-Regulate?*, 43 FOOD DRUG COSM. L.J. 85, 98 (1988) (maintaining that the FDA is recognized as the pre-eminent drug regulatory authority in the world); Henry E. Simmons, *The Drug Regulatory System of the United States Food & Drug Administration: A Defense of Current Requirements for Safety and Efficacy*, 4 INT'L J. HEALTH SERVS. 95, 97 (1974) (discussing the notion that the FDA is recognized as the most effective national drug regulatory agency in the world).

<sup>50</sup> Some element of risk is inevitable in life because it simply is not feasible to eliminate all sources of accidental death and injury. Danger is often impossible to disentangle from beneficial activities. For example, driving faster produces some benefits, but at the same time, faster speed may result in safety costs. Because safety involves both direct costs and costs in terms of avoided useful activities, economists perceive the function of accidents law as "reduc[ing] the sum cost of the costs of accidents and the costs of avoiding accidents." GUIDO CALABRESI, *THE COSTS OF ACCIDENTS* 26 (1970).

<sup>51</sup> In such a system, the tortfeasor must pay damages that compensate the victim for not only the economic losses incurred, but also for intangible losses such as pain and suffering and all other non-economic losses. Such damages must be included

equivalent to the amount a firm would have to pay all persons exposed to the risk in order to induce such persons to accept the risk voluntarily. Where compensation is given only for accidents that are efficient to avoid, financial incentives will force firms to invest in safety to the extent necessary to eliminate *all* awards of damages and *all* inefficient risk.<sup>52</sup> Thus, in this idealized tort system, the maximum number of accidents will be avoided given the level of safety investments deemed efficient.<sup>53</sup> The payment of compensatory damages through tort law will have deterred all socially irresponsible risks.

In order for tort law to achieve this goal, however, it must have perfect information about both the costs of accidents and the costs of avoiding them. In other words, the tort system must be able to distinguish between accidents that should be avoided and, therefore, compensable, and accidents that should not be deterred because the social cost of reducing the accident is greater than the cost of the accident itself.<sup>54</sup> In situations where the tort system cannot reliably determine where compensation should be awarded in order to maximize social welfare, tort law can easily create perverse incentives, thereby harming social welfare by reducing overall efficiency.<sup>55</sup>

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within the compensation rule if tort law is to provide appropriate deterrence. Efficient damages awards will make the victim whole in the cases of monetary losses. For non-monetary losses, the award will not make the victim whole, but will be based on the compensation amount that will induce efficient risk avoiding behavior. W. KIP VISCUSI, *REFORMING PRODUCTS LIABILITY* 89-94 (1991).

To the extent that the tort system adopts compensation rather than the deterrence of inefficient risks, as a goal, tort law acts as an insurer. Few people, however, would voluntarily choose to purchase first-party insurance that protects their non-economic interests from risks society finds inefficient to deter. This suggests that to the extent a tort regime is compensatory-only, tort law forces consumers to buy an insurance policy many do not really want. Richard B. Stewart, *Crisis in Tort Law? The Institutional Perspective*, 54 U. CHI. L. REV. 184, 188 (1987). In other words, the tort system cannot simultaneously provide both appropriate insurance and appropriate economic incentives unless the law provides two damages rules: one for negligence purposes, and another for insurance purposes. See generally *id.* at 188-90.

<sup>52</sup> The result is what economists call "Pareto optimality," and represents a world of allocative efficiency. In such a world, scarce resources have been allocated such that no one can be made "better off" without making someone else "worse off."

<sup>53</sup> See RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 143 (2d ed. 1977) ("As it happens, the right amount of deterrence is produced by compelling negligent injurers to make good the victim's losses. Were they forced to pay more . . . some economical accidents might also be deterred; were they permitted to pay less than compensation, some uneconomical accidents would not be deterred.").

<sup>54</sup> Judge Posner believes that the *negligence* standard is intended to be the switch for these binary decisions. See *id.* ("Its economic function is different; it is to deter uneconomical accidents.").

<sup>55</sup> In the context of pharmaceuticals, economic analysis seeks to achieve rational

## 2. The Regulated World

In the case of a regulated industry, tort law does not operate in a vacuum. In particular, the regulatory structure will alter the actions of the regulated community by imposing criminal or other sanctions on socially harmful behavior. Such direct regulation can sometimes achieve the social goal of deterring inefficient accidents more economically and accurately than the indirect incentives provided through tort law.<sup>56</sup> Moreover, if regulation already deters the inefficient accident, tort liability will not promote safety in a desirable manner.<sup>57</sup>

A body of economics literature has developed that compares various regulatory schemes in order to determine whether or not the schemes overdeter or underdeter accidents in the areas they regulate. The economic analysis generally involves two steps: 1) a yardstick representing a life valuation figure for the purpose of determining which accidents should be deterred and which would be tolerated; and 2) a determination of the cost of regulation versus its beneficial health and safety effects.

### a. *The Value of Life*

Economics can provide useful insights about how individuals value incremental risks to life—the type of risk typically found in pharmaceuticals. The standard economic approach to this issue is to consider the implicit value of a statistical life from the stand-

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prescribing such that social welfare, i.e., public health, shows the maximum improvement given the existing drug armamentarium and level of medical understanding. Classical microeconomics posits that allocative efficiency is achieved through perfect and costless information. As applied to drug labeling, this suggests that labeling should reflect current understanding and be in a form that conveys information rapidly and efficiently.

<sup>56</sup> See CALABRESI, *supra* note 50, at 102-03 (arguing that regulation can be more efficient than tort liability with regard to achieving societal goals); see also Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUDIES 357 (1984) (same, with thoughtful discussion of comparative utility of tort law and regulation in varying contexts).

<sup>57</sup> Indeed, the efficient accident will still generally occur because the payment of damages is less costly than liability, and tort law will merely act as a very expensive insurance system. See Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U.L. REV. 199, 233 (1992) (“[E]xposing pharmaceutical manufacturers to strict liability fails to take into account the FDA’s assessment of social utility. Strict liability thus creates excessive administrative or transactional costs in the form of litigation expenses, with little or no improvement in safety as measured by those actually injured.”). Of course, if pharmaceutical manufacturers are poor insurers, they will exit from product markets that impose extraordinary liability costs due to relatively high levels of risk that cannot be disaggregated from the product’s high level of social utility.

point of prevention. In particular, how much is it worth to individuals to alter a small risk of death that they face? To resolve this issue, economists have turned to labor market evidence, in particular the wage levels paid for hazardous jobs.

For example, the typical American worker receives compensation of approximately \$500 annually in return for bearing an annual fatality risk of 1/10,000.<sup>58</sup> These amounts are determined statistically based on large samples of workers rather than formal stipulations in contracts. Consequently, a group of 10,000 workers would receive a total of \$5 million to face a statistical risk of death of 1/10,000 each, or one expected death in their group. For this group, the implicit value of a statistical life is \$5 million.

The actual value of a statistical life varies depending on the particular sample of workers and their characteristics, such as earnings level. The value of life is not a constant, but instead reflects individuals' attitudes toward life and health. Estimated values-of-life figures for typical workers range from \$3 million to \$7 million,<sup>59</sup> but in some cases the estimates are quite different. Workers who have chosen very high risk jobs, such as those that pose an annual fatality risk in the order of 1/1000, typically have an implicit value of life of under \$1 million per life.<sup>60</sup>

Nevertheless, in all cases the implicit value of life based on prevention is well above the present value of earnings of the average worker in the group. In particular, the value of life from the standpoint of prevention often exceeds the present value of the worker's earnings by a factor of ten. This blow-up factor may, of course, vary depending on the individual circumstances as well as on the nature of the injury. In the case of fatalities for the typical American worker, however, this kind of proportionality is reflective of the kinds of differences between deterring a statistical death and the value of earnings associated with an individual's future earning stream.

These value-of-life figures are not unreasonable. An implicit value of life of \$5 million does not suggest that an individual would

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<sup>58</sup> See W. Kip Viscusi, *The Value of Risks to Life and Health*, 31 J. ECON. LITERATURE 1912, 1925-28 (1993) [hereinafter *The Value of Risks*].

<sup>59</sup> Surveys of value-of-life literature appear in W. KIP VISCUSI, *FATAL TRADEOFFS: PUBLIC & PRIVATE RESPONSIBILITIES FOR RISK* Chapter 4 (1992) [hereinafter *FATAL TRADEOFFS*]. See *id.* at 73 (valuing life in range of three million to seven million dollars); see also *The Value of Risks*, *supra* note 58, at 1942 (also reporting the three million to seven million dollar value-of-life range).

<sup>60</sup> See *FATAL TRADEOFFS*, *supra* note 59, at 56; *The Value of Risks*, *supra* note 58, at 1925-28.

pay \$5 million dollars to prevent certain death. Rather, it implicitly reflects the rate at which individuals would be willing to pay for greater safety if faced with very small risks of death, such as 1/10,000.<sup>61</sup>

These estimates of the implicit value of life are currently used throughout the federal government and are recommended by the Office of Management and Budget<sup>62</sup> to evaluate regulations that promote health and safety and that generate benefits in terms of reduced fatalities. These judgments are guided by the implicit value of life based on labor market evidence. The pertinence of these statistics does not arise because of the regulatory context, but rather because these values reflect the tradeoffs individuals have made between money and risks to their health. These tradeoff amounts are just as pertinent in legal contexts as in regulatory settings.<sup>63</sup>

b. *The Costs and Benefits of Various Regulatory Schemes  
Including the FDCA and Its Implementing Regulations*

The economically imputed value of life can be used to assess the effect of particular regulations and regulatory schemes in general. In some cases, legislation or its implementing regulations will call for stringent health and safety considerations with little consideration for cost.<sup>64</sup> In other cases, however, the regulatory scheme will demand less safety. For example, the Federal Aviation Administration (FAA) has long based its regulations on a valuation of life

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<sup>61</sup> Restricting these deterrence numbers to small probabilities is not a major limitation. The typical risks posed by products tend to be very small. Product-related fatalities are not the norm for products currently in use, though the lifetime risks associated with decades of consumption of very risky products such as cigarettes, or the lifetime risk associated with automobile travel, are quite substantial. The risk associated with each unit of consumption, such as a pack of cigarettes or each automobile trip, is not so inordinately large as to significantly alter the implicit value-of-life that is appropriate from the standpoint of deterrence.

<sup>62</sup> U.S. Office of Management and Budget, Regulatory Program of the United States Government, April 1, 1992 - March 31, 1993 (Washington: U.S. Government Printing Office, 1993). See *id.* at 633, 634, 637, 638 (discussing the value of life).

<sup>63</sup> See generally FATAL TRADEOFFS, *supra* note 59, at 34-50.

<sup>64</sup> The type of legislative restrictions that led to the very high cost-per-life saved figures in the accompanying table are often quite extreme. For example, the Clean Air Act requires that the EPA set its ambient air quality standards based on the risks associated with air pollutants, where the EPA is prohibited from taking costs into consideration when setting these standards. For further discussion, see FATAL TRADEOFFS, *supra* note 59, at 261. Similarly, in the case of the OSHA legislation, the United States Supreme Court has explicitly ruled out benefit-cost tests. See generally W. KIP VISCUSI, RISK BY CHOICE: REGULATING HEALTH AND SAFETY IN THE WORKPLACE (1983).



that is based on the present value of lost earnings, rather than on the higher, economically-imputed value of life.

A review of twenty-four final regulations shows that the regulations provide vastly different health and safety benefits for the same cost:<sup>65</sup>

Regulation	Year	Agency	Millions of dollars (1984) per life saved
Unvented space heaters	1980	CPSC	.10
Cabin fire protection	1985	FAA	.20
Passive restraints/belts	1984	NHTSA	.30
Underground construction	1989	OSHA-S	.30
Alcohol and drug control	1985	FRA	.50
Servicing wheel rims	1984	OSHA-S	.50
Seat cushion flammability	1984	FAA	.60
Floor emergency lighting	1984	FAA	.70
Crane suspended personnel platform	1988	OSHA-S	1.20
Concrete and masonry construction	1988	OSHA-S	1.40
Hazard communication	1983	OSHA-S	1.80
Benzene/fugitive emissions	1984	EPA	2.80
Grain Dust	1987	OSHA-S	5.30
Radionuclides/uranium mines	1984	EPA	6.90
Benzene	1987	OSHA-H	17.10
Arsenic/glass plant	1986	EPA	19.20
Ethylene oxide	1984	OSHA-H	25.60
Arsenic/copper smelter	1986	EPA	26.50
Uranium mill tailings/inactive	1983	EPA	27.60
Uranium mill tailings/active	1983	EPA	53.00
Asbestos	1986	OSHA-H	89.30
Asbestos	1989	EPA	104.20
Land disposal	1988	EPA	3,500.00
Formaldehyde	1987	OSHA-H	72,000.00

Because, as noted above, the FAA regulations incorporate the present value of lost earnings as the basis for measuring benefit, none of the FAA regulations produced an efficient level of safety, assuming a \$5 million valuation of life.

Moreover, the table shows that, as a general matter, regulations suffer from both under- and over-deterrence. This implies that regulatory schemes should not be treated identically for purposes of tort liability inasmuch as there are some regulatory schemes that fail to provide efficient deterrence. Tort law can supplement these efforts. On the other hand, where the regulation is already adequate and deters injuries at or above the efficient level, society would be better off using its resources to deal with injuries that are less costly to prevent. By focusing tort law on the regulatory schemes that are inadequate,

<sup>65</sup> FATAL TRADEOFFS, *supra* note 59, at 264.

society will achieve more social safety due to better allocation of society's investment in risk reduction.

There is a body of economics literature addressing the deterrent effects of the premarketing approval process required by the FDCA. The conclusion is that the NDA process is so stringent as to have created a drug lag that prevents American consumers from gaining access to new pharmaceuticals on a timely basis. At the margin, the denial of timely access produces more adverse health consequences than the injuries prevented by the NDA's filtering-out process. Therefore, the regulatory scheme already provides excess deterrence of risks.<sup>66</sup> This suggests that further regulation of pharmaceuticals through tort liability is inappropriate, except as a means to compel regulatory compliance with regulations requiring the sharing of adverse safety information.<sup>67</sup>

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<sup>66</sup> See Cass R. Sunstein, *Administrative Substance*, 1991 DUKE L.J. 607, 625 ("By delaying the entry of beneficial drugs into the market, the Food and Drug Administration has dramatically increased risks to life and health in some settings."); see also HENRY G. GRABOWSKI & JOHN M. VERNON, *THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS* (1983); William M. Wardell et al., *The Rate of Development of New Drugs in the United States, 1963 through 1975*, 24 CLINICAL PHARMACOLOGY AND THERAPEUTICS 133 (1978); William M. Wardell, *Introduction of New Therapeutic Drugs in the United States and Great Britain: An International Comparison*, 14 CLINICAL PHARMACOLOGY AND THERAPEUTICS 773, 786-87 (1973).

<sup>67</sup> This exception is an important one inasmuch as the criminal and other penalties for violations of the FDCA are much less than potential tort liability. Due to this divergence, tort liability provides additional and necessary economic incentives for manufacturers to provide full and complete risk information to the FDA so that the agency's approval and labeling judgments are based on proper data.

In situations like the MER/29 scandal of the early 1960s, the FDA's risk-benefit judgments were flawed by the tainted data upon which the agency relied:

We see no logical distinction between the labeling provisions of the act on the one hand and the reporting provisions on the other, with respect to the class of persons to be protected or the harm to be prevented. Permission to market a drug depends in part at least on an evaluation of test data submitted by an applicant. The submission of false and misleading reports of tests can only subvert the administrative decision, defeat the purposes of the act, and make the legend on the label a useless guide so far as protection of the public is concerned.

Toole v. Richardson-Merrell, Inc., 251 Cal. App. 2d 689, 704 (Cal. Ct. App. 1967); see also William L. Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791, 808 n.97 (1966) (providing a brief history of the MER/29 controversy and explaining that MER/29 was a cholesterol-reducing drug that caused severe adverse reactions by damaging cell structure). For this reason, litigation can play a useful role as an adjunct to ensure that the FDA receives truthful information.

Nonetheless, the potential for fraud on the agency still remains. For example, in the early 1980s, Smithkline Beckman marketed the anti-hypertensive drug Selacryn, but failed to report adverse reactions in a timely and adequate fashion, leading to at least 500 cases of severe reactions, including 36 deaths. *Drug Maker Pleads Guilty Over Lethal Side Effects*, N.Y. TIMES, Dec. 14, 1984, at A23. Even though the FDA recommended felony charges, the Reagan Justice Department settled for misdemeanor

c. *The Role of Punitive Damages*

Punitive damages are damage awards above and beyond the compensatory level required for tort law to deter inefficient accidents. Nonetheless, punitive damages are commonly justified on three grounds: deterrence, compensation and retribution. When these rationales are examined in depth, however, only the deterrence rationale withstands scrutiny.

Viewed from the standpoint of deterrence, the tort system is saddled with some imperfections. For example, wrongful death statutes typically undercompensate decedents without heirs by truncating recoverable damages. Other limitations on non-economic losses also cause the tort system to depart from the deterrence ideal. In addition, injured parties often do not pursue legal remedies even though they have been injured as a result of inefficient risk. Increasing awards with a punitive damage component can potentially offset the inadequate deterrence caused by these distortions. Determining the optimum *level* of additional compensation may, however, be quite difficult.

In addition, punitive damages can potentially augment safety incentives in situations where companies' safety efforts fall greatly short of what is required. This is the ideal context for using additional damages to enhance safety incentives. In such circumstances, punitive damages may force an irresponsible manufacturer to take swift remedial action, effectuating thereby greater marginal safety gains than in situations where the defendant is somewhat responsible, but not responsible enough. Again, however, there can be great difficulty in determining the appropriate additional award necessary to create appropriate deterrence, but not over-deterrence.<sup>68</sup>

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pleas. Philip Shenon, *Dispute Over Intent in Drug Case Divided F.D.A. and Justice Dept.*, N.Y. TIMES, Sept. 19, 1985, at A1.

Similarly, Eli Lilly & Company failed to report adverse reactions to the FDA for the non-steroidal, anti-inflammatory drug Oraflex. The failure to report adverse reactions led to Congressional hearings and criminal sanctions against Lilly. Philip Shenon, *Lilly Pleads Guilty to Oraflex Charges*, N.Y. TIMES, Aug. 22, 1985, at A16.

Although it is irrational for a drug company to fail to report adverse reactions—the product's shortcomings will eventually come out—tort law creates incentives for truthfulness above and beyond the criminal and other sanctions contained in the FDCA. Selacryn and Oraflex should have been withdrawn much sooner than they actually were. The manufacturers' misconduct in keeping the FDA in the dark imposed inefficient and irresponsible risks upon consumers. For this reason, violations of the FDCA's reporting requirements are appropriately seen as negligence per se. See *Stanton v. Astra Pharmaceutical Products*, 718 F.2d 553, 563-64 (3d Cir. 1983) (construing Pennsylvania law) (footnote omitted).

<sup>68</sup> Punitive damages are problematic, however, because they are so blunt an instru-

The second potential objective of punitive damages is that of compensation. This objective is implied by notions of corrective justice.<sup>69</sup> In cases of monetary loss, the objective of compensation is to restore the level of welfare to what it was prior to the accident. The objective of compensation, however, is addressed by the standard components of tort liability.

Damages rules already recognize the need to compensate for wrongfully-inflicted economic harm. In addition, even non-monetary components of the loss, such as pain and suffering damages and loss of consortium, are addressed through conventional components of liability awards. An additional component provided by punitive damages is not needed to compensate for these losses. In particular, the level of compensation the courts provide is intended to be optimal even in situations in which punitive damages are not awarded. As a result, the insurance/compensation rationale cannot provide an independent motivation for punitive damages.

The final potential objective of punitive damages is that of retribution. Some observers have suggested that punitive damages serve the function of retributive punishment. To arrive at an answer of whether an individual consumer would choose to have such retributive payments, the question becomes whether a higher product price due to the risk of punitive damages awards based on retribution is warranted by any additional value consumers derive from such punishment. One cannot rule out the possibility that consumers may in fact be willing to pay a higher product price for punitive damages that punish corporations, but it may also be the case that much of what is generally viewed as retribution is in fact a concern with deterrence. Specifically, consumers certainly would want corporations to exercise the efficient degree of responsibility with respect to product safety. That objective, however, is already

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ment that they can easily produce over-deterrence, even in the face of misconduct. See generally II Reporters' Study (American Law Institute), *Enterprise Responsibility for Personal Injury* 231-66 (1991) [hereinafter II Reporters' Study].

<sup>69</sup> Corrective justice conceives of tort law as a means of correcting wrongs to plaintiffs caused by an actor's wrongful conduct or invasion of another's rights. Unlike loss-spreading theories of tort, corrective justice requires an underlying wrong and focuses on restoring the equilibrium that existed between the wrongdoer and injured party before the wrong occurred.

Economic analysis attempts to give content to the definition of a "wrong" by positing that the tort system should achieve a balance between injury-preventing conduct and the benefits which are achieved by using the same resources in an alternative manner. In other words, the law and economics view of a "wrong" flows from society's need to use scarce resources efficiently.

served by the imposition of punitive damages to *deter* companies that have fallen greatly short of the efficient safety level.

Of course, the imposition of punitive damages cannot be justified where direct regulation *already* sufficiently deters inefficient risk. As we have already seen, the FDCA regulatory scheme already over-deters inefficient risk, provided that accurate and complete information is provided to the FDA. In such circumstances, the imposition of punitive damages will either create incentives to exit from a product market or create adverse effects on price which hinder overall allocative efficiency. Neither effect is desirable. Instead, the proper role of punitive damages should be limited to that of an adjunct to compensatory damages to assure that pharmaceutical companies provide full and complete information to the agency.

#### B. *How The Common Law Regulates Pharmaceuticals*

##### 1. The Collapse of Predictability

In order to determine the actual regulatory effect of the tort system, it is necessary to examine two issues: 1) what are the liability and damage rules in use; and 2) whether there are inherent institutional limitations in the tort system that suggest that lawsuits are an inappropriate mechanism to respond to the risks and uncertainties posed by pharmaceutical products.

##### a. *The Products Liability Revolution*

Products liability law underwent a revolution as a result of the *Restatement (Second) of Torts*.<sup>70</sup> Strict liability, as codified in Section 402A, generally replaced negligence as plaintiffs' preferred theory of liability because the strict liability theory reduced plaintiffs' barriers to recovery. Under Section 402A, liability is imposed whenever a product causes injury and is "in a defective condition unreasonably dangerous" even though "all possible care" was exercised "in the preparation and sale of the product."<sup>71</sup>

The drafters of the *Restatement (Second) of Torts* apparently did not intend that pharmaceuticals would be subject to strict liability. In particular, strict liability was not meant to apply to "unavoidably unsafe products" which comment k defines through examples, all of which involve drugs or vaccines:

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<sup>70</sup> Prosser, *supra* note 67, at 802-03 (discussing innovative concepts embodied in *Restatement (Second) of Torts* § 402A (1964)).

<sup>71</sup> *RESTATEMENT (SECOND) OF TORTS* § 402A (1964).

*Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidably high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this reason cannot legally be sold except to physicians or under the prescription of a physician. It is also true in many new<sup>72</sup> or experimental<sup>73</sup> drugs as to which, because of the lack of time and opportunity for sufficient medical experience, there can be no assurance of safety . . . but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.<sup>74</sup>

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<sup>72</sup> As noted above, "new drug" is a term of art under the FDCA:

(p) the term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21 U.S.C. § 321(p) (1988).

<sup>73</sup> Experimental drugs are those undergoing Phase I, Phase II, or Phase III clinical trials. See 21 C.F.R. § 312.21 (1993).

<sup>74</sup> RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1964).

Thus, under the *Restatement (Second) of Torts*, strict liability was to be imposed for all harms caused by "defective products, unreasonably dangerous" despite the exercise of due care, except that for "unavoidably unsafe" products, i.e., pharmaceuticals, proof of negligence would be necessary.<sup>75</sup>

After the adoption of Section 402A, the judiciary in various states were called upon to give meaning to the phrase "defective condition, *unreasonably dangerous*." Although the liability rule of Section 402A suggested that *negligence* was still important, the judicial gloss moved away from negligence and towards no-fault rules.

This movement was aided by judicial interpretations that may have conflicted with the intent of Section 402A's drafters. In particular, the drafting history of Section 402A shows that the participants in the ALI proceedings intended that liability was to be imposed after *two* findings: 1) defectiveness; and 2) unreasonably dangerous.<sup>76</sup> Significantly, the drafters intended that the "*unreasonably dangerous*" test—with its *negligence* aspect—be the primary liability test.<sup>77</sup> The defectiveness test was intended to insulate from potential liability products such as whiskey and cigarettes that presented known and substantial risks.<sup>78</sup> Such products were not "defective" and, therefore, the manufacturer was not strictly liable for the ensuing harm.

In *Cronin v. J.B.E. Olson Corp.*,<sup>79</sup> however, the California Supreme Court discarded the "unreasonably dangerous" test after finding that "the Restatement formulation of strict liability in practice rarely leads to a different conclusion than would have been reached under laws of negligence."<sup>80</sup> Negligence was no longer the liability rule in products litigation.<sup>81</sup> Henceforth, "defectiveness"—a term that the drafters of the *Restatement* did not carefully define—became the central tenet of products liability law.

The products liability revolution then concentrated on the defini-

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<sup>75</sup> Professor Page has written a brief history on the drafting of Section 402A. See Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Liability*, 58 N.Y.U. L. REV. 853, 864-66 (1983).

<sup>76</sup> J. Clark Kelso, *Brown v. Abbott Lab. and Strict Products Liability*, 20 PAC. L.J. 1, 16 (1988) (footnote omitted).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 17.

<sup>79</sup> 501 P.2d 1153 (Cal. 1972).

<sup>80</sup> *Id.* at 1162 (citations omitted).

<sup>81</sup> Numerous other courts eliminated the "unreasonably dangerous" requirement from non-comment k litigation. See, e.g., *Suter v. San Angelo Foundry & Mach. Co.*, 81 N.J. 150, 176-77, 406 A.2d 140, 153 (1979); *Berkebile v. Brantly Helicopter Corp.*, 337 A.2d 893, 900 (Pa. 1975) ("We hold today that the 'reasonable man' standard in any form has no place in a strict liability case.").

tion of "defectiveness."<sup>82</sup> Specifically, having concluded that negligence concepts should be excised from strict liability, the courts needed to find a verbal formula that delineated the liability rule.<sup>83</sup>

California again provided a leading approach. The California Supreme Court defined "defectiveness" in *Barker v. Lull Engineering Co.*<sup>84</sup> as follows:

[A] product is defective in design either (1) if the product has failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, or (2) if, in the light of the relevant factors discussed below, the benefits of the challenged design do not outweigh the risk of danger inherent in such design.<sup>85</sup>

Consumer expectations tests<sup>86</sup> and risk-utility<sup>87</sup> tests proliferated

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<sup>82</sup> During this phase of the products liability revolution, courts repeatedly insisted that manufacturers were not insurers of their products, i.e., they were not subject to absolute liability. See, e.g., *Brown v. Sears, Roebuck & Co.*, 667 P.2d 750, 754 (Ariz. Ct. App. 1983) ("Strict liability . . . cannot be equated with absolute liability.") (citation omitted); *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 181 (Mich. 1984) (holding that sellers not subject to absolute liability) (footnote omitted); *Shawver v. Roberts Corp.*, 280 N.E.2d 226, 231 (Wis. 1979) ("Strict liability does not make the manufacturer or seller an insurer nor does it impose absolute liability.").

<sup>83</sup> Commentators shrewdly questioned whether the new rule of strict liability, but not absolute liability, could ever be articulated in a meaningful manner. According to one such account: "despite the courts' recognition that strict liability must be limited, they have seldom been very confident in trying to describe the limits. Indeed, their efforts at answering the questions posed in strict liability cases seem in many cases to degenerate into . . . meaningless semantic disputes . . ." Guido Calabresi & Jon T. Hirschoff, *Toward a Test For Strict Liability in Torts*, 81 YALE L.J. 1055, 1056 (1972).

<sup>84</sup> 573 P.2d 443 (Cal. 1978).

<sup>85</sup> *Id.* at 446.

<sup>86</sup> See, e.g., *Syrie v. Knoll Int'l*, 748 F.2d 304, 306 (5th Cir. 1984) ("A defective product is one that is unreasonably dangerous, i.e., dangerous to an extent beyond that which would be contemplated by the ordinary user of the product, with the ordinary knowledge common to the community as to the product's characteristics.") (citations omitted); *Falkenbury v. Elder Cadillac, Inc.*, 440 N.E.2d 180, 185 (Ill. App. Ct. 1982) ("[T]he product must be dangerous beyond which would be contemplated by the ordinary consumer."); *O'Brien v. Muskin Corp.*, 94 N.J. 169, 181, 463 A.2d 298, 304 (1983) (stating that one standard for measuring the defectiveness of a product is the consumer expectation test in which "the failure of the product to perform safely may be viewed as a violation of the reasonable expectations of the consumer") (citation omitted).

<sup>87</sup> See, e.g., *Davidson v. Stanadyne, Inc.*, 718 F.2d 1334, 1339 (5th Cir. 1983) (whether a product has unreasonably dangerous defective design "requires a balancing by the jury of its utility against the likelihood and gravity of injury") (quotation omitted); *Johnson v. Salem Corp.*, 97 N.J. 78, 88, 477 A.2d 1246, 1251 (1984) (stating that the risk-utility analysis calls for a consideration and balancing of the "primary purpose of the product, the likelihood of injury due to design, and the effect of improvements in safety design on the utility or the price of the product") (citations omitted); *Cover v. Cohen*, 461 N.E.2d 864, 872 (N.Y. 1984) (whether a product is reasonably safe for its intended use is determined by whether a reasonable person



through the various jurisdictions.

The new liability rules unfortunately did not yield predictable results.<sup>88</sup> This lack of predictability undoubtedly has increased the complexity and cost of litigation.<sup>89</sup> As a result, the total transactional costs of litigation now exceed the total recoveries of all claimants.<sup>90</sup>

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with knowledge of the potential for injury and of the available alternatives, balancing the product's risk against its utility and costs, and against the risks, utility, and cost of the alternatives, would have concluded that the product should not have been marketed).

<sup>88</sup> As the Fifth Circuit has correctly noted:

[I]n the typical products liability case, the jury is asked to decide whether a product was defective. Stripped to essentials, jury instructions regarding defect are little more than an open-ended request to balance utility and safety. Absence of rigor in the inquiries that determine liability does not necessarily result from poor drafting of the charge; rather, the difficulty is often inherent in the underlying substantive law.

*In re Air Crash Disaster at New Orleans, Louisiana*, 795 F.2d 1230, 1233 (5th Cir. 1986).

<sup>89</sup> For example, Dean Wade's risk-utility test involved seven factors:

- The usefulness and desirability of the product—its utility to the user and to the public as a whole.
- The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
- The availability of a substitute product which would meet the same need and not be as unsafe.
- The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
- The user's ability to avoid danger by the exercise of care in the use of the product.
- The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
- The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

John W. Wade, *On the Nature of Strict Liability for Products*, 44 Miss. L.J. 825, 837-38 (1973) (footnote omitted). The Wade test is not brightline, and, in addition, the multiple inquiries that the test poses require the generation of considerable information.

In addition, the abolition of non-mutual issue preclusion has raised the stakes inasmuch as one adverse verdict can have an enormous impact on cases involving similar facts. Cf. I Reporters' Study (American Law Institute), *Enterprise Responsibility for Personal Injury* 60 (1991) [hereinafter I Reporters' Study] (noting the growth of "high stakes" litigation).

<sup>90</sup> DEBORAH R. HENSLEY ET AL., TRENDS IN TORT LITIGATION: THE STORY BEHIND THE STATISTICS at 26 (RAND Inst. Civ. Justice 1987) (1986 RAND study concludes that the annual overall transaction costs of the tort system exceed compensation to plaintiffs); Michael J. Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation—And Why Not?*, 140 U. PA. L. REV. 1147, 1283 (1992) (citing ROBERT W. STURGIS, THE COST OF THE U.S. TORT SYSTEMS: AN ADDRESS TO THE AMERICAN INSURANCE ASSOCIATION (1985)).

The expansion of products claims arising from the strict liability revolution has been extraordinary. For example, product liability filings in the federal courts increased from 2,393 in 1975 to 14,145 in 1987.<sup>91</sup> Likewise, the data show extraordinary increases in premium payments and payments for injuries.<sup>92</sup>

b. *The Strict Liability Revolution Strikes Pharmaceuticals*

Despite comment k, the products liability revolution also profoundly affected pharmaceuticals.<sup>93</sup> In particular, a number of jurisdictions found that pharmaceuticals were not unavoidably unsafe as a matter of law.<sup>94</sup> In addition, courts almost unanimously

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<sup>91</sup> W. Kip Viscusi, *The Dimension of the Product Liability Crisis*, 20 J. LEGAL STUDIES 147, 150 (1991).

<sup>92</sup> See, e.g., George L. Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1527 (1987) (explaining that the expanded scope of product liability laws has left product manufacturers with increases in liability insurance costs with increases of as much as 1500% in some cases); I Reporters' Study, *supra* note 89, at 60 (over the past 40 years, general liability insurance costs have increased over four times the rate of the growth of the economy).

<sup>93</sup> See Note, *supra* note 23, at 777-79 (despite extensive FDA regulation and potential exclusion under comment k to Section 402A, strict liability is often applied against pharmaceuticals).

<sup>94</sup> Instead, jurisdictions have generally applied comment k on a case-by-case basis. See, e.g., *Hill v. Searle Lab.*, 884 F.2d 1064, 1069 (8th Cir. 1989) ("The drafters of comment k did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability."); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 654-56 (1st Cir. 1981) (reasoning that a manufacturer of oral contraceptives could be held strictly liable on theories of defective design and inadequate warnings); *Martinkovic v. Wyeth Lab., Inc.*, 669 F. Supp. 212, 217 (N.D. Ill. 1987) (asserting that manufacturer of vaccine not entitled to pursue the comment k defense when it did not establish adequate warnings); *Graham v. Wyeth Lab., Inc.*, 666 F. Supp. 1483, 1497 (D. Kan. 1987) (whether a drug falls within comment k's protection involves weighing the benefits of the product against the risks, and the design must be as safe as the best available testing and research) (quotation omitted); *Toner v. Lederle Lab.*, 732 P.2d 297, 308 (Idaho 1987) (stating that comment k does not apply to all drugs, but rather, applies "when the situation calls for it"); *Feldman v. Lederle Lab.*, 97 N.J. 429, 441-42, 479 A.2d 374, 380 (1984) ("We do not agree that the protective shield of comment k immunizes all prescription drugs. Moreover, we are of the opinion that generally the principle of strict liability is applicable to manufacturers of prescription drugs."); *Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 52 (Wis. 1984) (noting a previous refusal to adopt the rule embodied in comment k, the court concluded that manufacturers could be held strictly liable if drugs are marketed without adequate prior testing).

Two jurisdictions have, however, noted that the need for predictability in pharmaceutical litigation requires that pharmaceuticals approved by the FDA automatically receive comment k protection for design defect claims. See *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (noting that strict liability is not an available theory of recovery in an action involving design defects of prescription drugs); *Grundberg v. The Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991) (adopting the principle that "all prescription drugs should be classified as unavoidably dangerous in design

held that compliance with the FDCA and its implementing regulations did not constitute a complete defense to a products liability action.<sup>95</sup> Thus, despite the presence of a comprehensive licensing system operating at the federal level, pharmaceutical manufacturers can be found responsible in tort even in the face of compliance with this system. In fact, comment k itself steered plaintiffs to the most prominent theory in pharmaceutical litigation: the inadequate warning or failure to warn claim.<sup>96</sup> This trend arose and persisted even though the FDA had comprehensive labeling control under the FDCA and its implementing regulations.

c. *The Failure to Adopt Regulatory Compliance in Pharmaceutical Litigation*

The failure to adopt regulatory compliance as a presumptive defense has defined the nature of pharmaceutical litigation. The common law generally proceeds with fairly broad legal propositions defining an appropriate standard of care, rather than with narrowly focused rules applicable only to specific fact patterns. In the absence of narrowly crafted rules of law, the role of the jury as policymaker is enhanced. Because the jury must give the broad standard substantive content, it serves not only as factfinder, but also as lawgiver.<sup>97</sup>

The judiciary's reluctance to adopt regulatory compliance as a presumptive defense is unsurprising. Historically, compliance with various regulatory statutes and schemes has not been a complete

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because of their unique nature and value, the elaborate regulatory system overseen by the FDA," and the inherent difficulties of the use of tort to review a drug's design).

<sup>95</sup> Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulations and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 243 (1987) (concluding that compliance with FDA regulation provides "only modest protection against the successful lawsuit"); Thomas Scarlett, *The Relationship Among Adverse Drug Reaction Reporting, Drug Labeling, Product Liability, and Federal Preemption*, 46 FOOD DRUG COSM. L.J. 31, 39 (1991) (compliance with government standards merely a factor in liability determination).

<sup>96</sup> See, e.g., *Plummer v. Lederle Lab.*, 819 F.2d 349, 352 (2d Cir.) ("[I]n assessing the potential liability of prescription drug manufacturers, it is essential to review the informational inserts provided with the drugs."), *cert. denied*, 484 U.S. 898 (1987); PRODUCTS LIABILITY: PHARMACEUTICAL DRUG CASES 122 (Donald E. Vinson & Alexander H. Slaughter eds., 1988) (due to "special social position of pharmaceutical products," manufacturers are burdened with "failure to warn" liability).

<sup>97</sup> See generally Richard A. Epstein, *The Risks of Risk/Utility*, 48 OHIO ST. L.J. 469, 475-76 (1987). In contrast, narrow rules of law constrain the jury's policy function. For example, in many jurisdictions there are detailed, standardized charges to deal with automobile accidents. In such cases, the function of the jury will be to determine the facts and apply them to a rule that is outcome determinative. In such cases, the jury's function is to determine credibility and nothing else.

defense in a tort action.<sup>98</sup> Instead, the general rule is that the defendant's compliance with statutes and regulations is evidence of due care.

This common law rule emerged from early railroad cases.<sup>99</sup> State statutes and regulations set guidelines for safeguards at railroad crossings, but accidents occurred and lawsuits followed anyway.<sup>100</sup> A review of these statutes shows that the drafters never intended that compliance with the statutes would necessarily absolve the railroad from liability.<sup>101</sup> Thus, in 1892, the United States Supreme Court, in *Grand Trunk Railway Co. v. Ives*,<sup>102</sup> noted that almost all states had held that regulatory compliance was not a complete defense to tort actions in railroad crossing cases. The minimum standards doctrine survived the horse and buggy era and was transplanted into automobile liability litigation.<sup>103</sup>

The drafters of the *Restatement* accepted the minimum standards doctrine and established the rule still in effect today: "Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions."<sup>104</sup> Consequently, the black-letter rule is that compliance with regulatory standards does not presumptively establish non-liability; such regulations represent only a floor, not a ceiling for liability.<sup>105</sup>

Initially, there were a few courts willing to accept the FDA's

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<sup>98</sup> See generally Paul Dueffert, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 188-213 (1989) (providing overview of courts' acceptance and nonacceptance of regulatory compliance defense).

<sup>99</sup> STEPHEN G. BREYER & RICHARD B. STEWART, ADMINISTRATIVE LAW AND REGULATORY POLICY 26-29 (2d ed. 1985).

<sup>100</sup> Dueffert, *supra* note 98, at 180.

<sup>101</sup> *Id.* at 182.

<sup>102</sup> 144 U.S. 408 (1892).

<sup>103</sup> Dueffert, *supra* note 98, at 180-88. There were, however, early cases involving automobile accidents in which courts accepted regulations as stating the appropriate standard of care. *Id.* at 186 n.53. These cases led to a comment with great potential significance, as yet unrealized, to pharmaceutical litigation: "Where there are no special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by . . . the court as a matter of law, as sufficient for the occasion . . ." *Id.* at 186 (quoting RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1964)). The factors that a court should apply to make this discretionary ruling are not set forth in the Restatement. *Id.* at 187.

<sup>104</sup> RESTATEMENT (SECOND) OF TORTS § 288C (1964); see also W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 36, at 233 (5th ed. 1984).

<sup>105</sup> Dueffert, *supra* note 98, at 175-76; see also 4 INTERAGENCY TASK FORCE ON PRODUCT LIABILITY, U.S. DEPT. OF COMMERCE, ITFPL-77/02, PRODUCT LIABILITY: FINAL REPORT OF THE LEGAL STUDY 137 (1977) (indicating that so few courts regard regulatory compliance as a complete defense that it is not even a minority rule).

judgment on drug approval and labeling. For example, the Oregon Supreme Court ruled that:

[A] drug, properly tested, labeled with appropriate warnings, approved by the Food and Drug Administration, and marketed properly under federal regulation, is, as a matter of law, a reasonably safe product. Accordingly, a person claiming to have suffered adverse effects from using such a drug, unless he can prove an impurity or an inadequacy in labeling, may not recover against the seller for breach of warranty.<sup>106</sup>

This decision was overruled by the Oregon Supreme Court in less than a decade.<sup>107</sup>

Acceptance of the FDA regulatory compliance defense has always represented a minority position. The overwhelming majority of state and federal court decisions do not defer to the FDA.<sup>108</sup> Most of these

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<sup>106</sup> *Lewis v. Baker*, 413 P.2d 400, 404 (Or. 1966) (citation omitted). Likewise, in *McDaniel v. McNeil Lab., Inc.*, the Nebraska Supreme Court acknowledged that:

[T]here is a difference of opinion among expert witnesses as to whether [the] facts establish that Innovar is or is not a defective and unreasonably dangerous drug. That issue was presented to the [FDA] in 1968. Its determination is persuasive and controlling in the absence of evidence that the determination was based upon inaccurate, incomplete, misleading, or fraudulent information.

241 N.W.2d 822, 828 (Neb. 1976); *see also* *Ramirez v. Plough, Inc.*, 863 P.2d 167, 175-78 (Cal. 1993) (holding that FDA-drafted Reyes syndrome warnings for over-the-counter aspirins were adequate as a matter of law; a "minimum" legislative standard may be accepted by the court as sufficient where the record shows that the standard addresses the specific conduct at issue).

<sup>107</sup> *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 533-34 (Or. 1974).

<sup>108</sup> *See, e.g.*, *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1030 (D.N.J. 1988) (FDA regulation of prescription drugs may establish minimum design and warning standards, but compliance does not necessarily relieve manufacturers from tort liability); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) ("[C]ompliance with federal laws and regulations . . . though pertinent, does not in itself absolve a manufacturer of liability.") (citation omitted); *MacGillivray v. Lederle Lab.*, 667 F. Supp. 743, 746 (D.N.M. 1987) ("Statutes and regulations of federal agencies, while setting minimum standards, are not necessarily dispositive of whether or not a product is 'defective' under state products liability law.") (citation omitted); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483, 1491 (D. Kan. 1987) ("FDA regulations of prescription drugs are generally viewed as setting *minimum* standards, both as to design and warning.") (citations omitted); *Martinkovic v. Wyeth Lab., Inc.*, 669 F. Supp. 212, 217 (N.D. Ill. 1987) ("Wyeth's asserted compliance with FDA requirements regarding the vaccine does not establish this element in favor of Wyeth: compliance is but one factor for the jury to consider in deciding the reasonableness of the manufacturer's conduct.") (citations omitted); *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991, 997 (D.N.D. 1966) ("Although all of the Government regulations and requirements had been satisfactorily met in the production and marketing of Quadrigen, the standards promulgated were minimal."), *aff'd*, 411 F.2d 1390 (8th Cir. 1969); *see also* *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973); *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038 (Kan.), *cert. denied*, 469 U.S. 965 (1984); *Feldman v. Lederle Lab.*, 97 N.J. 429, 461, 479 A.2d 374, 391 (1984); *Barson v. E.R. Squibb & Sons, Inc.*,

opinions note that the FDA does not prevent *all* potentially harmful drugs from reaching the market. Thus:

Despite the FDA's best efforts, negligently designed drugs may and apparently do sometimes reach the market. Nothing in federal statutory or regulatory law indicates that FDA certification intends to preclude allegations of negligence in these cases.<sup>109</sup>

Indeed, the newer state tort reform measures do not significantly aid the pharmaceutical manufacturer because they do not treat the FDCA any differently than other regulatory schemes which may in fact be minimal.<sup>110</sup> Once the FDA's role is "minimalized," pharmaceutical lit-

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682 P.2d 832, 836 (Utah 1984); *Mahr v. G.D. Searle & Co.*, 390 N.E.2d 1214, 1229 (Ill. App. Ct. 1979) (FDA regulations are minimum standards, compliance does not change common law duties) (citations omitted).

<sup>109</sup> *Toner v. Lederle Lab.*, 732 P.2d 297, 311 n.12 (Idaho 1987) (citations omitted). The court also remarked: "FDA certification represents only the FDA's opinion, albeit an informed one, of the safety and efficacy of the drug. Regrettably, drugs occasionally prove not so safe as the FDA first believed." *Id.*

Unfortunately, the Idaho Supreme Court never really explains how the pharmaceutical at issue—the DPT whole-cell vaccine—proved not to be as safe as the FDA first believed. Ironically, after criticizing the FDA for allegedly not understanding the safety profile of DPT and thereby failing to protect public health, the court abdicates its responsibility for weighing the public health and policy implications of imposing liability on a drug manufacturer:

No doubt liability flowing from the occasional injuries inflicted by the vaccine acts as a disincentive to its manufacture. However, this Court is not equipped to decide as a matter of public health policy that the relative efficacy and safety of the whole cell vaccine is so well established and the plight of Lederle so dire that injured persons such as Kevin Toner should be denied any recourse.

*Id.* at 312.

<sup>110</sup> In 11 states, tort reform measures have incorporated the general rule that regulatory compliance is merely evidence of due care. *See* ARIZ. REV. STAT. ANN. § 12-683(1) (West 1992) (providing that proof of compliance with state of art constitutes complete defense in any product liability defective design or fabrication action); ARK. CODE ANN. § 16-116-105(a) (1987) (providing that proof of compliance with governmental standards is evidence that product is not unreasonably dangerous in product liability action); COLO. REV. STAT. § 13-21-403(1)(a) & (b) (West 1989) (providing that proof of compliance with either "state of the art" or governmental standard gives rise to rebuttable presumption of non-negligence and non-defectiveness in any product liability action); KAN. STAT. ANN. § 60-3304(a) (1992) (if there is compliance with governmental standard, the product is deemed not defective unless the claimant proves that a reasonably prudent manufacturer would have taken additional precautions); KY. REV. STAT. ANN. § 411.310(2) (Michie 1992) (providing that compliance with "generally recognized and prevailing standards or state of the art" gives rise to rebuttable presumption of non-negligence and non-defectiveness in any product liability action); MICH. COMP. LAWS ANN. § 600.2946(2) (West 1986) (evidence concerning compliance with governmental standards is admissible); N.H. REV. STAT. ANN. § 507-D:4 (1983) (compliance with government standards is an element of an affirmative defense); TENN. CODE ANN. § 29-28-104 (1980) (providing that compliance with governmental standard gives rise to rebuttable presumption that the product was not unreasonably dangerous with regard to matters covered by the regulation); UTAH

igation tends to proceed like any other products case.

The failure to recognize regulatory compliance as a presumptive defense leaves the factfinder without any meaningful yardstick.<sup>111</sup> Yet, the jury must determine issues that potentially can have a profound effect on public health.

## 2. The Failure of Tort Law As a Regulatory Mechanism

As noted, there is often very little legal structure involved in litigation involving pharmaceuticals. Comment k may or may not exempt the manufacturer from strict liability.<sup>112</sup> Regulatory compliance likewise provides uncertain protection. As a result, jurors are left with few yardsticks to decide cases involving failures to provide warnings in pharmaceutical products liability cases.<sup>113</sup> Application of broad liability rules and the application of 20-20

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CODE ANN. § 78-15-6(3) (Michie 1992) (rebuttable presumption that a product is free from defect where it complies with government standards); WASH. REV. CODE ANN. § 7.72.050(1) (West 1992) (evidence concerning compliance with governmental standards can be considered by trier of fact).

The various state legislatures, like the common law, treat all regulated products in the same manner. Although this is consistent with the judiciary's treatment of the regulatory compliance test, this broad brush treatment is inappropriate because each regulatory scheme should be individually analyzed to see if it provides over- or under-deterrence. By creating a presumption that *all* regulatory schemes are sufficient, the statutes have lumped all regulations together. As noted above, economic analysis shows that this is not the proper method to maximize social welfare.

New Jersey is the only jurisdiction to specifically address pharmaceuticals in tort reform legislation. See N.J. STAT. ANN. § 2A:58C-4 (West 1987) (providing for rebuttable presumption that warning approved by FDA is adequate). On the other hand, Texas specifically excludes pharmaceuticals from the reach of its tort reform. TEX. CIV. PRAC. & REM. CODE ANN. § 82.005(d)(2) (Vernon 1993 & Supp. 1994) (tort reform statute not applicable to design defect claims for products regulated under the FDCA).

<sup>111</sup> See James A. Henderson, Jr., *Manufacturer's Liability for Defective Product Design: A Proposed Statutory Reform*, 56 N.C. L. REV. 625, 638 (1978) ("The utility of federal product safety regulations as standards for decision is their specificity."). To the extent that legal commentary concerns itself solely with the ease of making a decision, Professor Henderson is surely correct. Bright line rules are, all things being equal, preferable to multifactorial, indeterminate standards.

The larger consequences of a rule of decision are generally more important. Simplicity alone is not enough. After all, the simplest rules would be either to *always*, or *never*, impose liability. Regulation should be decisive only where it adequately protects society. Of course, where a regulation adequately protects society, the simple rule of law has the additional benefit of reducing litigation costs.

<sup>112</sup> This determination, in turn, may be made by the court or the jury. See generally George H. King, Note, *A Prescription for Applying Strict Liability: Not All Drugs Deserve Comment k Immunization*, 21 ARIZ. ST. L.J. 809, 819-20 (1989) (discussing *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988)).

<sup>113</sup> As noted above, most states employ standardized jury charges in products liability cases that use broad standards of care, rather than specific rules of law. Quite often, jury charges in pharmaceutical litigation are the same or quite similar to the

hindsight often places juries in the position of second guessing the FDA on the types of warnings that should be provided with prescription drug products and which products should be marketed. Too often these judgments collide.

a. *Labeling Litigation*

In the context of warnings litigation, the absence of meaningful standards is quite troublesome. In particular, when reviewed after a drug-induced injury, there are few, if any, warnings that cannot be criticized in some aspect.<sup>114</sup> A factfinder can always find that a warning should have been more prominent or more specific. The context in which that judgment will be made—after a plaintiff's serious injury—can hardly give the manufacturer comfort. Indeed, in a number of instances juries have deemed inadequate warnings that even the FDA has either drafted or required manufacturers to include in labeling.<sup>115</sup>

In such an environment, pharmaceutical companies have real incentives to adopt a warnings strategy that warns of nearly everything.<sup>116</sup> Such a warnings strategy conflicts, however, with the FDA's regulatory goals of both reliability and brevity. Overwarning is also not in the interests of consumers because it hinders the ability of health care professionals to distinguish the relative risks posed by various drugs. Some courts have correctly recognized that the present litigation environment creates incentives for manufacturers to adopt a warnings strategy that actually hinders these goals.<sup>117</sup>

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charges that would be given in any other products liability case, inasmuch as strict liability model charges are as muddled as the underlying strict liability case law.

<sup>114</sup> See Kellen F. Cloney, Note, *AIDS Vaccine Manufacturers v. Tort Regime: The Need for Alternatives*, 49 WASH. & LEE L. REV. 559, 578 (1992) ("Even if the FDA has required, approved or actually drafted the specific warning in question, a lay jury can still conclude that [the warning] was inadequate.").

<sup>115</sup> See Charles J. Walsh & Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 FOOD DRUG COSM. L.J. 171, 185-188 (1986) (discussing *Feldman v. Lederle Lab.*, 97 N.J. 429, 479 A.2d 374 (1984), where manufacturer was not insulated from liability as a matter of law, even though the FDA had rejected the manufacturer's attempt to warn of the injury plaintiff suffered).

<sup>116</sup> W. KIP VISCUSI, *REFORMING PRODUCTS LIABILITY* 151 (1991); Aaron D. Twerski et al., *The Use and Abuse of Warnings in Product Liability—Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495, 514 (1976).

<sup>117</sup> The court in *Finn v. G.D. Searle & Co.* explained that:

[I]t seems obvious that liability ought not to be imposed for failure to warn based on every piece of information [available] . . . . Moreover, both common sense and experience suggest that if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would



The FDCA and its implementing regulations ensure that the FDA ultimately controls the presentation and content of risk information. In some circumstances, the FDA will prevent manufacturers from issuing a warning where the agency believes that the scientific evidence does not warrant a warning.<sup>118</sup> Certainly in cases where the FDA has acted to prevent a proposed warning or labeling change, tort law should not attempt to co-regulate through damage awards. Once the FDA has made a determination about proposed pharmaceutical labeling, it would be a violation of federal law for the manufacturer to attempt to deviate from that judgment.<sup>119</sup> Because the FDA should have the primary responsibility for determining appropriate labeling, there can be little utility in permitting a tort system to impose liability on a company for complying with that judgment.<sup>120</sup>

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be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given.

677 P.2d 1147, 1153 (Cal. 1984) (citations omitted). *See* *Dunn v. Lederle Lab.*, 328 N.W.2d 576, 581 (Mich. Ct. App. 1982) (recognizing that warnings must be selective to be effective and that excessive warnings might dissuade physicians from reading them).

<sup>118</sup> The FDA rarely directs manufacturers *not* to include a warning without good reason. In particular, preliminary information poses two types of risk of error: false positives and false negatives. A "false positive" occurs when preliminary information seems to indicate that a warning about a side effect is appropriate, but later, more complete information shows that the drug did not cause the side effect. A "false negative" occurs when preliminary information tends to show that a warning about a side effect would be inappropriate, but later, more complete information shows that a warning should be given.

The FDA, of course, has institutional incentives to err on the side of caution. When a warning is given about a side effect and that warning turns out to be wrong, only the medical community and the manufacturer are angered. Prescribing habits may have been erroneously changed, but there are no visible victims. On the other hand, if the FDA has preliminary information and fails to require or approve a warning and the harm ensues, the agency makes news.

<sup>119</sup> A new drug not labeled in accordance with an approved NDA is misbranded. 21 U.S.C. § 352(f)(1) (1988 & Supp. IV 1993); 21 C.F.R. § 201.100(c) (1993). A misbranded drug is subject to seizure, 21 U.S.C. § 334 (1988 & Supp. IV 1993), and the manufacturer becomes subject to criminal penalties. 21 U.S.C. § 333 (1988 & Supp. IV 1993).

<sup>120</sup> Obviously, the FDA's policy of maintaining the brevity of package inserts comes at a price. In particular, at the margin, the agency may in some instances exclude information that is more valuable than the costs of keeping the information from the package insert. If, however, the package insert is to retain its current role, it cannot become a treatise: "[t]here are very few statements in prescription drug labeling on which some controversy could not be found within the medical profession. . . . To permit or require statements of conflicting opinion on all of these matters would destroy the present usefulness of prescription drug labeling." 39 Fed. Reg. 33,229, 33,232 (1974); *see also* 21 C.F.R. § 1.21 (1993) (prohibiting "statement[s] of differences of opinion with respect to warnings").

b. *Design Defect Litigation and Vaccines*

While labeling issues predominate pharmaceutical cases, there are some tort actions that challenge a drug product's design. In doing so, these tort actions collide with the FDA's risk-benefit judgment that a particular drug should be marketed. The design defect challenges raised in DPT litigation<sup>121</sup> of the 1980s best exemplify this clash of the federal regulatory and state tort law systems. In the case of the DPT vaccine, this clash led to liability being imposed on manufacturers through design defect theories, even though the FDA had determined that the risks of the DPT vaccine were clearly and substantially outweighed by the vaccine's benefits.<sup>122</sup> Although many courts invoked the strict liability ra-

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The package insert is only part of the medical education system and is not particularly well-suited for communicating uncertain, preliminary scientific information. In other words, although doctors rely extensively on the package insert, they can also consult other authorities. Indeed, in a world undergoing an information revolution, the role of the package insert undoubtedly is diminishing and will continue to diminish.

<sup>121</sup> DPT litigation arose in response to preliminary medical reports in the early 1980s suggesting that the pertussis component of the three-in-one "whole cell" vaccine for diphtheria, tetanus and pertussis ("DPT") was responsible for as many as 25 annual serious adverse reactions including brain damage and occasional death. At that time, no other vaccine was licensed—proven to be safe and efficacious—for use in the United States. Because no better alternative to the whole cell vaccine had been identified, the benefits to using the vaccine substantially outweigh the vaccine's potential risks. Indeed, the current science suggests that the safety concerns of the early 1980s were overstated. See James D. Cherry, 'Pertussis Vaccine Encephalopathy': *It Is Time to Recognize It as the Myth That It Is*, 263 JAMA 1679 (1990); Vincent A. Fulginiti, *A Pertussis Vaccine Myth Dies*, 144 AM. J. DISEASES OF CHILDREN 860-61 (1990); Kim R. Wentz & Edgar K. Marcuse, *Diphtheria-Tetanus-Pertussis Vaccine and Serious Neurologic Illness: An Updated Review of the Epidemiologic Evidence*, 87 PEDIATRICS 287 (1991).

<sup>122</sup> The cases involved similar benefits versus similar risks—for example, the risk of vaccine-induced whooping cough as opposed to contracting the illness because of non-vaccination. In the early 1900s, pertussis was a leading cause of death in children in the United States. In 1934, when the United States suffered its worst pertussis epidemic, there were 265,000 reported cases of pertussis that year, and 7,500 related deaths. By the early 1940s, pertussis was responsible for two and one-half times the number of deaths of all of the following childhood diseases combined: measles, mumps, rubella, diphtheria, polio, meningitis, chicken pox, and scarlet fever. Alan R. Hinman & Jeffrey P. Koplan, *Pertussis and Pertussis Vaccine: Re-Analysis of Benefits, Risks, and Costs*, 251 JAMA 3109 (1984). From 1943 to 1976, the United States showed a 99% decrease in the reported cases of pertussis per 100,000, and an even more dramatic reduction in the number of deaths. James D. Cherry, *The Epidemiology of Pertussis and Pertussis Immunization in the United Kingdom and the United States: A Comparative Study*, 14 CURRENT PROBLEMS IN PEDIATRICS 7, 19, 33 (1983). In the absence of a pertussis vaccination program, the Centers for Disease Control estimates that there would be approximately 322,000 additional cases of whooping cough per year, with 450 annual deaths. See generally Hinman & Koplan, *supra*, at 3113.

Where there are such direct tradeoffs, it is hard to see how the presence or lack of a warning will affect individual behavior. In particular, given the identical adverse

tionale that the imposition of liability would encourage a safer vaccine, the prospect of multi-million dollar verdicts instead induced manufacturers to abandon the vaccine market altogether.<sup>123</sup>

In response to the wave of litigation against vaccines, the number of vaccine manufacturers has shrunk by over fifty percent since 1968.<sup>124</sup> Many vaccines, including those for polio, rubella, measles, mumps, and rabies are currently provided by a single company. Thus, the effect of the court awards has been to create incentives for a monopoly.<sup>125</sup> Moreover, many pediatric vaccines are produced by a single supplier.<sup>126</sup> The effect of litigation and con-

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consequences, so long as the *ex ante* risk of the vaccine is lower than not being vaccinated, all will categorically prefer to be vaccinated. Thus, where risks are directly comparable and exposure to the drug is the only rational choice, a failure to warn will not be the *cause* of injury. Basing liability on a failure to warn or inadequate warning will not rationalize the use of vaccines.

In contrast, where the risks of treatment and the risks of disease are not comparable, individual autonomy must be respected. Therefore, where the tradeoffs are not readily comparable, the patient should make the treatment decisions based on his or her own values:

If, however, a drug poses a very small risk of fatal reaction and promises general relief from the discomfort of a non-fatal disease, such as arthritis, or relieves only the symptoms rather than the cause of a serious illness, risks and benefits are comparable. . . .

Such measurement problems may prevent FDA from reaching categorical risk-benefit judgment[s].

Richard A. Merrill, *Risk-Benefit Decisionmaking by the Food and Drug Administration*, 45 GEO. WASH. L. REV. 994, 1008 (1977).

<sup>123</sup> See Peggy J. Naile, Note, *Tort Liability for DPT Vaccine Injury and the Preemption Doctrine*, 22 IND. L. REV. 655, 703 (1989) (explaining that large damages awards "are . . . likely to induce manufacturers to abandon the vaccine market altogether").

<sup>124</sup> See generally AMA Board of Trustees, *Impact of Product Liability on the Development of New Medical Technologies*, 137 PROC. HOUSE OF DELEGATES 79-91 (1988) [hereinafter AMA Board]. In addition, foreign manufacturers are reluctant to enter the United States market because of liability concerns. See, e.g., INSTITUTE OF MEDICINE, VACCINE SUPPLY AND INNOVATION 11 (1985) ("Increasingly, the liability situation and its consequences . . . have been cited [by pharmaceutical companies] as major factors in the decision to withdraw [from the vaccine market].").

<sup>125</sup> The economic incentives arose because all firms are not equally capable of bearing risk and uncertainty. Smaller firms could neither self-insure nor purchase insurance at affordable rates. Indeed, even the insurance companies were not eager or able to bear the risk: "The presumption in the courts has been that insurance will solve everything. But it hasn't, because insurance companies are no more eager to lose their shirts to unpredictably generous juries than are the vaccine manufacturers themselves." Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 287 (1985).

In a climate of legal uncertainty, even if the adverse reactions are in and of themselves predictable, the liability consequences are not. Uncertainty, as opposed to risk, is very difficult, if not impossible to insure. In other words, tort cannot act simply as insurer in the pharmaceutical context unless both damages and liability rules are relatively certain.

<sup>126</sup> See generally *Vaccine Injury Compensation: Hearing on H.R. 1780, H.R. 4777, and*

comitant market concentration has led to an extraordinary rise in vaccine prices, with increases far in excess of the inflation rate.<sup>127</sup> There is no evidence that public health in the United States has benefitted from the DPT vaccine litigation.<sup>128</sup> To the contrary, the increasing cost of vaccines is a factor in the declining immuniza-

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*H.R. 5184 Before the Subcomm. on Health and the Environment of the Comm. on Energy and Commerce, 99th Cong., 2d Sess. 115 (1986), at 7 (assessing the precipitous decline in the number of vaccine manufacturers in the United States).*

<sup>127</sup> AMA Board, *supra* note 124, at 7. See also Gina Kolata, *Litigation Causes Huge Price Increases in Childhood Vaccines*, 232 SCIENCE 1339 (1986) (the price of DPT went from 11¢ in 1982 to \$11.40 in 1986; \$8.00 of the increase went towards products liability insurance).

<sup>128</sup> As noted, American products liability law produced *exit* from the market, not product improvement. See *supra* notes 123-26 and accompanying text. The only new pertussis vaccine, an acellular version, was developed in Japan. Currently, it is uncertain whether the new vaccine is preferable to the whole-cell vaccine. In any event, a severe loss of Japanese public confidence in the DPT whole-cell vaccine, which led to widespread failure to vaccinate, not product liability concerns, led to development of the new vaccine.

Specifically, the Japanese determination to develop a new vaccine was the result of a public health decision that led to disaster. Japanese health authorities temporarily suspended the use of whole-cell DPT vaccine in the winter of 1974-75 after the death of two infants following immunization. *Pease v. American Cyanamid Co.*, 795 F. Supp. 755, 757 (D. Md. 1992). The suspension was quickly lifted, but usage of the DPT vaccine swiftly declined and the incidence of whooping cough climbed to epidemic levels. *Id.* In 1979, 13,092 cases were reported in Japan, leading to 41 deaths. See generally Koomi Kanai, *Japan's Experience in Pertussis Epidemiology and Vaccination in the Past Thirty Years*, 33 JAPAN J. MED. SCI. BIOLOGY 107, 109 (1980). After the Japanese government funded the development of a new pertussis vaccine, the acellular vaccine was introduced in Japan in October 1982. *Pease*, 795 F. Supp. at 757.

At the time that the new vaccine was introduced, there had been little pre-marketing testing. *Id.* Very little was known about the safety and efficacy of the new vaccine. *Id.* Given the dearth of information, especially about efficacy, the FDA did not approve the Japanese acellular pertussis vaccine until 1991. *Id.* The concerns about efficacy have not been entirely resolved and the only approved indication is for infants two years and above, who are at less risk of dying from pertussis than newborns and younger infants. *Id.*

The rapid introduction of the acellular vaccine in Japan is instructive because it may ultimately demonstrate that there can be public health costs to the FDA's premarket approval process and litigation. In particular, the whole-cell DPT vaccine was known to be efficacious, but was also implicated in severe, but rare, adverse reactions. Given the apparent rarity of these reactions, it literally would take the administration of millions of doses of a new vaccine to prove that the vaccine produced a better safety profile than whole-cell DPT. It is, of course, not feasible to conduct such large scale clinical trials in the United States for an alternative pertussis vaccine. At the time DPT was first being used, there simply were not enough persons who were not being vaccinated by the whole-cell vaccine to create such a pool. In addition, liability concerns would create another substantial disincentive: if the new vaccine were not as safe and efficacious as the whole-cell vaccine, the innovator could face lawsuits. Over-deterrence can, in fact, harm public health.

tion rates in the United States.<sup>129</sup>

c. *The Regulatory Consequences of Systemic Error in the Tort System*

Litigation based on failure to warn or design defect theories has a profound regulatory effect even where the product does not cause injury. In particular, under the current tort system, judges' and juries' abilities to make appropriate decisions is suspect in the face of conflicting scientific evidence.<sup>130</sup> The saga of the Bendectin litigation illustrates this problem.

Bendectin was an anti-nausea drug frequently prescribed for morning sickness from 1957 to 1983.<sup>131</sup> In 1956, the FDA approved Bendectin for combatting morning sickness and that approval remains in effect.<sup>132</sup> Despite the FDA's judgment that the

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<sup>129</sup> Sara Rosenbaum, *Rationing Without Justice: Children and the American Health System*, 140 U. PA. L. REV. 1859, 1867-68 (1992).

<sup>130</sup> The paradox of admitting expert testimony because it involves matters beyond the understanding of the ordinary person, and then asking that same ordinary person to evaluate the proffered information, has long been recognized. In fact, Learned Hand noted at the turn of the century that "logically the expert is an anomaly . . . [and] from the legal anomaly serious practical difficulties arise." Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40, 50 (1902). Hand succinctly described the paradox:

The whole object of the expert is to tell the jury . . . general truths derived from his specialized experience. But how can the jury judge between two statements each founded upon an experience confessedly foreign in kind to their own? It is just because they are incompetent for such a task that the expert is necessary at all.

. . . .  
[W]hen any conflict between really contradictory propositions arises, or any reconciliation between seemingly contradictory propositions is necessary, the jury is not a competent tribunal.

. . . .  
Theirs is not, and in the nature of things cannot be, the function to decide between two sets of such truths . . . .

. . . .  
One thing is certain, they will do no better with the so-called testimony of experts than without, except where it is unanimous. If the jury must decide between such they are as badly off as if they had none to help. The present system in the vast majority of cases—there being some dispute upon almost all subjects of human inquiry—is a practical closing of the doors of justice upon the use of specialized and scientific knowledge.

*Id.* at 54-56. Consequently, Hand concluded that when the conflict between the experts is direct and open, "the absurdity of our present system is apparent." *Id.* at 54.

<sup>131</sup> See *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 824 (D.C. Cir. 1988) (30 million pregnant women used Bendectin between 1957 and 1983), *cert. denied*, 493 U.S. 882 (1989).

<sup>132</sup> *Id.* at 824.

drug is safe to the unborn child,<sup>133</sup> and despite the fact that no jury finding that Bendectin caused birth defects has ever been sustained, Bendectin has been withdrawn from the market. The costs of lawsuits and the risk of litigation error literally drove this product from the market.<sup>134</sup>

If the only adverse effect of Bendectin litigation was Bendectin's removal from the market by its manufacturer, the price might arguably be acceptable.<sup>135</sup> The real problem, however, is that if a court of law can find Bendectin capable of causing birth defects, any substance which is used by pregnant women, regardless of its safety, presents a real litigation risk to a pharmaceutical manufacturer.<sup>136</sup> Thus, when a company has the choice of developing therapies for use by pregnant women or pediatric patients, or to devote its efforts to a less risky enterprise, there is a substantial financial incentive to invest in a therapeutic area that poses less of a litiga-

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<sup>133</sup> The scientific community concurs in this judgment. See, e.g., *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1353-56 (6th Cir. 1992) (describing 35 epidemiological studies which concluded that Bendectin did not cause birth defects); *Wilson v. Merrell Dow Pharmaceuticals, Inc.*, 893 F.2d 1149, 1154-55 (10th Cir. 1990) (sustaining verdict for the manufacturer based, *inter alia*, on approximately 40 epidemiological studies showing that Bendectin did not cause birth defects).

<sup>134</sup> Despite the generally accepted belief among scientists that Bendectin does not produce birth defects, plaintiffs have received favorable verdicts in approximately 36% of the cases that go to trial. The absence of jury-decision reliability arises from a combination of factors, including jurors' inability to distinguish good science from bad science. Part of this is due to the inherent limits of jurors, who, after all, are not scientists. Poor cross-examination of "hired gun" experts is also inevitable inasmuch as litigating a pharmaceutical case tests counsels' scientific training and lawyering skills to the utmost. See generally Joseph Sanders, *Jury Deliberation in a Complex Case: Havner v. Merrell Dow Pharmaceuticals*, 16 JUST. SYS. J. 45 (1993) (assessing juries' performance in Bendectin case when plaintiff obtained a substantial verdict); Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301 (1992) (exploring the rapid decline in the rate of plaintiff success in Bendectin lawsuits).

<sup>135</sup> Such a price would, however, be acceptable only if the tort system was less prone to error than the FDA. If that were the case, Bendectin's loss would be counterbalanced by systematically more accurate deterrence of risk. The appropriate question is not whether the FDA or the tort system is perfect—neither are—but rather which is better. Society is better protected if the more reliable and accurate decisionmaker, in this case the FDA which has full and complete risk data, has the final say.

<sup>136</sup> Chance alone dictates that children with birth defects will be born:

If 40 per cent of women are taking a particular medicine during pregnancy, then you would expect an average of 40 per cent of women who have babies with a particular birth defect to have also been receiving that medication during pregnancy. For this reason, almost every commonly used medicine has at some time been a suspected cause of birth defects.

DAVID W. SMITH, *MOTHERING YOUR UNBORN BABY* 61 (1979).

tion risk.<sup>137</sup>

In short, *laissez faire* pharmaceutical litigation often creates perverse incentives. These incentive effects can lessen the value or even countermand the judgments of the FDA, thereby overturning the agency's well-considered risk-benefit assessments. Because a fully informed FDA almost certainly makes erroneous risk-benefit judgments less often than our tort system, the role of tort law in this context needs to be refocused.

#### IV. THE NEED FOR NATIONAL STANDARDS IN PHARMACEUTICAL LITIGATION

State tort reform efforts in recent years have produced some enhanced recognition of the regulatory compliance defense. Unfortunately, few, if any, states have reviewed regulatory schemes on an individualized basis. Rather, the states have adopted one rule that applies to all regulatory schemes regardless of whether the regulations have set appropriate safety standards for particular products. As noted, economic analysis shows that regulatory schemes should be subject to individualized treatment, not the broad brush currently in vogue with tort reformers.<sup>138</sup> Consequently, in most cases, the distinct issues presented by pharmaceuticals have not been addressed by legislation relating to compensatory damages.<sup>139</sup>

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<sup>137</sup> Louis Lasagna, *The Chilling Effect of Product Liability Development*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* 334, 335-37 (Peter W. Huber & Robert E. Litan eds., 1991); NATIONAL RESEARCH COUNCIL & INSTITUTE OF MEDICINE, *DEVELOPING NEW CONTRACEPTIVES* 141 (1990) (unpredictable nature of litigation is a significant disincentive for fertility research and development); AMA Board, *supra* note 24, at 79 ("Innovative new products are not being developed or are being withheld from the market because of liability concerns . . . . Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy but because product liability suits have exposed manufacturers to unacceptable financial risks.").

<sup>138</sup> In the late 1970s, the Carter administration determined that federal legislation addressing products liability law was not appropriate, but that there was a need for greater uniformity in the law. The administration caused the Commerce Department to publish the Model Uniform Products Liability Act ("MUPLA") for voluntary use by the states. 44 Fed. Reg. 62,714 (1979). The MUPLA provided that products complying with government regulations were presumed to be non-defective, but that the claimant could overcome that presumption by a preponderance of the evidence. *Id.* at 62,730. Although state reform efforts can generally be traced to the MUPLA, the resulting legislation was anything but uniform.

<sup>139</sup> The New Jersey Legislature has, however, addressed compensatory damages. See *supra* note 110 for a discussion of N.J. STAT. ANN. § 2A:58C-4 (West 1987). Significantly, even though N.J. STAT. ANN. § 2A:58C-4 may provide pharmaceutical manufacturers some measure of protection from labeling claims, the statute may not be given a broad reading by the New Jersey Supreme Court inasmuch as the court apparently subscribes to the notion "that state-tort claims advance a substantial goal apart from

A few states have specifically focused on pharmaceuticals and punitive damages and statutorily provide an FDA regulatory compliance defense against such damages.<sup>140</sup> While these reform measures are to be encouraged, their effect should not be overstated.<sup>141</sup> Thus, except for some progress being made on the puni-

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regulating behavior: to provide compensation to those injured by deleterious products when that result is consistent with public policy." *Dewey v. R.J. Reynolds Tobacco Co.*, 121 N.J. 69, 90-91, 577 A.2d 1239, 1249 (1990) (citations omitted).

<sup>140</sup> The five states that have proscribed punitive damages where the manufacturer has complied with the FDCA are: Arizona, ARIZ. REV. STAT. ANN. § 12-701 (West 1992); New Jersey, N.J. STAT. ANN. § 2A:58C-5(c) (West 1987); Ohio, OHIO REV. CODE ANN. § 2307.80(c) (Anderson 1991); Oregon, OR. REV. STAT. § 30.927 (1993); and Utah, UTAH CODE ANN. § 78-18-2 (Michie 1992).

<sup>141</sup> The award of punitive damages against pharmaceutical companies who have complied with the FDCA is quite rare. See *Product Liability Government Standards Defense Proposal*, 53 F.D-C REP. (The Pink Sheet), Sept. 23, 1991, at 6 (quoting Northeastern University Law Professor Michael Rustad) ("Since almost all the [punitive damages] drug cases we studied involved either fraudulent test results, suppression of negative impacts or withholding information from the Food and Drug Administration, compliance with the government standard provisions in S 640 will have little impact."); II Reporters' Study, *supra* at note 68, at 232 (noting that news stories have fueled an erroneous general perception that punitive damages are commonly rendered in tort cases).

Even though punitive damages are only a small part of the problem—the real problem is the unregulated award of compensatory damages—the availability of punitive damages undoubtedly has untoward effects on the course of pharmaceutical litigation. According to some commentators:

The mere presence of punitive damage counts has an undesirable effect on the course of drug product liability litigation. As is true for punitive damage claims involving other products, these counts are only rarely dismissed on summary judgment . . . . Punitive damage claims, therefore, have caused substantial increases in settlement and litigation costs for pharmaceutical manufacturers.

Kuhlik & Kingham, *supra* note 31, at 697. This effect alone warrants preclusion of punitive damages where there has been regulatory compliance.

In addition, the total absence of control over punitive damages has led to the potential for enormous liability where the manufacturer has acted in a socially responsible manner. The Depo-Medrol case in Chicago, *Proctor v. Michael J. Davis, M.D. & Upjohn Co.*, No. 84 L 3213 (Ill., Cook Cty. Cir. Ct. Oct. 18, 1991) is perhaps the most notorious example of such a case. Depo-Medrol is an injectable anti-inflammatory drug whose directions for use call for intramuscular injection, usually the gluteal muscle. When Upjohn became aware that the product was being used by physicians near the eye, it petitioned the FDA to warn against this improper use. The agency, however, in 1981, refused to permit the inclusion of the proposed labeling. Nonetheless, physicians continued to misuse Depo-Medrol, and as a result, the plaintiff lost an eye. A Chicago jury awarded the plaintiff \$3.1 million in compensatory damages and \$124.6 million in punitive damages. At trial, the court refused to allow evidence that the FDA had rejected Upjohn's application to add a warning about this misuse.

After the verdict, the trial court remitted the punitive damages to \$35 million. Upjohn then appealed to the Illinois Appellate Court. Oral argument was heard on November 18, 1993, and a decision is pending. Telephone Interview with Andrew L. Frey, Esq., Counsel for Upjohn (Mar. 23, 1994).



tive damages issue,<sup>142</sup> state legislative efforts do not appear to have significantly reduced litigation uncertainty for pharmaceutical manufacturers.

Indeed, courts throughout the fifty states still answer the same liability questions differently.<sup>143</sup> By the same token, commentators have persuasively argued that the answers to fundamental tort issues change over time within single jurisdictions.<sup>144</sup> Consequently, piecemeal legislative reform at the state level will not produce uniform results when looking at these regulatory schemes.<sup>145</sup> Since there is a genuine need for national standards in pharmaceutical litigation, federal legislation addressing the specific issues presented by pharmaceuticals must be considered.<sup>146</sup>

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In the Depo-Medrol case, the manufacturer did nothing wrong, let alone substantially or intentionally depart from appropriate safety norms. Unfortunately, the jury never knew why Upjohn failed to warn or the FDA policy rationale which led the agency to prohibit the warning. *See generally* Joseph A. Mahoney, Note, *Senate Bill 640: Proposed Federal Product Liability Reform and Its Potential Effect on Pharmaceutical Cases and Punitive Damages Claims*, 36 ST. LOUIS U. L.J. 475, 475-77 (1992).

<sup>142</sup> The current products liability reform bill before Congress contains a categorical exclusion of punitive damages for FDA-approved drugs, which is overturned if the manufacturer withheld safety data, explicitly including DERs, or bribed FDA officials. Product Liability Fairness Act of 1993, S. 687, 103d Cong., 1st Sess. § 203(b) (1993). Its immediate predecessors, S. 640, 102d Cong., 1st Sess. (1991), the Product Liability Fairness Act of 1991, and the Fairness in Product Liability Act of 1991, H.R. 3030, 102d Cong., 1st Sess. 1991, also barred punitive damages against FDA-approved pharmaceuticals except where the manufacturer withheld safety data from the agency or bribed FDA officials. The legislation failed to become law because there were insufficient votes to close the Senate debate. *Prod. Safety & Liab. Rep. (BNA)* 995 (Sept. 11, 1992). For a full description of S. 640, see Robert A. Goodman, *Proposed Federal Standards For Product Liability*, 30 HARV. J. ON LEGIS. 253 (1993); S. Rep. No. 215, 102nd Cong., 1st Sess. (1991).

Prior to the 1991 and 1993 bills, the Uniform Product Safety Act of 1988, H. 1115, 100th Cong., 2d Sess., § 207(d)(1) (1988) contained a similar provision.

<sup>143</sup> *See* Naile, *supra* note 123, at 673 n.122 (noting the inconsistent treatment of identical issues in DPT litigation).

<sup>144</sup> *See* J. Clark Kelso, *One Lesson From the Six Monsanto Lectures on Tort Reform and Jurisprudence: Recognizing the Limits of Judicial Competence*, 26 VAL. U. L. REV. 765 (1992). According to Professor Kelso:

The fact that the law in a jurisdiction can be easily stated at any particular moment in time is not, however, the test of a well-functioning judicial system. The proper question—and the minimum requirement—is whether the substantive law remains relatively stable . . . . This is where products liability has failed. The Supreme Court of California, for example, has changed the law in products cases every ten or fifteen years.

*Id.* at 780 n.63.

<sup>145</sup> *Cf. id.* at 780-81 ("[T]he cases around the country are hopelessly in conflict concerning even the most basic issues . . . . [T]he court-made expansions have at least partly contributed to a perceived crisis and legislative response which undermines public confidence in the judiciary and creates its own social problems.").

<sup>146</sup> Several commentators have made similar suggestions. *See, e.g.,* Note, *supra* note

Such legislation must recognize that the FDCA does not establish minimum standards for prescription drug products or their labeling. Rather, where the FDA has applied its expertise under the FDCA, courts should be prohibited from co-regulating pharmaceuticals through the award of tort damages. Federal legislation containing express preemptive language with regard to FDA regulatory compliance should be adopted.

First, pharmaceutical design defect litigation should be preempted in the absence of fraud on the FDA. In particular, where the FDA has approved a pharmaceutical for marketing, the agency has made an explicit judgment that the product will aid the public health. This judgment should be respected absent fraud, i.e., the provision of false information, the failure to include material safety information in the NDA, or the failure to provide post-marketing information which would have led to withdrawal of the product or changes in the approved uses of the product. As we have shown, the requirements for an NDA are so extensive that, at the margin, the FDCA probably over-deters. In such a case, tort liability provides no additional societal benefits. It is only where pharmaceutical manufacturers have provided false or misleading information to the FDA that tort actions will play a legitimate regulatory role.

Second, legislation must recognize that the regulatory scheme decreed by the FDCA ensures a reasoned decision by the FDA about appropriate labeling information. Thus, once the manufacturer can show that the agency has exercised its judgment about the sufficiency of a warning, this legislation should remove the possibility of co-regulation through tort liability. The preemptive legislation, however, should be carefully drafted to ensure that the agency has in fact affirmatively acted on accurate information provided by a manufacturer before the potentially powerful regulatory effect of tort law is removed.<sup>147</sup>

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23, at 793 (concluding, in argument based on limited preemption, that courts should review FDA determinations on administrative law standards); Dueffert, *supra* note 98, at 223-24 (setting forth statutory language proposed by author for purpose of affording a "strong presumption of non-negligence for manufacturers such as those selling FDA-approved drugs").

<sup>147</sup> In the past decade, physicians have increasingly prescribed drugs for uses not approved by the FDA—so called "off-label" uses. Off-label prescribing is believed to be widespread, particularly in the treatment of cancer. William L. Christopher, *Off-Label Prescription: Filling the Regulatory Vacuum*, 48 FOOD & DRUG L.J. 247, 248 (1993). For example, a recent survey of prescribing practices by oncologists revealed that one-third of prescriptions for cancer patients were for off-label uses. Thomas Laetz & George Silberman, *Reimbursement Policies Constrain the Practice of Oncology*, 266 JAMA 2996, 2997 (1991). The same survey found that 56% of cancer patients were found to have received at least one drug for an off-label purpose. *Id.*

In both the design and labeling situations, plaintiffs should be permitted to establish that the FDA's judgments were obtained through fraud or deceit. In order to ensure, however, that the regulatory compliance defense is not easily set aside, a plaintiff should be obliged to satisfy the judge by a preponderance of the evidence that fraud exists. Only if the judge finds in a separate pretrial hearing that such evidence exists should the question of fraud be presented to a jury.

Other FDA decisions about labeling are also entitled to preemptive effect. Thus, in a situation where a manufacturer has petitioned the FDA for a new warning, but the FDA has explicitly prohibited the warning, tort liability is inappropriate and should be preempted.<sup>148</sup> As noted elsewhere, because the FDA has institutional incentives to adequately warn, a determination by the agency that a warning is inappropriate generally will occur only in those situations where the harm is speculative, or where serious issues of dilution or brevity are presented in labeling.

Likewise, where the manufacturer has applied for a labeling change and the FDA has approved it, the resulting labeling should be regarded as adequate. Because the FDA has exercised its expertise in its review, the agency has necessarily found that the proposed language is appropriate to the risk by directing the information to be placed in the package insert. Given the agency's involvement in decisions reflecting the specific language ultimately incorporated in such package inserts, further micro-management of the labeling process through tort law will not result in systematic, beneficial changes.

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In virtually all instances of off-label uses, the drug previously has been approved by the FDA for other medical indications. Nevertheless, in the case of off-label uses, the FDA has not had the opportunity to exercise its regulatory judgment as to whether the drug is safe and effective for the use in question either because the pharmaceutical manufacturer has not submitted a supplemental NDA, or a supplemental NDA has been submitted but has not yet been approved by the agency. Obviously, any legislation that preempts tort remedies based on regulatory compliance must take into account these situations. Generally, in such circumstances a pharmaceutical manufacturer should not be entitled to assert the regulatory compliance defense.

It also should be noted that pharmaceutical manufacturers are obligated to advise the FDA of adverse reactions where their drugs are being used for unapproved indications. The agency may require the drug's labeling to warn of the risks posed by off-label uses. 21 C.F.R. § 201.57(e) (1993). In such instances, the regulatory compliance defense may be available.

<sup>148</sup> These are not theoretical concerns, but rather have happened in New Jersey and Kansas. See *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038 (Kan.), cert. denied, 469 U.S. 965 (1984); *Feldman v. Lederle Lab.*, 97 N.J. 429, 479 A.2d 374 (1984).

## V. CONCLUSION

The network of pharmaceutical regulations is more complex and thorough than the safety regulations for any widely-marketed consumer product. Before pharmaceutical products are marketed, they must undergo extensive testing following clinical trials whose results are reviewed by the FDA. Overall, no drug is marketed until after the FDA makes a judgment that the benefits associated with the product outweigh the product's risks. Because the standards for safety applied by the FDA generally go beyond what is economically efficient, there is the strong presumption that meeting FDA standards implies that an efficient level of safety is being provided, based on the knowledge available at the time the drug is marketed.

In addition, the warnings language associated with such products must be approved by the FDA which, in practice, leads to substantial FDA involvement in the drafting of warnings language. Labeling decisions should be made on a centralized basis so that the language used has consistency and uniformity. In contrast, *laissez faire* litigation creates perverse incentives that may both dilute and overload the drug product labeling.

Tort law in the pharmaceutical context has proven to be an extraordinarily expensive regime that suffers from institutional constraints limiting its accuracy. The experiences with Bendectin and especially DPT show that tort liability can create perverse incentives that actually harm social welfare. By the same token, where the manufacturer has complied with the FDCA and its implementing regulations, tort law does not appear to have significant ability to generate safer drugs. In short, tort law's role should be to ensure that pharmaceutical companies provide full and complete disclosure to the FDA so that the agency can properly make judgments necessary to protect the public health.

In the usual case where there has been regulatory compliance, society's goal of promoting public health will have been achieved. This is all that should be asked of the tort system. Litigation has proven to be too expensive a mechanism to compensate injuries unless deterrence of irresponsible conduct is simultaneously being achieved.