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# A Unified System for Ensuring Drug Safety

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## ABSTRACT

There are currently two systems in the United States to ensure the safety of pharmaceutical products: tort and regulation. The shared goal of tort law and Food and Drug Administrative (“FDA”) regulation is to make beneficial drugs available to patients while keeping unsafe drugs off the market. This goal will be better served if the two are combined into a unified system, wherein each functions in the role best suited to its relative strengths and weaknesses. In the proposed unified system FDA would be the decision maker, setting the standard for drug safety, and tort would be the enforcer, safeguarding the process of FDA regulation. FDA is the better institution for making scientific decisions on a society-wide basis. Tort is the better institution for ensuring FDA has all available information about a drug’s safety and for restraining undue political influence over FDA decision-making. Tort should therefore hold pharmaceutical manufacturers liable if they withhold safety information from FDA or if they attempt to force a decision on any basis except safety. Absent interference with FDA regulation, there is no need for tort liability. In these distinct roles, regulation and tort can each complement the decision-making of the other instead of overruling it. This shared governance of drug safety promises greater efficiency, less confusion, and ultimately more protection for patients.

There are currently two systems in the United States to ensure the safety of pharmaceutical products: tort law and regulation. These separate systems have developed side by side, pursuing the same objective of safe drugs for patients, with little communication and no cooperation between them. This separation has led to conflicting decisions. The classic example is Bendectin, a drug for morning sickness that was driven off the market by tort litigation despite the Food and Drug Administration (“FDA”) concluding it was safe.<sup>11</sup>

A more recent example is Rezulin, the first drug in a new chemical class for treating type II diabetes.<sup>22</sup> FDA approved Rezulin because its benefits to diabetics outweighed its risk of liver damage. Three years later FDA requested that it be withdrawn from the market, after two new drugs in the same chemical class were shown to provide the same benefits with less risk of liver damage. Despite FDA acknowledging the public benefits of Rezulin during its time on the market, the manufacturer has since been subject to an onslaught of lawsuits claiming compensation for injuries caused by the drug.

The shared goal of tort law and FDA regulation is to make beneficial drugs available to patients while keeping unsafe drugs off the market. This goal will be better served if tort law and FDA regulation are combined into a unified system, wherein each functions in the role best suited to its relative strengths and weaknesses. A unified system will have a single standard for drug safety. This prevents redundant decision-making and conflicting decisions. A double standard can only lead to reduced protection for patients and increased confusion for pharmaceutical manufacturers. In the proposed unified system FDA would be the decision maker, setting the standard for drug safety, and tort would be the enforcer, safeguarding the process of FDA regulation. FDA is the better institution for making scientific decisions on a society-wide basis. It has access

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<sup>11</sup> W. Kip Viscusi, et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale For the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1473–75 (1994).

<sup>22</sup> See discussion *infra* Part IV.

to the highest levels of scientific expertise, and furthermore has a broad national perspective that allows it to make rational risk-benefit trade-offs on a nation-wide basis. FDA should therefore decide which drugs are safe to be on the market. Tort is the better institution for ensuring FDA has all available information about a drug's safety and for restraining undue political influence over FDA decision-making. The prospect of a multi-million-dollar damage award provides a financial incentive for law firms to invest heavily in discovering exactly what a pharmaceutical manufacturer knew about a drug's safety and when it knew it. The tort system is also designed to make the decision-makers immune to outside political influence. Tort should therefore hold pharmaceutical manufacturers liable if they withhold safety information from FDA or if they attempt to force a decision on any basis except safety. Absent interference with FDA regulation, there is no need for tort liability. In these distinct roles, regulation and tort can each complement the decision-making of the other instead of overruling it. This shared governance of drug safety promises greater efficiency, less confusion, and ultimately more protection for patients.

## **I. The Current System of Dual Governance**

**I. The Current System of Dual Governance** Tort law and FDA both seek to ensure the safety of the nation's pharmaceuticals. FDA derives its authority as the nation's principal regulator of pharmaceuticals from the Food, Drug, and Cosmetic Act of 1938 ("FD&C Act").<sup>33</sup>

Pursuant to its directive as a "public health protector," FDA employs a comprehensive scheme of pre-market testing and post-market surveillance to ensure that all pharmaceutical products on the market are safe.<sup>44</sup>

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<sup>33</sup> 21 U.S.C. § § 301-393 (1982 & Supp. 1989).

<sup>44</sup> *See, e.g.*, 21 U.S.C. § 355(d) (1982) (authorizing the Secretary to deny licensing approval in the absence of adequate evidence that the drug is "safe for use under the conditions prescribed").

Prior to allowing a drug on the market, the manufacturer must conduct extensive clinical testing to ensure that the potential benefits of the pharmaceutical outweigh its associated risks.<sup>55</sup>

FDA's involvement begins with the submission of an Investigational New Drug application ("IND").<sup>66</sup>

The IND contains information about the proposed drug's chemistry, manufacturing, pharmacology, and toxicology. If approved, the IND permits the drug's manufacturer to begin testing on animal and eventually human subjects with the goal of submitting an application for marketing approval, a New Drug Application ("NDA"). The NDA must include data from all animal studies and clinical testing done with the drug, reports of any adverse reactions, and any other pertinent information from worldwide scientific literature.<sup>77</sup>

In addition to safety and efficacy data, the FD&C Act also requires the NDA to contain "specimens of the labeling proposed to be used for such drug."<sup>88</sup>

The statutory labeling requirement serves two central functions.<sup>99</sup>

First, it provides the analytic framework under which the FDA makes a more refined evaluation of the safety and efficacy of the medication. Second, if the drug satisfies this initial threshold, FDA oversight of the medication's labeling ensures that information necessary to an informed medical decision concerning the drug is conveyed as effectively as possible. Approval of the NDA allows the manufacturer to begin marketing

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<sup>55</sup> See, e.g., *United States v. Rutherford*, 442 U.S. 544, 555 (1979) (stating that the FDA "generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use").

<sup>66</sup> 21 U.S.C. § 355(i) (1982). See generally David Kessler, *The Regulation of Investigational Drugs*, 320 NEW ENG. J. MED. 281 (1989) (discussing the regulatory process of pre-market FDA screening).

<sup>77</sup> 21 U.S.C. § 355(b)(1) (1982); 21 C.F.R. § 314.50 (1989).

<sup>88</sup> 21 U.S.C. § 355(b)(6) (1982).

<sup>99</sup> Note: *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 777 (1990).

the drug. This approval reflects FDA’s risk-benefit judgment that, on the whole, the drug will enhance public health.<sup>1010</sup>

Given the inherent limitations of pre-market testing, FDA also conducts extensive post-marketing surveillance. Manufacturers are required to monitor and follow up on adverse drug experiences reported by practitioners and patients as well as on research studies.<sup>1111</sup>

The FD&C Act empowers FDA to enforce these reporting requirements. Any failure to comply may subject a manufacturer to civil and criminal penalties.<sup>1212</sup>

As a result of post-market findings, FDA may require labeling changes in order to meet the requirements of section 352 of the FD&C Act,<sup>1313</sup>

or, if necessary, withdraw NDA approval and thereby revoke the license to market the drug.<sup>1414</sup>

In addition to extensive FDA regulation, drug safety is also overseen by the tort system. Numerous courts have concluded that in enacting the FD&C Act, Congress evinced no intention to preempt state tort liability for drug injuries. The Supreme Court of New Jersey found “nothing in the federal scheme to support the assertion that manufacturers of prescription drugs and antibiotics who literally comply with [FDA regulations] must be immune from state tort liability for injuries caused by their products.”<sup>1515</sup>

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<sup>10</sup>10 Viscusi, *supra* note, 1 at 1444.

<sup>11</sup>11 Robert Faich, *Adverse Drug Experience Reporting and Product Liability*, 41 FOOD DRUG COSM. L.J. 444, 444 (1986) (citing 21 C.F.R. § 314.80 (1985)).

<sup>12</sup>12 Prohibited acts are subject to injunction, 21 U.S.C. § 332 (1982); criminal penalties, *id.* § 333; and seizure, *id.* § 334(a).

<sup>13</sup>13 *Id.* § 352 (setting out the statutory specifications of a “misbranded drug”).

<sup>14</sup>14 *Id.* § 355(e)(3).

<sup>15</sup>15 *Feldman v. Lederle Laboratories*, 125 N.J. 117, 147 (1991).

The Fourth Circuit held that federal law does not preempt imposition of Virginia’s common law liability for failure to warn, despite the fact that labeling, “once approved, cannot be changed without FDA approval.”<sup>1616</sup>

A plurality of the Supreme Court stated that negligence and strict liability claims for failure to warn about risks of a medical device were not preempted by federal regulations.<sup>1717</sup> Few courts are willing to relinquish control over any aspect of tort law to a government agency.

The most common tort claim involving drug safety is failure to warn.<sup>1818</sup>

Companies are liable for failing to warn of risks of which they knew or should have known at the time that the product was sold.<sup>1919</sup>

“[W]hen the drug manufacturer fails to give an adequate warning, the drug may be considered ‘defective’ and unreasonably dangerous, thereby subjecting the manufacturer to strict liability for resulting injuries.”<sup>2020</sup>

Claims of manufacturing defects are rare.<sup>2121</sup>

FDA regulation ensures a high level of quality control in drug manufacturing. Claims of design defects are

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<sup>16</sup>16 *Abbot by Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1112 (4th Cir.1988).

<sup>17</sup>17 *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (plurality opinion of Stevens, J.).

<sup>18</sup>18 STEVEN GARBER, ET AL., PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES 40 (1993); DONALD E. VINSON & ALEXANDER H. SLAUGHTER, PRODUCTS LIABILITY: PHARMACEUTICAL DRUG CASES 122 (1988). RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. d (1998).

<sup>19</sup>19 Garber, *supra* note 18, at 40.

<sup>20</sup>20 *Seley v. G. D. Searle & Co.*, 423 N.E.2d 831, 836 (1981).

<sup>21</sup>21 Garber, *supra* note 18, at 39.



similarly rare for drugs.<sup>2222</sup>

For most other types of products, a design defect exists if the risks outweigh the benefits. However a drug is only defective if its risks outweigh its benefits for every class of patient.<sup>2323</sup>

Therefore a drug is not defective if it provides a net benefit to one class of patient, even if it poses a serious risk to other patients. This rule reflects the view that, as long as a given drug is beneficial for some group of patients, it should be available to that group, albeit with adequate warnings.<sup>2424</sup> Physicians must therefore be relied upon to prescribe the appropriate drug for the appropriate patients. Furthermore, unlike power saws and swimming pools, no reasonable alternative design is possible for a drug. Current pharmaceutical technology is incapable of reducing a drug's adverse effects by rearranging the various carbon, oxygen, and other atoms that make up the drug molecule. Any change in a drug's chemical structure creates a new drug, with unique physiological effects that are impossible to predict accurately. Therefore, under the risk-benefit test, a drug is only defectively designed in the rare case where its overall risks outweigh its overall benefits.

In practice, therefore, tort law ensures the safety of drugs on the market by submitting the drug's label to review by a jury. The jury will then decide if the manufacturer should have provided more information to physicians about the drug's safety. FDA approval is evidence that the pharmaceutical manufacturer met its duty to warn, but it is not conclusive.<sup>2525</sup>

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<sup>2222</sup> *Id.*

<sup>2323</sup> *Williams v. Ciba-Geigy Corp.*, 686 F.Supp. 573, 578 (W.D.La.), *aff'd*, 864 F.2d 789 (5th Cir.1988) (holding that the drug Tegretol was not defective because it had utility for sufferers of psychomotor and grand mal seizures who did not respond to conventional anticonvulsants); *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410 (Colo.1986) (holding that defendant's drug was nondefective because it was the drug of choice for at least one class of patients); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998).

<sup>2424</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 RN to cmt. f (1998).

<sup>2525</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*

As a result, tort law and FDA regulation can reach directly conflicting results. Juries have found pharmaceutical manufacturers liable for inadequate warnings where the FDA mandated, verbatim, the warning at issue.<sup>2626</sup>

Moreover, juries have held manufacturers liable for inadequate disclosure where the manufacturer's attempts to warn against the very adverse effect at issue were expressly rejected by FDA on the ground that there was no credible scientific basis for including it in the warning.<sup>2727</sup>

Tort law effectively grants juries *de novo* review of FDA decisions on drug labeling. However juries are deciding drug safety in hindsight, and hindsight bias can lead jurors to overestimate a drug's known risks at the time it was approved.<sup>2828</sup>

Independent review coupled with 20-20 hindsight place juries in the position of second-guessing the extensive FDA regulation of warnings that accompany prescription drugs.<sup>2929</sup>

Tort law should complement FDA regulation instead of creating an inconsistent standard of conduct for pharmaceutical manufacturers to attempt to follow. Tort law can do this by ensuring that FDA is able to regulate properly. Pharmaceutical manufacturers should be held liable in tort for withholding drug safety

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*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>2626</sup> See, e.g., *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (N.H. 1981) (rejecting an argument that warnings were adequate because they were drafted by FDA as required for uniform labeling of all oral contraceptives); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 534 (Or. 1974) (holding the manufacturer liable for an inadequate warning even though FDA wrote the warning and federal law required its inclusion).

<sup>2727</sup> See, e.g., *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038, 1057 (Kan. 1984); *Feldman v. Lederle Laboratories*, 479 A.2d 374, 378-79 (N.J. 1984).

<sup>2828</sup> W. Kip Viscusi, *The Social Costs Of Punitive Damages Against Corporations In Environmental And Safety Torts*, 87 GEO. L.J. 285, 328 (1998).

<sup>2929</sup> Viscusi, *supra* note 1, at 1467-68.

information from FDA or for exerting undue political influence over FDA's regulatory process. Absent interference with the ability of FDA to regulate, pharmaceutical manufacturers should not be held liable in tort. Compliance with FDA regulations should therefore be a complete defense to liability in tort. Tort law should complement FDA's efforts by safeguarding the process of FDA regulation, not by second-guessing the results arrived at by that process.

The dual systems of tort law and FDA regulation will inevitably run into conflict if both attempt to ensure drug safety by the same means. This conflict creates inconsistent safety standards, which can only result in confusion for pharmaceutical manufacturers and diminished protection for users of prescription drugs. Instead, tort and FDA should function in distinct roles determined by their relative strengths.

## **II. Integrating Tort Law and FDA Regulation**

**II. Integrating Tort Law and FDA Regulation** Tort law and federal regulation each have distinct advantages in their shared goal of ensuring that only safe drugs are allowed onto the market. In their shared goal of ensuring drug safety, tort and FDA should adopt complementary roles that take advantage of their respective strengths, instead of cancelling each other out. FDA has greater scientific expertise and the ability to make decisions on a nation-wide basis. FDA should therefore set the national standard for drug safety. Tort law has greater resources and political independence. The tort system should therefore safeguard the process of FDA regulation, by holding a pharmaceutical manufacturer liable for withholding safety information from the FDA or attempting to force a regulatory decision on any basis except safety. In these distinct roles, regulation and tort can each complement the decision-making of the other instead

of overruling it. This will avoid the problems of the current system of dual governance with its overlapping roles, inefficient rule-making, and conflicting standards of conduct for pharmaceutical manufacturers.

#### **A. Advantages of Tort: Resources**

**A. Advantages of Tort: Resources** The tort system can ensure compliance with FDA regulations, because it has the resources that FDA lacks. Damage awards provide law firms with a financial incentive to conduct extensive investigations that FDA cannot afford. Damages in pharmaceutical products liability litigation topped \$100 million in 1985.<sup>3030</sup>

This creates a financial incentive for law firms to invest in discovery of a pharmaceutical manufacturer's records to establish what it knew about a drug's safety and when it knew it. A plaintiff's lawyer can estimate the recovery from a client's claim, based on the amount of past damage awards and the probability of success at trial. This is the same calculation that a pharmaceutical manufacturer does when making a settlement offer. The lawyer will then be willing to invest in the claim up to the amount of the expected contingency fee portion of that recovery. Entrepreneurial plaintiffs' lawyers therefore have a financial incentive to invest many millions of dollars in factfinding and discovery. For example, two separate law firms representing different plaintiffs with fen-phen claims went through millions of documents from American Home Product's warehouse of raw fen-phen data.<sup>3131</sup>

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<sup>30</sup>30 W. Kip Viscusi et al., *Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 SETON HALL L. REV. 1418, 1430 (1994).

<sup>31</sup>31 ALICIA MUNDAY, DISPENSING WITH THE TRUTH: THE VICTIMS, THE DRUG COMPANIES, AND THE DRAMATIC STORY BEHIND THE BATTLE OVER FEN-PHEN 152-53 (2001).

By contrast, FDA is chronically short of resources to meet its statutory responsibilities.<sup>3232</sup>

In particular, FDA lacks the resources “to monitor manufacturer post-approval reporting behavior, detect violations, impose adequate sanctions, and thereby provide an appropriate deterrent.”<sup>3333</sup>. Instead of actively investigating a pharmaceutical manufacturer’s records to determine whether it has told the full story about a drug’s safety, FDA is forced to rely on noticing inconsistencies in the data presented to it. The threat of a thorough review of its records, should a drug be associated with a future injury, motivates pharmaceutical manufacturers to provide complete safety information to FDA. Given that investigation is much more resource-intensive than decision-making, tort is the better institution to ensure compliance with FDA regulations

## **B. Advantages of Tort: Independence**

**B. Advantages of Tort: Independence** FDA is subject to political pressure. Many injured patients have alleged that Warner-Lambert exerted undue political influence over FDA by successfully seeking the removal of an FDA official critical of Rezulin’s safety. Dr. John Gueriguian, a veteran FDA medical officer assigned to evaluate Rezulin, reviewed the NDA and after documenting its possible danger to the liver recommended on October 9, 1996, that the agency reject the drug.<sup>3434</sup>

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<sup>3232</sup> See Advisory Committee On the Food and Drug Administration, Final Report 11 (1991) (“It is glaringly apparent that the FDA cannot now execute all of its statutory responsibilities within the limitations of existing resources, a conclusion that is repeated throughout this report.”); Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 530 (1988) (“Virtually all observers, including medical device manufacturers, share the view that the FDA’s resources are inadequate to meet its obligations under the Medical Device Amendments.”).

<sup>3333</sup> Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 499 (1997).

<sup>3434</sup> *Class Actions, Wrongful Death Complaints Follow Withdrawal of Rezulin*, Mealey’s Emerging Drugs and Devices, Apr. 6, 2000, at 4.

Warner-Lambert is alleged to have complained to one of Gueriguian's superiors, Dr. Murray Lumpkin, deputy director of the FDA Center for Drug Evaluation and Research and shortly afterwards, on November 4, 1996, Gueriguian was removed by Dr. Solomon Sobel, chief of the FDA's diabetes drug division.<sup>3535</sup>

Dr. Gueriguian has subsequently accused Warner-Lambert of deliberately biasing study protocol in an attempt to speed the drug through its approval process.<sup>3636</sup>

FDA is also subject to direct political pressure from Congress. While FDA reviewers were debating the NDA for Redux, a weight-reduction drug, Senator Ted Kennedy of Massachusetts wrote to FDA urging them to approve the drug, which was made by a Boston company.<sup>3737</sup>

This sort of direct pressure can be particularly threatening since Congress decides the FDA budget annually.<sup>3838</sup> Due to the huge profits at stake in the drug approval process, FDA is a target of political influence. Only a systemic solution can control this influence. While a congressional committee will investigate blatant political pressure if it raises enough alarms on Capitol Hill, a systemic solution can address ongoing political influence on a daily basis. One possibility is for FDA to form an ad hoc committee or assign a separate department to investigate allegations of political influence over its regulation. Alternatively, these allegations can be reviewed in a court of law.

A jury is the better institution to assess allegations of political influence because it is politically independent.

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<sup>35</sup>35 *Id.*

<sup>36</sup>36 *Ex-FDA Reviewer Says Rezulin Maker Doctored Studies to Gain Approval*, Mealey's Emerging Drugs and Devices, Apr. 16, 1999, at 25.

<sup>37</sup>37 DISPENSING WITH THE TRUTH, *supra* note 31, at 74.

<sup>38</sup>38 FDA Office of Financial Management, About OFM (Apr. 11, 2001) at [http://www.fda.gov/oc/oms/ofm/internet\\_default.htm](http://www.fda.gov/oc/oms/ofm/internet_default.htm).

Unlike an administrative agency, a jury can only be addressed in the limited forum of an open courtroom. It is a violation of both criminal law<sup>3939</sup>

and American Bar Association rules<sup>4040</sup> for a lawyer to have any contact with a juror outside of a courtroom. A jury is therefore able to make an independent assessment of undue influence over FDA's drug approval process. By contrast, any internal FDA review would itself be subject to pressure to resolve the allegations in favor of one side or the other. Furthermore, a jury has no stake in its own decision. A jury can freely criticize the decision-making processes of the FDA because it has no stake in the FDA's political image. Any separate department or committee of the FDA created to investigate political influence would be reluctant to find undue political influence if this would reflect poorly on the agency's decision-making or on familiar individuals within the agency.

### **C. Advantages of Tort: Deciding Standards of Conduct**

**C. Advantages of Tort: Deciding Standards of Conduct    A jury is the better institution to decide the acceptable level of political influence over FDA. The issue of undue political influence is not a technical one amenable to regulation. No special expertise is necessary to decide whether pressure to remove a particular reviewer was beyond the acceptable bounds of behavior. Political influence is an issue of standard of conduct, that is, of whether a pharmaceutical manufacturer exceeded acceptable standards of political behavior in its attempt to influence FDA regulation. Juries have traditionally measured individual behavior against a socially accepted standard of conduct, the classic example being a criminal trial. Allowing juries to decide whether FDA**

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<sup>39</sup>39 See, e.g., *United States v. Forrest*, 623 F.2d 1107 (5th Cir. 1980); *United States v. Ogle*, 613 F.2d 233 (10th Cir. 1979).

<sup>40</sup>40 MODEL RULES OF PROF'L CONDUCT § 3.5 (1999).

was subject to undue political influence would allow ordinary citizens to determine on a case-by-case basis the extent of acceptable influence over an agency that regulates the basics of life. Allowing undue political influence to be decided by a jury does not imply that juries will also review FDA policy. A jury is only empowered to decide the issue before it, which would be a single case of alleged political influence resulting in injury caused by an identifiable defendant. Juries would not be empowered to review broad FDA policies, such as a campaign by AIDS activists that led to accelerated review for certain new AIDS drugs.<sup>4141</sup> Jury decisions would be limited to judging a single act of political influence by a pharmaceutical manufacturer in an attempt to influence approval of a new drug.

#### **D. Advantages of Regulation: Scientific Expertise**

**D. Advantages of Regulation: Scientific Expertise** FDA's scientific expertise makes it the better institution to evaluate a drug's safety. FDA employs a large number of scientists and medical doctors, and can also form advisory committees to gain access to the highest levels of scholarship on any scientific issue.<sup>4242</sup>

By contrast, the average juror has a high school education and must be educated about scientifically complex issues in the course of a trial lasting a few weeks. Jury verdicts imposing tort liability in cases involving Bendectin, breast implants, and vaccines have been directly contrary to the overwhelming consensus of knowledgeable independent scientists regarding these products' potential to cause harm.<sup>4343</sup>

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<sup>41</sup>41 *FDA's Fast-track Approval Process Blamed for 'Seven Deadly Drugs,'* Medico-Legal Watch, Feb. 2001, at 146.

<sup>42</sup>42 *Use of Advisory Committees by the Food and Drug Administration: Hearings Before a Subcommittee of the House Committee on Government Operation*, 93d Congress, 2d Session (1974) (statement of FDA Commissioner Alexander M. Schmidt).

<sup>43</sup>43 Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J.



“Because the typical juror does not possess the scientific expertise to evaluate the validity of the substantive scientific evidence at issue, however, resolution necessarily becomes merely an analysis of the credibility and demeanor of competing expert witnesses, and may often yield outcomes in conflict with generally accepted scientific understandings.”<sup>4444</sup> Juries are competent to assess credibility but not scientific evidence. Accordingly, FDA is the better institution to decide if a drug is safe to be on the market.

In addition to its expertise, FDA has a better decision-making structure for resolving issues of drug safety. Following submission of an NDA, FDA can initiate further investigation of a particular aspect of a drug’s safety by requesting more studies from the pharmaceutical manufacturer. FDA is not hesitant to require further information before it approves an NDA.<sup>4545</sup>

A jury, by contrast, is passively limited to the safety information presented to it by the two sides at trial. FDA is also able to modify its decision-making structure and adapt to new experience. For example, following concerns about a clinical bias on the part of the advisory committee that reviewed Rezulin, FDA resolved to eliminate this bias by adding epidemiological experts to future advisory committees.<sup>4646</sup>

Juries have traditionally been limited since the ratification of the Constitution to six or twelve citizens chosen at random from the local population. Commentators have argued for decades that the jury structure should be changed to better address scientific issues, but there has been no systemic change to the traditional jury structure.<sup>4747</sup> FDA’s decision-making structure coupled with its scientific expertise makes it the better

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2167, 2171 (2000).

<sup>4444</sup> *A Question of Competence: the Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 781 (1990).

<sup>4545</sup> Michael Kimball, *FDA To Hasten Approval*, HEALTH WEEK, Nov. 9, 1987 (“A study of 637 NDAs received since 1981 found that the FDA returned two-thirds to the sponsor with requests for more information.”).

<sup>4646</sup> *US FDA Rezulin withdrawal study sees communication, other problems, at CDER*, MKLTR, Nov. 27, 2000, at 1.

<sup>4747</sup> See, e.g., Jan Beyea & Daniel Berger, *Scientific Misconceptions among Daubert Gatekeepers: the Need for Reform of Expert Review Procedures*, 64 LAW AND CONTEMP. PROBS. 327, 365 (2001).

institution to resolve issues of drug safety, provided it has complete information on a drug's safety.

### **E. Advantages of Regulation: Broad Perspective**

E. Advantages of Regulation: Broad Perspective     FDA's broad regulatory perspective make it the better institution to decide scientific issues on a society-wide basis. In addition to advisory committees and a staff of scientists, FDA's society-wide outlook better enables it to decide whether a drug is safe for marketing. Most jurisdictions hold that a drug should be available to the public if its benefits outweigh its risks for at least one class of patients.<sup>4848</sup>

FDA is better able to weigh the risks and benefits of a drug because it considers the drug in the context of the entire national population instead of focusing on a single victim. For example, FDA decided to keep Rezulin on the market despite 3 deaths associates with the drug because its life-saving benefits to 500,000 type II diabetes patients outweighed the small risk of harm.<sup>4949</sup>

A jury may have assessed sufficient damages against Warner-Lambert to force the drug off the market. While FDA may or may not have made the right decision to keep Rezulin on the market, the important point is that it made the decision in the right way. Juries make decisions case by case, in an isolated and uncoordinated fashion. They are not institutionally equipped to make the risk-risk tradeoffs and benefit-benefit tradeoffs required for risk regulation.<sup>5050</sup>

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<sup>48</sup>48 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. a (1998).

<sup>49</sup>49 FDA talk paper, Patient Testing and Labeling Strengthened for Rezulin (December 1, 1997) *available at* <http://www.fda.gov/bbs/topics/ANSWERS/ANS00837.html>.

<sup>50</sup>50 Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2173 (2000).

A jury is typically confronted with a single victim and asked to decide whether the drug should have been available to the entire population. This is the wrong context in which to make social policy, because a jury is faced with a concrete example of the risks of a drug without comparable evidence of its benefits. Furthermore a jury's judgment will be blinded by natural sympathy for the victim. It is difficult to rationally weigh the benefits of a drug to millions of diabetics when confronted with the case of a man who has died following a liver transplant. Finally a jury would be deciding social policy in hindsight, and hindsight bias can lead jurors to overestimate a drug's known risks at the time it was approved.<sup>5151</sup> Juries are not institutionally equipped to decide whether the risks of a drug outweigh its benefits for the entire national population. This is a decision best made by FDA, which has both the expertise and the proper perspective to make it.

#### **F. Merging Regulation and Tort into a Unified System of Governance**

**F. Merging Regulation and Tort into a Unified System of Governance** Regulation and tort can function in distinct roles within a unified system to ensure the safety of drugs on the market. Tort law provides resources and the incentive to dig into a pharmaceutical manufacturer's records to ensure it has provided all relevant safety data to FDA. The tort system also has the independence to fairly assess undue political influence over FDA, and is the better institution to set the standard for acceptable political influence. FDA has access to the highest levels of scientific expertise for evaluating drug safety. Its broad outlook also enables it to make safety decisions on a society-wide basis, instead of assessing liability for individual injuries without any overall plan. The strengths and weakness of regulation and tort suggest distinct roles for each in a unified system. Instead of acting like two kings striving to rule the same territory, regulation and tort should share responsibility for drug safety. FDA is the better institution for making

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<sup>5151</sup> Viscusi, *supra* note 28, at 328.

scientific decisions on a society-wide basis. FDA should therefore decide which drugs are safe to be on the market. Tort is the better institution for ensuring FDA has all available information about a drug's safety and for restraining undue political influence over FDA decision-making. Tort should therefore hold pharmaceutical manufacturers liable only if they withhold safety information from FDA or if they attempt to influence approval of a drug by political means. In these distinct roles, regulation and tort can each complement the decision-making of the other instead of overruling it. This shared governance of drug safety promises to be a more efficient and more consistent means of ensuring drug safety for patients.

### III. Criticism of a Unified System

**III. Criticism of a Unified System** Commentators have argued forth for decades about whether FDA or tort should have the final responsibility for drug safety, but there has been little discussion of a unified system that combines the strengths and weakness of each.<sup>5252</sup> In the context of this ongoing debate, however, arguments have been raised that could be critical of the proposed unified system.

#### A. Criticism: The Role of Tort Law Is to Compensate Injured Patients

A. Criticism: The Role of Tort Law Is to Compensate Injured Patients **Some authors have argued that tort law is essential to provide compensation to the victims of drug injuries. In this view,**

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<sup>5252</sup> Compare Viscusi, *supra* note 1, at 1475–79 (advocating a regulatory compliance defense in which tort law would defer to FDA regulation), with Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REF. 461, 507–10 (1997) (arguing that tort law deference to FDA regulation is problematic and ultimately unhelpful).

the purpose of tort law is to compensate the injured at the expense of the wrong-doer by awarding compensatory damages.<sup>5353</sup>

Tort law “is directed toward the compensation of individuals . . . for losses they have suffered within the scope of their legally recognized interests.”<sup>5454</sup>

In the context of pharmaceutical products, Professor Robert Rabin has argued that tort law has “a legitimate interest in ensuring compensation to its citizens in **accidental harm situations**.”<sup>5555</sup>

Similarly, Professor Richard Merrill has suggested that pharmaceutical manufacturers be held strictly liable for all injuries that are not the result of a physician’s negligence.<sup>5656</sup>

In contrast, other authorities have argued that the primary purpose of tort law is to prevent injury, not to compensate the victims. The Restatement (Third) on Torts has premised tort law liability for pharmaceutical products on the “instrumental function of creating safety incentives.”<sup>5757</sup>

Professor David Rosenberg has argued that individuals would rationally prefer a legal system “that allocates enforcement resources to prevent unreasonable risk rather than merely to compensate it.”<sup>5858</sup>

Reducing the total amount of injury increases social welfare, thereby increasing each individual’s share of

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<sup>53</sup>53 Id. § 2, at 7.

<sup>54</sup>54 W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 1, at 5-6 (1984).

<sup>55</sup>55 Rabin, Reassessing Regulatory Compliance, 88 Geo. L.J. 2049, 2073.

<sup>56</sup>56 Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 5-6 (1973).

<sup>57</sup>57 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. a (1998).

<sup>58</sup>58 David Rosenberg, *Mandatory-Litigation Class Action: The Only Option for Mass Tort Cases*, 115 HARV. L. REV. 831, 840 (2002).

the pie.<sup>5959</sup> Accordingly, the tort system should only compensate victims for unreasonable injuries and not for all injuries.

The issue of compensation ultimately turns on the perceived role of tort law. One side argues that the role of tort is to prevent future injuries, while the other side maintains it is to provide compensation for past injuries. If the role of tort is to prevent future injuries, then a pharmaceutical manufacturer would only pay compensation for injuries caused by unreasonably dangerous drugs. In this view there would be no compensation once a drug received FDA approval, because FDA's judgment as to drug safety trumps that of a lay jury. The duty of a pharmaceutical manufacturer would therefore be limited to producing safe drugs. If instead the role of tort is to provide compensation for past injuries, then a pharmaceutical manufacturer would pay compensation every time a patient was harmed by its drug. In this view there would be compensation following FDA approval. The pharmaceutical manufacturer would therefore be required to pay for every injury caused by a drug, regardless of whether FDA found the drug to be safe or not. This decision is too important to be decided by juries on a case-by-case basis. Given its broad impact on health care and the structure of the pharmaceutical industry, this decision should instead be made by a legislature. If pharmaceutical manufacturers are required to compensate all victims of drug injuries, they will effectively be forced into the business of health insurance. Instead of simply being required to market safe drugs, tort law will also hold them responsible for paying the medical bills of injured patients as well as compensation for their pain and suffering. This is in stark contrast to the deterrent role of tort, which seeks to ensure drug safety but does not place responsibility for health care on pharmaceutical manufacturers. While tort can certainly be used as a source of compensation for drug injuries, this does not mean that pharmaceutical

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<sup>5959</sup> *Id.* at 843.

manufacturers should be the insurers of their drugs absent an express mandate from a legislature.

## **B. Criticism: Tort Sets a Higher Standard for Drug Safety than Regulation**

**B. Criticism: Tort Sets a Higher Standard for Drug Safety than Regulation** Regulation has been described as setting only a minimum standard for safety, with tort law setting a higher standard above this floor. Professor Robert Rabin has argued that there is reason to treat compliance with FDA regulation as a “safe harbor” for a defendant whose product is alleged to be defective.<sup>6060</sup>

Tort therefore sets its own safety standard independent of regulation The Restatement (Third) of Torts confirms that product safety statutes and regulations are generally taken to be minimum standards. Regulations set a “floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied.”<sup>6161</sup>

This argument has been borne out in the courts. For example, in *McEwen v. Ortho Pharmaceutical Corp.* the Oregon Supreme Court scrutinized the manufacturer’s FDA-approved warning labels and held that the warnings may be found inadequate even though all governmental regulations had been satisfactorily met.<sup>6262</sup>

The court noted that the federal agency’s approval represented compliance that was “minimal in nature.”<sup>6363</sup>

FDA regulation of drug safety is different from regulation of other products by other agencies. FDA regula-

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<sup>6060</sup> Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2051 (2000).

<sup>6161</sup> RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. e (1998).

<sup>6262</sup> 528 P.2d 522 (Or. 1974).

<sup>6363</sup> *Id.* at 534.

tions allow a drug to be approved for marketing only if tests show it to be “safe”.<sup>6464</sup>

There is no mention of minimal safety. This is in contrast to FAA regulations, which explicitly prescribe only “minimum standards”.<sup>6565</sup>

Furthermore FDA officials do not see themselves as setting minimum standards for safety, but optimal standards.<sup>6666</sup>

Their goal is to keep all unsafe drugs off the market, not merely the very unsafe. Finally “minimally safe” is a meaningless term that has never been defined in the context of prescription drugs. In the context of other consumer products, “minimally safe” has been interpreted to mean that the product will not cause injury “when used in the customary, usual, and reasonably foreseeable manners.”<sup>6767</sup> The terms “minimally safe” and “safe” can therefore be used to distinguish between foreseeable and unforeseeable use of a product. However there is only one use for prescription drugs. The warning label on a drug specifies the safe dosage that a physician can prescribe, and a patient is expected to use the drug only as prescribed. A pharmaceutical manufacturer is not liable for off-label use by physicians or for overdose by a patient. Since there is only a single accepted use for a drug, there is no application for the term “minimally safe” in the context of pharmaceutical products. It is unrealistic and meaningless to conclude that FDA sets minimal standards for drug safety.

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<sup>6464</sup> 21 U.S.C. § 355(d)(2) (1982) (requiring FDA to reject an NDA if “the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions”).

<sup>6565</sup> 49 U.S.C. § 44701 (“(a) The Administrator of the Federal Aviation Administration shall promote safe flight of civil aircraft in air commerce by prescribing (1) minimum standards required in the interest of safety for appliances and for the design, material, construction, quality of work, and performance of aircraft, aircraft engines, and propellers.”).

<sup>6666</sup> Interview with Peter B. Hutt, FDA Chief Counsel (1971–75), in Cambridge, Mass. (Jan. 22, 2002).

<sup>6767</sup> *Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 258–59 (1995).



### C. Criticism: Juries Are Incompetent to Decide Complicated Issues

**C. Criticism: Juries Are Incompetent to Decide Complicated Issues** Some authors have argued that tort deference to FDA decisions is infeasible because juries are incapable of determining whether a pharmaceutical manufacturer has actually complied with FDA regulations. Professor Michael Green argues that juries will be unable to determine whether a pharmaceutical manufacturer has complied with FDA regulations.<sup>6868</sup>

FDA regulations are very complicated. While FDA itself might indicate when a pharmaceutical manufacturer has violated its regulations, the agency will rarely indicate when a manufacturer has complied. Professor Lars Noah has suggested that as a result of this complexity, regulation should preempt tort law only in those situations in which a regulatory infraction is apparent, as when the agency undertakes an enforcement action.<sup>6969</sup>

As a preliminary matter, juries already make these complicated determinations, wholly apart from any regulatory compliance defense. In defense to a failure to warn claim, pharmaceutical manufacturers typically argue that they have complied with FDA regulations. They present evidence of data provided to FDA and FDA's response. This evidence is strong support for a manufacturer's argument that it was not negligent in warning physicians about all of a drug's known risks. So juries already decide the issue of regulatory compliance. A regulatory compliance defense would change the effect of their decision, but not the fact of their making it. Without the defense, a finding of compliance is strong support for a pharmaceutical manufacturer's defense. With the defense, this finding would be a complete defense to liability. In addition,

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<sup>68</sup>68 Michael D. Green, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2140-41 (2000).

<sup>69</sup>69 Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 954-57 (1996).

this determination is not overly complicated. In practical terms, a typical failure to warn claim will involve a piece of data withheld from FDA and the allegation that withholding the information caused a plaintiff's injury. A jury is therefore required to decide whether the data was material to the drug's safety or not. Details of the exact date by which the data should have been provided, the sort of complication that Professor Green hints at, might well be argued over but are likely to have little influence on the jury's decision. If a jury decides that the data was important enough for FDA to know about, regulatory fine print and loopholes will not save the pharmaceutical manufacturer that withheld it.

More broadly, holding pharmaceutical manufacturers liable for withholding safety information from FDA is not the same as creating a regulatory compliance defense. A jury's role in the proposed unified system is to determine whether a pharmaceutical manufacturer has interfered with the process of FDA regulation. It is irrelevant whether FDA would have approved a drug despite a manufacturer withholding information about the drug's safety.<sup>7070</sup> The issue is not what FDA's decision would have been, but whether a manufacturer withheld information or not. The proposal is that withholding information from FDA would return a pharmaceutical manufacturer to the traditional tort system. Compliance would no longer be any defense to liability. This is consistent with the argument that if FDA has all available information about a drug's safety, there is no need for a jury to assess tort liability. FDA is the better institution to ensure the safety of drugs on the market, provided it has complete information. However if a pharmaceutical manufacturer withholds information then FDA is unable to function properly in its role, and tort liability then becomes the appropriate institution for assessing liability.

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<sup>7070</sup> *cf.* Michael v. Shiley, 46 F.3d 1316, 1328–29 (3d Cir. 1995) (interpreting regulatory compliance defense to require determination of whether FDA would have approved medical device despite manufacturer's misrepresentations).

#### **IV. The History of Rezulin**

**IV. The History of Rezulin** Rezulin, a diabetes drug, was withdrawn from the market three years after receiving FDA approval. The history of Rezulin is an example of the interaction between FDA regulation and the tort system. It can thus serve as a demonstration of the current system of dual governance for ensuring drug safety, as well as an illustration of how the proposed unified system of governance might work in practice.

On December 11, 1996 the FDA's Endocrinologic and Metabolic Drugs Advisory Committee unanimously recommended approval of Rezulin to treat type II diabetes poorly controlled by insulin.<sup>7171</sup>

Rezulin allowed certain diabetes to reduce or eliminate their dependence on insulin. Diabetes affects about 16 million Americans and can cause damage to the eyes, kidneys, heart and peripheral circulation. Type II diabetes, non-insulin dependent diabetes, affects nearly 90 percent of all diabetics in the United States. It usually starts in adulthood and is commonly associated with being overweight. Approximately three million type II diabetics require regular insulin injections. Rezulin was expected to help the approximately one million patients with type II diabetes who do not respond adequately to insulin. The new drug was the first in its chemical class. In clinical trials involving about 500 patients, Rezulin was shown to significantly improve patients' ability to use insulin in managing their diabetes. In general, Rezulin was well tolerated. Commonly reported adverse events included infection, pain and headache, but these occurred at rates comparable to placebo. Approximately two percent of all patients in the trials were found to have elevated liver enzymes in the blood. These elevations, which serve as markers of potential liver injury, were mostly mild, unassociated

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<sup>7171</sup> FDA Talk Paper, FDA Approves Rezulin for Diabetes Patients Poorly Controlled on Insulin Therapy (January 30, 1997) at <http://www.fda.gov/bbs/topics/ANSWERS/ANS00783.html>.

with symptoms, and usually resolved when the drug was discontinued.<sup>7272</sup> On the basis of these studies, FDA recommended caution in prescribing Rezulin for patients with liver disease.

FDA officially approved Rezulin in January 1997, making it the most quickly endorsed diabetes pill in the agency's 60-year history.<sup>7373</sup>

The six months it took to make the decision was less than half the normal approval time. During this approval process, Dr. John Gueriguian, a veteran FDA medical officer assigned to evaluate Rezulin, reviewed the NDA and after documenting its possible danger to the liver recommended on October 9, 1996, that the agency reject the drug.<sup>7474</sup>

On November 4, 1996, Gueriguian was removed by Dr. Solomon Sobel, chief of the FDA's diabetes drug division.<sup>7575</sup>

On October 28, 1997 Parke Davis, the manufacturer of Rezulin, sent a letter to physicians advising of 35 post-marketing reports of liver injury associated with Rezulin.<sup>7676</sup>

These reports ranged from mildly elevated liver enzymes in the blood to liver failure leading to one liver transplant and one death. At the time of the letter, about 500,000 diabetics in the United States had been treated with Rezulin. Of those, approximately 85,000 had been taking the drug for six months or more.

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<sup>7272</sup> FDA Talk Paper, Patient Testing and Labeling Strengthened for Rezulin (December 1, 1997) at <http://www.fda.gov/bbs/topics/ANSWERS/ANS00837.html>.

<sup>7373</sup> Robert K. Jenner, *Rezulin: Fast Track to Failure*, TRIAL, July 2000, at 39.

<sup>7474</sup> *Class Actions, Wrongful Death Complaints Follow Withdrawal of Rezulin*, Mealey's Emerging Drugs and Devices, Apr. 6, 2000, at 4.

<sup>7575</sup> *Id.*

<sup>7676</sup> Letter from Parke Davis to healthcare professionals (Oct. 28, 1997) at <http://www.fda.gov/medwatch/safety/1997/rezuli.htm>.

FDA found it unclear whether Rezulin was solely responsible for these reported injuries, or whether they were due to other medical factors.<sup>7777</sup>

Based on these reports, FDA recommended that liver enzyme levels be monitored during Rezulin therapy and that liver function tests be obtained for patients with any symptom of liver damage. FDA also recommended a new label warning. FDA did not suggest that the risks of Rezulin outweighed its benefits, and there was no mention of market withdrawal.<sup>7878</sup>

By December 1, 1997 FDA had received approximately 150 reports of injury linked to Rezulin, including three deaths from liver failure in Japan.<sup>7979</sup>

These deaths occurred in patients treated before the stronger label warning and recommendation for liver enzyme testing took effect there. FDA recommended more frequent monitoring of liver function. The agency explicitly found that the benefits of Rezulin continued to outweigh the risks for certain diabetics.<sup>8080</sup>

Parke Davis sent letters to physicians on December 1, 1997 and again on July 27, 1998 recommending more frequent monitoring of liver function.<sup>8181</sup>

On July 27, 1998 Public Citizen, a non-profit health watchdog, petitioned FDA to withdraw Rezulin from the United States market.<sup>8282</sup>

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<sup>77</sup>77 FDA Talk Paper, Rezulin Labeling Changes (Nov. 3, 1997) at <http://www.fda.gov/bbs/topics/ANSWERS/ANS00831.html>.  
<sup>78</sup>78 *Id.*

<sup>79</sup>79 FDA Talk Paper, Patient Testing and Labeling Strengthened for Rezulin (Dec. 1, 1997) at <http://www.fda.gov/bbs/topics/ANSWERS/ANS00837.html>.

<sup>80</sup>80 *Id.*

<sup>81</sup>81 Letter from Parke Davis to healthcare professionals (Dec. 1, 1997) at <http://www.fda.gov/medwatch/safety/1997/rezul3.htm>.

<sup>82</sup>82 Public Citizen's Health Research Group, Petition to the Food and Drug Administration to ban troglitazone/Rezulin due

Public Citizen noted that the FDA had received 560 injury reports associated with Rezulin, including 21 deaths from liver failure and three patients requiring liver transplants. It estimated that only about one in ten injuries were reported, and argued that the actual number of deaths could be as high as 200. Public Citizen's petition was opposed by certain physicians, who argued that its estimate of under-reporting was exaggerated and that the benefits of Rezulin outweighed its risks since 150,000 diabetics die each year from the disease.<sup>8383</sup>

Ultimately, on May 26, 1999 FDA declined to withdraw Rezulin from the market.<sup>8484</sup>

Instead, it recommended that Rezulin continue to be available to diabetics who did not respond well to other diabetes drugs. The FDA found that with careful monitoring, the benefits of Rezulin outweighed its risks. The American Diabetes Association agreed that the benefits of Rezulin significantly outweighed its risks, noting that almost all deaths associated with Rezulin took place before monitoring of liver function was required.<sup>8585</sup>

On March 21, 2000 the FDA asked Parke Davis to remove Rezulin from the market.<sup>8686</sup> FDA review of recent safety data on Rezulin and two similar drugs, Avandia and Actos, showed that Rezulin was more liver toxic than the other two drugs. Avandia and Actos, both approved in the past year, offered the same benefits as Rezulin but at less risk of liver damage. In light of these two new drugs for treating type II

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to its causing several cases of liver failure (July 27, 1998) at <http://www.citizen.org/publications/release.cfm?ID=6647>.

<sup>8383</sup> Letter from Leann Olansky, M.D., to FDA (Mar. 1, 1999) at <http://www.fda.gov/ohrms/dockets/dailys/032299/c0005.pdf>; Letter from Kathleen A. Alm, M.D. to FDA (Feb. 22, 1999) at <http://www.fda.gov/ohrms/dockets/dailys/032599/C00010.PDF>; Letter from Lawrence D. Kelley, M.D., to FDA (Mar. 8, 1999) at <http://www.fda.gov/ohrms/dockets/dailys/032299/c0007.pdf>.

<sup>8484</sup> Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research at FDA, to Sidney Wolfe, Director, Public Citizen's Health Research Group (May 26, 1999) at <http://www.fda.gov/ohrms/dockets/dailys/061499/pdn0001.pdf>.

<sup>8585</sup> W-L "Disappointed" By Media Reports On Rezulin, MARKETLETTER, Dec.14, 1998.

<sup>8686</sup> HHS News, *Rezulin to Be Withdrawn from the Market* (Mar. 21, 2000) at <http://www.fda.gov/bbs/topics/NEWS/NEW00721.html>.

diabetes, FDA decided that the benefits of Rezulin no longer outweighed its risks.

Following withdrawal of Rezulin, dozens of class actions and individual complaints were filed in courts across the country alleging that the drug had caused serious liver damage and deaths.<sup>8787</sup>

The complaints seek compensation for medical expenses, injury, non-economic damages, and medical monitoring. The first nationwide federal class-action lawsuit was filed in the U.S. District Court for the District of New Jersey.<sup>8888</sup>

Class representative Marilyn Appel accused the manufacturer of engaging in “calculated silence” despite knowing of the growing public misconception regarding the drug’s safety.<sup>8989</sup> Common to all the lawsuits filed were claims that the manufacturer pushed to have Rezulin placed on the fast track for FDA approval, despite questions about the drug’s side effects. Plaintiffs also alleged that the company successfully sought removal of an FDA official who was critical of Rezulin’s safety.

## V. Which Issues Should a Jury Decide?

**V. Which Issues Should a Jury Decide?** On December 17, 2001, in the first Rezulin case to make it to trial, a state court jury in Houston took eight hours to reject the claims of two women who alleged that Rezulin caused their mother’s fatal liver failure.<sup>9090</sup> The jury effectively reviewed FDA’s approval and warning recommendations, finding that the drug was not defectively designed and that the manufacturer

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<sup>8787</sup> *Warner-Lambert Faces Rash of Lawsuits on Heels of Rezulin Recall*, 3 ANDDL 10, 10 (June 2000).

<sup>8888</sup> *Class Actions, Wrongful Death Complaints Follow Withdrawal of Rezulin*, Mealey’s Emerging Drugs and Devices, Apr. 6, 2000, at 4.

<sup>8989</sup> *Id.*

<sup>9090</sup> *Texas Jury Rejects \$25 Million Rezulin Claim*, DRUG RECALL LR, Jan. 2001, at 1.

had provided adequate warning to physicians. This was not an efficient use of tort resources because, as discussed earlier, a jury is not adequately equipped to decide issues of drug safety. Instead, the jury should have decided two distinct issues. First, did the manufacturer provide complete safety information to FDA? If Parke Davis provided all of its safety data on Rezulin to FDA, then FDA was able to make an informed decision about whether to grant marketing approval. In this case, the threat of tort liability would not provide any additional protection to diabetics. Instead tort would provide at best a redundant process, and at worst an inconsistent decision that would only serve to needlessly punish Parke Davis for marketing a safe drug. However if Parke Davis did withhold safety information from FDA then its approval would be uninformed and therefore irrelevant. In this case, the manufacturer should be subject to ordinary tort liability. The second issue for the jury is whether the manufacturer exerted undue political influence over FDA's decision to approve Rezulin. If Parke Davis did successfully push for the removal of Dr. Guerigian then it should be subject to liability, because FDA's decision would be based on politics and not on an objective evaluation of the drug's safety. However if a jury found that Dr. Sobel had sound reasons for removing Guerigian then FDA approval should not be reviewed by a jury.

## **VI. Conclusion**

**VI. Conclusion** The current dual system of governance for drug safety will inevitably result in tort and FDA arriving at conflicting decisions. This conflict is inefficient and creates inconsistent safety standards, which can only result in confusion for pharmaceutical manufacturers and diminished protection for users of prescription drugs. Instead, tort and FDA should function in complementary roles determined by their relative strengths. FDA has scientific expertise and a broad regulatory perspective that make it the better institution to evaluate drug safety. Tort has much greater resources and political independence that



make it the better institution to decide whether FDA decisions were based on complete safety information. Tort can thus safeguard the process of FDA decision-making. This unified system of governance eliminates inconsistent standards of drug safety and promotes more efficient use of resources for the protection of patients.