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DRUG REVIEW “BEHIND THE CURTAIN”: A RESPONSE TO PROFESSOR STRUVE

James T. O’Reilly†

INTRODUCTION

The architecture of accident compensation does not mesh well with the architecture of regulatory product approval. Accident compensation, which occurs through public jury trials, is overtly adversarial and virtually transparent. In contrast, regulatory product approval,¹ which occurs through specific negotiation between the product sponsor and the regulatory body, is cooperative and consciously opaque.² Indeed, the content of regulatory negotiations remains hidden behind the curtain, shrouded in confidentiality rationales.³ Consequently, giving regulators a potentially determinative say in tort suits is highly problematic.

A decade-old debate is raging in product liability law over the proper role of Food and Drug Administration (FDA) approval of prescription drug designs and attendant warnings. Participants disagree about whether such approval establishes a “floor” or a “ceiling” that limits the sponsor’s duty of care.⁴ Into this debate steps Professor Catherine Struve, whose excellent article⁵ offers wall-to-wall coverage of the primary jurisdiction doctrine. Traditionally, regulatory product approval has set a floor, which is a minimum level for the sponsor’s duty of care.⁶ Accordingly, courts or juries in tort cases could find

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¹ Product approval includes the approval of new drug applications. See 21 U.S.C. § 355(a) (2000).

² Details of negotiations are not publicly disclosed to protect the confidentiality of product sponsors. See 5 U.S.C. § 552(b)(4) (2000) (excluding trade secrets from public reporting requirements of federal agencies); see also 21 C.F.R. § 314.430(b) (2007) (barring the FDA from publicly disclosing a drug application until an approval letter has been sent to the drug sponsor).

³ For example, Freedom of Information Act exemptions are available to the FDA. See 5 U.S.C. § 552(b)(3)–(5) (2000); see also 1 JAMES T. O’REILLY, FEDERAL INFORMATION DISCLOSURE § 14:93 (3d ed. Supp. 2007).

⁴ See, e.g., W. Kip Viscusi et. al., *Detering Inefficient Pharmaceutical Litigation*, 24 SETON HALL L. REV. 1437, 1478–79 (1994) (arguing that approval should establish a ceiling on manufacturers’ duty of care).

⁵ Catherine T. Struve, *Greater and Lesser Powers of Tort Reform: The Primary Jurisdiction Doctrine and State-Law Claims Concerning FDA-Approved Products*, 93 CORNELL L. REV. 1039 (2008).

⁶ See RESTATEMENT (THIRD) OF PRODUCTS LIABILITY § 4(b) cmt. e (1998); RESTATEMENT (SECOND) OF TORTS § 288C (1965) (“Compliance with . . . an administrative regulation does not prevent a finding of negligence where a reasonable man would take

that reasonable care requires drug makers to use safer ingredients, additional warnings, or more stringent controls.⁷ Courts have permissibly imposed such heightened duties of care for decades while the FDA has been reluctant to take sides.⁸ But recently, as Professor Struve notes, the FDA has viewed its approval as creating a ceiling with its sharp swing toward supporting the preemption doctrine, which interposes a defense for drug makers whose drugs have received FDA approval.⁹

Support for implied preemption¹⁰ appears to be in fashion among conservative political leaders because it can extinguish liability suits.¹¹ Bush Administration appointees include recent FDA Commissioners Andrew von Eschenbach and Mark McClellan—both Bush supporters from Texas¹²—as well as conservative FDA counsel.¹³ These and other Bush appointees have led to a shift in FDA policy, which now supports the implied preemption doctrine. Yet, despite this shift, drug industry advocates have failed to persuade skeptical

additional precautions.”); *see also* Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 14–15 (1973) (describing the FDA policy of creating an “irreducible minimum” of risk to certain patients).

⁷ The landmark case establishing the additional duty to warn is *Feldman v. Lederle Laboratories*, 479 A.2d 374 (N.J. 1984). Indeed, the traditional rule was that “‘compliance with regulations or directives as to warnings, such as those issued by the United States Food and Drug Administration . . . , may not be sufficient to immunize the manufacturer or supplier of the drug from liability.’” *Plenger v. Alza Labs.*, 13 Cal. Rptr. 2d 811, 819 n. 7 (Cal. Ct. App. 1992) (quoting *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973)).

⁸ In fact, the FDA consistently rejected preemption prior to 2006. *See* James T. O’Reilly, *Losing Deference in the FDA’s Second Century: Judicial Review, Politics and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 967–72 (2008) (outlining the history of the preemption doctrine in medical products liability cases).

⁹ *See* Struve, *supra* note 5, at 1040–42; *see also* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006).

¹⁰ The preamble to the new labeling regulation acknowledges that Congress has not expressly provided for preemption, but it argues that Congress has impliedly provided for preemption because preemption allows the FDA to consistently apply the federal drug labeling regulations. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3922; *see also* Timothy Ardizzone, Comment, *The FDA: Advocate or Regulator of the Pharmaceutical Industry?*, 75 U. CIN. L. REV. 763, 766–68 (2006).

¹¹ *See, e.g.*, Daniel E. Troy, *The Case for FDA Preemption*, in FEDERAL PREEMPTION: STATES’ POWERS, NATIONAL INTERESTS 81, 100–05 (Richard A. Epstein & Michael S. Greve eds., 2007).

¹² Von Eschenbach was an official at the University of Texas. *See* Bio of Andrew von Eschenbach, M.D., <http://www.fda.gov/oc/voneschenbach/bio.html> (last visited Apr. 9, 2008). McClellan’s family held significant public offices in Texas. *See* Lisa Trei, *Bush Nominates Mark McClellan to Head the FDA*, STAN. REP., Oct. 1, 2002, <http://news-service.stanford.edu/news/2002/october2/fda-102.html>.

¹³ *See* Jeanne Lenzer, *FDA’s Counsel Accused of Being Too Close to Drug Industry*, 329 BRIT. MED. J. 189, 189 (2004) (describing criticisms of FDA counsel Daniel Troy, a Bush appointee).

judges to adopt the doctrine.¹⁴ Consequently, drug industry advocates have now turned their support to an approach based on primary jurisdiction, which Professor Struve discusses in her article.¹⁵ Professor Struve prudently avoids embracing these advocates' positions.¹⁶

CONSTITUTIONAL AND PRACTICAL DIMENSIONS

I concur with Professor Struve's thorough review of the constitutional issues surrounding primary jurisdiction. There has been ample writing on the Seventh Amendment issues and on the constitutional conflicts that arise in preemption cases,¹⁷ and she admirably covers the cases in the field. Professor Struve constructs hypothetical legislation as a helpful paradigm for evaluating the agency's role in the context of jury trials.¹⁸ Her analysis is an interesting exercise in what-if legislating. Realists, however, would observe that many congressional decision makers were once state legislators¹⁹ and thus likely remain opposed to federal bureaucrats preempting state remedies. This opposition may well be one reason why Congress has never expressly adopted the preemption doctrine. Indeed, opposition on the part of Congress and the plaintiffs' bar²⁰ combines to make the discussion of such legislation hypothetical, not imminent.

But beyond Professor Struve's exploration of the constitutional issues surrounding what *could* be done are the practical constraints on what *should* be done. No drug or medical device can be perfectly risk-free.²¹ Even worse, some have extensive, serious risks of harm that manufacturers understate or improperly explain to prescribing physicians. Consequently, some patients will inevitably become victims of unreasonably harmful or badly-prescribed drugs and medical devices. And of course, some of those victims will ultimately seek compensation.

¹⁴ Senior Judge Jack Weinstein, for example, called the FDA's new preemption claims "not persuasive." *Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 489 F. Supp. 2d 230, 273 (E.D.N.Y. 2007).

¹⁵ See Struve, *supra* note 5.

¹⁶ See *id.*

¹⁷ See, e.g., JAMES T. O'REILLY, FEDERAL PREEMPTION OF STATE & LOCAL LAW § 12.5 (2006).

¹⁸ See Struve, *supra* note 5, at 1064–66.

¹⁹ For example, 39 Senators and 236 Representatives in the 109th Congress had previously served in state legislatures. See MILDRED AMER, MEMBERSHIP OF THE 109TH CONGRESS: A PROFILE, at CRS-3 (2006), available at <http://www.senate.gov/reference/resources/pdf/RS22007.pdf>.

²⁰ See Louis M. Bograd, *Taking on Big Pharma—and the FDA*, TRIAL, Mar. 2007, at 30.

²¹ The classic description in tort law is that some prescription drugs are "unavoidably unsafe." RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). If such drugs have a net social benefit and appropriate warning labels, however, they can be sold on the market without the seller being held strictly liable for the resulting harm. *Id.*

The Bush Administration policy supporting preemption is as much about economic loss shifting as it is about politics. Precluding compensation to victims decreases drug sponsors' insurance costs,²² and thus increases the potential profitability of engaging in the high-risk quest of making novel, effective drugs. Absolute bars to recovery in tort claims involving FDA-approved drugs and medical devices, through preemption, would save hundreds of millions of dollars in transaction costs including insurance and legal fees. Congress surely recognizes this economic loss shifting, and yet—despite the efforts of drug industry lobbyists²³—Congress has declined to expressly preempt state tort actions involving prescription drugs in the same manner as it has preempted similar actions involving nonprescription drugs.²⁴

THE HYPOTHETICAL LEGISLATION

Professor Struve addresses hypothetical legislation that would define an additional task for the FDA, namely, acting as the “primary jurisdiction” gatekeeper for tort suits involving drug and medical devices.²⁵ In a procedure analogous to those created under state laws, which compel medical screening boards to review malpractice claims initially, a plaintiff would have to wait while the drug label or design at issue was referred “to the FDA for a non-binding advisory determination.”²⁶ Presumably, a drug sponsor would gain a great advantage if the FDA found that sponsor's product reasonably formulated or that sponsor's label appropriate.

The problem with this hypothetical legislation is that it is hard to imagine an FDA determination that would not favor the defendant, because the FDA previously approved the drug, device, or label at issue. An FDA bureaucrat would implicitly admit failure by formally blessing a lawsuit that alleges that an FDA-approved drug or device was unsafe or inadequately labeled. The likelihood that a highly politicized FDA management would support plaintiffs in product liability actions during a conservative administration is minimal. And even under a more liberal administration, bureaucratic self-esteem is

²² It decreases insurance costs by decreasing the demand for products liability insurance. This demand shift, however, likely lags behind the creation of new legislative shields, as pre-enactment injuries would continue to be litigated for several years. Industry advocates successfully lobbied for new legislation in Ohio in 2005, but decreases in insurance costs did not occur immediately upon enactment. *See generally* James O'Reilly, 2005 OHIO TORT REFORM 23–28 (2005) (describing the reforms).

²³ *See, e.g.*, Bograd, *supra* note 20, at 20.

²⁴ *See* Federal Food, Drug, and Cosmetic Act § 751, 21 U.S.C. § 379r (2000) (expressly preempting state tort actions involving nonprescription drugs, but remaining silent on preemption of state tort actions involving prescription drugs).

²⁵ *See* Struve, *supra* note 5, at 1064–66.

²⁶ *Id.* at 1064.

so great that the FDA would still probably decline to support plaintiffs, because supporting plaintiffs would be supporting claims contrary to the prior approval of bureaucratic peers.

The hypothetical legislation creates a new form of adjudication that transforms the FDA from the gatekeeper of product approval into the gatekeeper of private tort actions.²⁷ Why would the FDA concede weakness in its own approval process, which allowed such products and labels into the market in the first place? Furthermore, the lives of plaintiffs and FDA regulators likely intersect only once, whereas the lives of defendant manufacturers and FDA regulators intersect repeatedly. And the "critical path" process will move FDA regulators and defendant manufacturers even closer together through Reagan-Udall Institute research grants.²⁸ Moreover, users of the "revolving door," which has led FDA counsels and other leaders to move in and out of the ranks of drug industry advocates,²⁹ would be directly offended by decisions supporting plaintiffs' claims that a drug or device was unsafe or inadequately labeled.

ERRONEOUS ASSUMPTIONS

Professor Struve's enlightening article makes several important points that will help courts navigate this swamp of uncharted territory. I agree with her that FDA approval is "at most, prima facie evidence" of a drug's safety,³⁰ but I am even more skeptical than she is about the wisdom of foreclosing jury review of tort claims involving prescription drugs and medical devices. The primary jurisdiction doctrine is flawed because it is based on the same erroneous assumptions about the FDA approval process that underlie parallel arguments for the preemption doctrine—arguments that drug industry advocates have pressed during the current Bush Administration.³¹

Indeed, the primary jurisdiction doctrine suffers the same flaws as the preemption doctrine, which I address elsewhere in this issue.³² In the climax of a classic motion picture, the Wizard of Oz spoke to

²⁷ See *id.*

²⁸ Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 770, 121 Stat. 823, 891 (to be codified at 21 U.S.C. § 379dd). The Reagan-Udall Foundation, created by statute, provides for collaborative research opportunities between the FDA and drug companies. See *id.* Commentators have criticized the venture, as they remain suspicious of the agency working closely with those that it is meant to regulate. See, e.g., Richard A. Miller, *Innovating the FDA—With the Drug Industry's Help?*, HUFFINGTON POST, Nov. 13, 2007, http://www.huffingtonpost.com/richard-a-miller/innovating-the-fda-wit_b_72490.html (identifying criticisms of the program but ultimately supporting it).

²⁹ See Troy, *supra* note 11, at 106 n.4.

³⁰ Struve, *supra* note 5, at 1049.

³¹ See, e.g., *Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 489 F. Supp. 2d 230, 273–74 (E.D.N.Y. 2007); see also Bograd, *supra* note 20, at 30.

³² See generally O'Reilly, *supra* note 8, at Part XIII.

frightened pilgrims in a booming voice, accompanied by smoke and majesty. But when the heroine's dog unveiled a small, old man manipulating the mechanical image from behind a curtain, Oz's booming voice warned, "Pay no attention to that man behind the curtain!"³³ In the same way, the defense bar, in search of a preemption defense,³⁴ has urged courts to defer to the FDA review process and to pay no attention to its hidden weaknesses. Importantly, the preemption defense can leave injured consumers without any recourse. If a plaintiff claims that the FDA overlooked the flaws in a drug, the defendant responds that primary jurisdiction requires deference to the initial FDA approval. And if the plaintiff claims that the FDA was misled when it issued its initial approval, the defendant responds by citing the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*³⁵ to bar any recourse. Checkmate!

IMPERFECTIONS OF THE APPROVAL PROCESS

Ironically, the drug industry has spun around from its years of opposition to FDA regulatory decisions, recently asserting that the new drug approval process is pure and deserving of deference, now that approval is a potential defense in medical tort cases.³⁶ Studies,³⁷ congressional reports,³⁸ and news coverage,³⁹ however, have shown that the prescription drug approval process is imperfect and quite susceptible to influence, leading to drug approval based on questionable efficacy claims. This showing undermines the drug industry's assertion that the new approval process is pure and deserving of deference.

³³ THE WIZARD OF OZ (Warner Bros. 1939).

³⁴ See, e.g., Troy, *supra* note 11, at 106 n.4.

³⁵ 531 U.S. 341 (2001). Under *Buckman*, federal law preempts a plaintiff's state tort claim if the plaintiff asserts that the FDA was misled. See *id.* at 348.

³⁶ Prior to current preemption assertions, drug defendants opposed the deferential acceptance of FDA drug application decisions. See, e.g., *Am. Cyanamid Corp. v. FDA*, 606 F.2d 1307, 1323-24 (D.C. Cir. 1979).

³⁷ See, e.g., U.S. GOV'T ACCOUNTABILITY OFFICE, DRUG SAFETY: FDA NEEDS TO FURTHER ADDRESS SHORTCOMINGS IN ITS POSTMARKET DECISIONMAKING PROCESS (2007), available at <http://www.gao.gov/new.items/d07599t.pdf>; FDA, FDA SCIENCE AND MISSION AT RISK (2007), available at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA_Report_on_Science_and_Technology.pdf; INST. OF MED. OF THE NAT'L ACADEMIES, THE FUTURE OF DRUG SAFETY: ACTION STEPS FOR CONGRESS (2006), available at http://www.iom.edu/Object.File/Master/37/331/11750_report_brief_congress.pdf.

³⁸ Recent congressional reports critical of the FDA drug process include MINORITY STAFF OF H. COMM. ON GOV. REFORM, SPEC. INVESTIGATION DIV., PRESCRIPTION FOR HARM (2006), available at <http://oversight.house.gov/documents/20060627101434-98349.pdf>.

³⁹ Published criticism of the FDA drug approval process has been frequent among advocates for patients. See e.g., Allison Torres Burtka, *Jurors and FDA Scientists Lack Confidence in Agency, Surveys Say*, TRIAL, Oct. 2006, at 20; Robert K. Jenner, *Rezulin: Fast Track to Failure*, TRIAL, July 2000, at 39; Rita Rubin, *FDA Called 'Cozy' with Drugmakers*, USA TODAY, June 11, 2007, at 7D; Carmel Sileo, *FDA's Oversight of Drug Trials is Dangerously Lax, Report Says*, TRIAL, Dec. 2007, at 17.

Moreover, it makes the drug industry seem Oz-like, given its aversion to allowing plaintiffs to reveal the behind-the-curtain claims that led to approval, instead hoping to reveal only the booming voice of the approval decision.

Experienced skeptics will object to the suggestion that primary jurisdiction somehow permits the FDA to "intermediate" tort claims, just as they have loudly objected to the preemption doctrine.⁴⁰ Such skeptics might point out that current time limits on reviews and certain intra-agency incentives⁴¹ have strengthened the drug industry's influence over the drug approval decision. The new 2007 Reagan-Udall Institute process further strengthens this influence.⁴² And the drug industry has now gained influence over critical FDA post-approval remedy decisions, such as whether to require additional warnings and restraints on the distribution and prescription of newly approved drugs.⁴³

I applaud Professor Struve's recommendation for a greater evidentiary exposition of the FDA, which would allow juries to weigh some of the weaknesses in the approval process. This would certainly be an improvement. Yet, despite the benefits inherent in Professor Struve's proposal, a better recommendation would be to make no change at all. As is the case in most other product liability contexts, the current approach allows juries to weigh all of the competing factual and opinion evidence.

WHAT REALLY OCCURS

Under Professor Struve's hypothetical legislation, a plaintiff faces "dismissal of the claim as a matter of law if the plaintiff *failed to present evidence to rebut an FDA finding* in the defense's favor on safety or causa-

⁴⁰ See e.g., Allison M. Zieve & Brian Wolfman, *The FDA's Argument for Eradicating State Tort Law*, 34 *Prod. Safety & Liab. Rep.* (BNA) 308 (Mar. 27, 2006).

⁴¹ Reviewer incentives inside the FDA Center for Drug Evaluation and Research tend to favor approval without recycling the application—i.e., without making further demands for data from the drug sponsor. This ensures that the reviewer can satisfy the specified time periods for application clearance under the Prescription Drug User Fee Act. Reviewers are hesitant to recycle an application because of "strong criticism the agency has received for prolonged review times." See *CTR. FOR DRUG EVAL. & RESEARCH, NEW DRUG GUIDANCE DOCUMENT: REFUSAL TO FILE 2* (1993), available at <http://www.fda.gov/cder/guidance/rtf.pdf>.

⁴² Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 770, 121 Stat. 823, 891 (to be codified at 21 U.S.C. § 379dd); see *supra* note 28 and accompanying text.

⁴³ Negotiations between the FDA and drug sponsors are vulnerable to legislative provisions that have increased the sponsor's ability to argue against additional testing requirements. See § 104, 121 Stat. at 832. Recent amendments to the drug application process produced more favorable terms for the industry in the negotiation of new drug advertising claims. See *id.*

tion.”⁴⁴ This would be a novel adjudication⁴⁵ in which the FDA would likely struggle to decide the cause of death or illness in the time allotted. Of course, causation is fact-specific. And the vast majority of reports to official databases such as MedWatch and the Manufacturer and User Facility Device Experience (MAUDE) are unwieldy and unfiltered narrative paragraphs, or forms.⁴⁶ In most cases, these reports do not lead the FDA to dispatch a local inspector, and a physician specializing in pathology or disease causation rarely assesses the plaintiff’s medical records.

The typical person files a MedWatch report to the FDA without substantive interaction with the agency. Indeed, the FDA remains passive if the reporting person marks “Product Use Error” or “Product Problem” in Box B-1 on FDA Form 3500.⁴⁷ Under the primary jurisdiction doctrine, only after a plaintiff files suit—perhaps as long as twelve to twenty-four months after injury and six to twelve months after the court processes the initial pleadings—would the district court formally refer the case to the FDA. Presumably, the FDA would then have several months to respond.

FUNDING THE COLD CASE SQUAD

The hypothetical legislation sets up a new process of adjudication by the FDA. A “cold case squad” of FDA physicians would try to determine the causation of the plaintiffs’ injuries from MedWatch narratives or the MAUDE database files. To perform this new process of adjudication, the FDA would require more funding for field office staff, more funding for specialists, and more funding for a dedicated expert team to examine MedWatch entries from several years before the initial FDA finding. This would result in three separate versions of causation: the plaintiff’s, the defense’s, and the FDA’s—the latter being the least funded and least timely of the three.

⁴⁴ Struve, *supra* note 5, at 1066 (emphasis added).

⁴⁵ Under the Administrative Procedure Act, this is an “adjudication” because it is a fact-specific determination concerning specific persons’ injuries. See 5 U.S.C. § 551(1) (2000).

⁴⁶ MedWatch and Manufacturer and User Facility Device Experience (MAUDE) are the principal FDA databases for reporting adverse health effects of drugs and medical devices. MedWatch, which gathers reports from doctors and patients and disseminates important safety information through its website, is available at <http://www.fda.gov/medwatch/index.html> (last visited Apr. 10, 2008). MAUDE, which contains voluntary facility, distributor, and manufacturer reports involving medical devices, is available at <http://www.fda.gov/cdrh/maude.html> (last visited Apr. 10, 2008).

⁴⁷ Form 3500 is available at <http://www.fda.gov/medwatch/SAFETY/3500.pdf> (last visited Apr. 10, 2008).

THE HUMAN AND OPPORTUNITY COSTS

We must consider the human consequences of investing substantial FDA reviewer time and field inspector resources to produce a finding that would most likely favor the defendant manufacturer.⁴⁸ Under the above scenario, the injured party must either go uncompensated and bear the loss or survive on government disability payments (which the government can never recoup from the accused tortfeasor). Although the defendants and defense counsel profit, the plaintiffs' counsel—likely working for a contingency fee—go unpaid, and are therefore deterred from pursuing future drug cases.

We must also consider the opportunity costs. For example, every dollar that the FDA spends on saving a defendant from facing a jury trial is another dollar that the FDA is not able to spend on application or labeling review for new drug products. Moreover, the Administrative Procedure Act might allow plaintiffs to appeal for injunctive relief from FDA findings, further draining FDA resources.⁴⁹

THE LESSER OF TWO EVILS

Primary jurisdiction, like implied preemption, limits the ability of drug and device victims to obtain tort compensation.⁵⁰ Nonetheless, primary jurisdiction is a kinder, gentler version of preemption. Instead of an abrupt preemptive strike that absolutely prohibits compensation, primary jurisdiction is an affirmative defense that allows for judicial balancing.⁵¹ Professor Struve's hypothetical legislation allows the trial judge to hear both sides argue about the primacy of the FDA's opinions on the safety of a drug or medical device, and the product's causal relationship to the plaintiff's injury.⁵² The judge can then opt to defer to the "primary" wisdom of the FDA, which might result in dismissal.⁵³ Alternatively, the judge could opt to let the jury hear the FDA's safety and causation opinion.⁵⁴

When making key decisions on primary jurisdiction claims during a drug tort case, the judge should decide whether the FDA made its initial approval decision with as much information as is available during trial. Thus, the judge's decision should allow for civil discovery of the defendant's medical knowledge before and after FDA approval. Discovery could reveal evidence of drug safety doubts within the con-

⁴⁸ See *supra* notes 26–29 and accompanying text.

⁴⁹ Final agency action on the requested FDA determination would be reviewable. See 5 U.S.C. § 706(2)(A) (2000).

⁵⁰ See *supra* notes 10–16, 26–27 and accompanying text.

⁵¹ See *supra* notes 9, 25–26 and accompanying text.

⁵² See Struve, *supra* note 5, at 1066.

⁵³ See *id.*

⁵⁴ See *id.*

tract research organization, the hospital that housed the clinical study, the manufacturer itself, or inside the medical community. Allowing the jury to hear such doubts and the defendant's responses to them would more justly resolve tort disputes than giving the defense a preemptive strike with every FDA approval letter.

WHAT EXPERIENCE TEACHES

Decades of experience with many federal agencies teaches that, when a judge asks, an agency will invariably assert that regulatory approval sufficiently assures the public of the adequacy of the regulated product. When drug industry counsel asserts the primary jurisdiction defense, the trial judge should keep in mind that the defendant's approval negotiations with the FDA preceded the injury by several years. Thus, the scientific knowledge about the risks of that drug will likely have improved by the time of trial.

Delay is inherent to the system of drug products liability. Prescribing physicians usually provide data on the adverse effects of drugs and devices to the product sponsor before they provide them to the FDA. So too, sponsors likely pay much closer attention to the marketplace experience of their drug than the actual capability of the FDA reviewing division. If the sponsor consciously misleads the FDA or selectively shares safety data with the FDA, the agency might in rare cases charge fraud;⁵⁵ however, courts have not permitted plaintiffs to use claims of fraud on the FDA to support their cause of action.⁵⁶

NEGOTIATIONS LEAD TO APPROVAL

The fallacy that underlies the preemption debate⁵⁷ is that all drug approvals reflect a measured scientific evaluation. But veterans of the system will confess that approval of specific drugs often results from great advocacy and only modest data.⁵⁸ For example, well-argued, persistent efforts to gain approval might move the Office of Drug Evaluation to sign off on a drug, even over objections from re-

⁵⁵ See Federal Food, Drug, and Cosmetic Act § 702, 21 U.S.C. § 372 (2000) (empowering the FDA to investigate fraud); see also *id.* §§ 302, 303(a), 303(f)(1)(A), 304(a)(2)(D), 332, 333(a), 333(f)(1)(A), 334(a)(2)(D) (empowering the FDA to respond in various ways to findings of fraud).

⁵⁶ See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (concluding that Congress has preempted "fraud-on-the-FDA claims").

⁵⁷ Elsewhere in this issue, I dissect the controversial attempt of the drug industry to stretch the limits of the implied preemption doctrine during the current Bush Administration. See O'Reilly, *supra* note 8, at Part III.

⁵⁸ I am not suggesting that the FDA routinely approves bad drugs. Rather, I am suggesting that, based on my observations during more than three decades working with the FDA review process, advocacy is a very important factor in drug approval—perhaps even more important than the sufficiency of data in support of clinical testing end points.

viewers in the specialized drug review divisions.⁵⁹ Although records of this are discoverable, they are often exempt from public disclosure.⁶⁰ Thus, the public generally sees only the Wizard side of the Oz-like FDA, not the FDA action behind the curtain that actually led to approval.

Some preemption advocates seem to view the FDA's new drug approval process as analogous to the religious rituals for conferring sainthood inside the Vatican. To knowledgeable observers of the FDA, however, the negotiation of a new drug application (NDA) is every bit as subjective and eclectic as any governmental choice can be. Before the government building security upgrades of the last decade, "hall-walker" representatives from the several major drug companies had easy access to the offices of drug reviewers. At lunch and dinner conversations, drug company representatives and drug reviewers debated the need for greater efficacy proofs, and final label approval was as much an art of negotiation as it was a science of clinical data analysis. The hall-walker "won" when the drug company received the final approval letter,⁶¹ which allowed it to immediately ship the stockpiled product filling its warehouses into the waiting distribution channels of the market. The bribery and fraud cases of FDA drug approvals in 1989,⁶² however, ultimately led to the establishment of a more formalized system of drug sponsor and drug reviewer interactions.

That said, there is a procedural benefit to Professor Struve's proposed system. Preemption advocates have sometimes naively assumed that the motives behind NDA reviewer actions were pure, not even allowing for a hearing to examine the initial approval. In contrast, primary jurisdiction advocates would at least allow for a hearing at which opponents could expose the realities of the initial approval

⁵⁹ The FDA's internal personnel rewards program and its recognition of those managers who meet the Prescription Drug User Fee Act of 1992 (PDUFA) schedules also affect the agency's level of resistance to drug approval. Federal Food, Drug, and Cosmetic Act § 736, 21 U.S.C. § 379h.

⁶⁰ See 21 C.F.R. § 314.430(g) (2007) (listing data and information that is unavailable for public disclosure).

⁶¹ See 21 C.F.R. § 314.105(d) (stating that one cannot introduce a drug into interstate commerce without first receiving an approval letter).

⁶² In 1994, prosecutors obtained nine guilty pleas and a tenth conviction after investigators discovered that FDA reviewers had received cash in return for approval actions. See *Prison Term for Inspector in Bribe Case*, N.Y. TIMES, Dec. 18, 1994, at A55. In response, FDA leaders committed to strengthen the ethical conduct of the review process. See David A. Kessler, *Remarks by the Commissioner of Food and Drugs*, 50 FOOD & DRUG L.J. 327, 327 (1995) (stressing his duty to "rebuild the agency's credibility after the generic drug scandal"); Louis W. Sullivan, *Remarks by the Secretary of Health and Human Services at the Food and Drug Law Institute's 33rd Annual Educational Conference*, 45 FOOD DRUG COSM. L.J. 1, 4 (1990) ("I am . . . troubled by the revelation of illegalities [that] threaten to compromise the integrity of the FDA. . . . I will not tolerate bribery, fraud, or other illegalities or improprieties.").

before a judge could find the approval process sufficient and hold that the plaintiff's claim was preempted.

GATEKEEPER ROLES

Primary jurisdiction has as its core the displacement of juries' opinions on the adequate safety of drugs with judges' acceptance of FDA scientific assessments of product risks and benefits. The societal choice reflected in the 1938 Act and its several amendments⁶³ was that there should be a technical gatekeeper to evaluate drug company submissions.⁶⁴ But as the FDA's drug review process has become more complex, the Act has required increasingly more skilled reviewers than Congress has been willing to fund.⁶⁵ This problem led to the Prescription Drug User Fee Act of 1992 (PDUFA).⁶⁶ While the shortage of personnel and expertise has improved somewhat in the post-PDUFA era, FDA review is still not the idealized calculus of pure science that outsiders might presume.

Consider what juries and expert witnesses see in the exhibits at a drug tort trial. The incentive for a plaintiff to prevail on a failure-to-warn claim drives an extensive presentation about adverse data in the NDA file.⁶⁷ But even by the time of the plaintiff's injury, which is often years after the drug was marketed, all relevant data on the drug still may not have reached the FDA.⁶⁸ And the plaintiff's experts, who may once have been drug review officials inside the FDA, might opine to the jury about the relevance of the unreported information to the decision process as a whole. Finally, the defendant is free to blast back against the plaintiff's aggressive search for records.

⁶³ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 (2000).

⁶⁴ For the historical background of the 1938 Act's gatekeeper role, see 1 JAMES T. O'REILLY, *FOOD AND DRUG ADMINISTRATION* §§ 3:4, 13:2 (3d ed. 2007).

⁶⁵ See Gardiner Harris, *For F.D.A., a Major Backlog Overseas*, N.Y. TIMES, Jan. 29, 2008, at A15 ("In the last 14 years, the drug agency has lost 1,311 employees and nearly \$300 million in appropriations to inflation while Congress has passed more than 100 laws defining or expanding its regulatory responsibilities.").

⁶⁶ Pub. L. No. 102-571, 106 Stat. 4491.

⁶⁷ Much of the failure-to-warn litigation relates to the gap between the time of the defendant's notice of the risk and the time that the defendant communicated the risk to prescribing physicians. See JAMES M. BECK & ANTHONY VALE, *DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK* § 2.04[1] (2004).

⁶⁸ The 2007 amendments to the PDUFA may, however, improve the quantity and timeliness of incoming risk reports. See Prescription Drug User Fee Amendments of 2007, Pub. L. No. 110-85, 121 Stat. 823, 825 (2007) (amending 21 U.S.C. §§ 379g-379h (2000)) (expanding the duty to provide adequate post-marketing information about drugs). In addition, the parties could find more of the data on post-approval experiences by searching company and contractor files obtained in civil discovery.

DISCOVERY IS BETTER THAN VOLUNTARY SUBMISSIONS

Overall, the expensive, messy, and difficult process of civil discovery does a better job of uncovering flaws in drug approval decisions than does the FDA's time-sensitive drug review process. Contingency-fee arrangements give the plaintiff's attorneys direct incentives to discover facts relevant to causation: if the manufacturer did not cause the plaintiff's injury, then the plaintiff's attorney will not want to pursue the claim because it has a high risk of nonpayment.

Conversely, in the FDA process, reviewers have an incentive to act quickly⁶⁹ and, as a result, a disincentive to find flaws and identify shortcomings in drug applications. Moreover, the applicant's funds ultimately pay for the FDA drug reviewer's salary, albeit indirectly via the wizardry of federal accounting practices.⁷⁰ For example, the FDA ties the individual reviewer's rewards to the "productivity" of review and approval⁷¹—potentially creating a great conflict of interest. In the current climate of faster clearance times, FDA reviewers have a disincentive to criticize drug industry data presentations.

Moreover, plaintiffs have an incentive to use experts to find the flaws in a new drug application even though the FDA may have missed them. With these contrasting incentives in mind, I question why the courts would use a doctrine like preemption or primary jurisdiction to lessen the jury's role in determining the adequacy of warnings.

⁶⁹ See FDA, OFFICE OF PLANNING AND EVALUATION, FY 1998 PERFORMANCE REPORT TO CONGRESS app. B [hereinafter FDA, FY 1998 PERFORMANCE REPORT TO CONGRESS], available at <http://www.fda.gov/ope/pdufa/report98/appendb.htm> (last visited Apr. 10, 2008) (establishing twenty-nine performance goals based on timing).

⁷⁰ The statutory reauthorization of PDUFA provides for much of the funding of the drug review process. See § 103(e), 121 Stat. at 831. In recent years, congressional critics have noted that fifty percent of FDA drug regulation budgets came from user fees. See, e.g., Maurice Hinchey, Improving the Food and Drug Administration, http://www.house.gov/hinchey/issues/fda_reformbill.shtml (last visited Apr. 10, 2008); see also Food and Drug Administration Improvement Act of 2005, H.R. 2090, 109th Cong. (2005) (arguing that fees paid by drug manufacturers should be placed in the general treasury). Now, FDA drug review funding comes from the allocation of receipts of the user fee payments under PDUFA, rather than from the more traditional budget appropriations of general fund tax receipts. See OFFICE OF MGMT. & BUDGET, THE BUDGET FOR FISCAL YEAR 2009, at 67–68 (2008), available at <http://www.gpoaccess.gov/usbudget/fy09/pdf/budget/hhs.pdf>; see also OFFICE OF MGMT. & BUDGET, THE BUDGET FOR FISCAL YEAR 2007, at 123 (2006), available at <http://www.gpoaccess.gov/usbudget/fy07/pdf/budget/hhs.pdf> ("Since the authorization of the Prescription Drug User Fee Act of 1992, the collection of fees has been critical in leading to performance improvement in drug review.").

⁷¹ Critics of the PDUFA process have argued that FDA perceptions are skewed in favor of approval. Representative Maurice Hinchey has been a stalwart critic of the administration of the fee-based drug approval process. See Maurine Hinchey, *Hinchey Introduces Sweeping FDA Reform Measure*, May 10, 2007, http://www.house.gov/apps/list/press/ny22_hinchey/morenews/051007FDAIAintro.html (last visited Apr. 10, 2008) (arguing that the FDA is not fully accountable to U.S. taxpayers because it must collect fees from drug companies in order to fully function).

PROBLEMS WITH DIVERTING CASES

The recent suggestion by a drug industry defense counsel that the FDA should initially assess failure-to-warn tort claims⁷² is an unrealistic diversion for three reasons. First, more facts will always be available at the time of injury than on the time of approval.

Second, because of its limited resources, the FDA could not prioritize tort-based inquiries. In the past, all FDA employees received their salaries from the federal government's domestic discretionary budget.⁷³ Today, in contrast, the PDUFA statutory scheme rewards the leaders of the drug review division for complying with a congressionally set timetable.⁷⁴ Because PDUFA does not reward tort claim referrals, the FDA would not likely receive sufficient resources to support Professor Struve's hypothetical legislation. Granted, such legislation could devote money from user fees to pay for FDA screening of litigated claims. But this would diminish the primary role intended for these funds by PDUFA.⁷⁵

Last, an FDA team separate from the approving division conducts post-marketing review of new drug experiences, in the conscious separation of functions.⁷⁶ This team's workload has already begun to grow. It is unclear whether adding tort referrals to the team's responsibilities would lead to a full appraisal of risks, or simply to a restatement of the self-serving rationale that led to the initial approval.

CONCLUSION

Professor Struve's article merits close attention from courts faced with a defensive claim of FDA primary jurisdiction. If Congress passes her hypothetical legislation, should the courts defer and await FDA evaluations? I think not, because the FDA is not likely to give a timely or unequivocal response to such referrals. The costs of further litigation delay and the high likelihood of an equivocal response make Professor Struve's proposal less desirable than the current method of airing opposing views before a jury.

We must acknowledge that the drug approval process is a series of intense negotiations. The FDA is no Oz, and those who would with-

⁷² See William A. Dreier, *Liability for Drug Advertising, Warnings, and Frauds*, 58 RUTGERS L. REV. 615, 644 (2006).

⁷³ See OFFICE OF MGMT. & BUDGET, THE BUDGET FOR FISCAL YEAR 2008, at 71 (2007), available at <http://www.gpoaccess.gov/usbudget/fy08/pdf/budget/hhs.pdf>.

⁷⁴ See FDA, FY 1998 PERFORMANCE REPORT TO CONGRESS, *supra* note 69.

⁷⁵ Litigation screening is not included among the functions to be paid by the fees. See Federal Food, Drug, and Cosmetic Act § 735(7), 21 U.S.C. § 379g(7) (2000).

⁷⁶ See U.S. Food and Drug Administration, The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective, http://www.fda.gov/fdac/features/2002/402_drug.html (last visited Apr. 10, 2008).

hold tort remedies from juries must justify their position in light of these realities. The better solution is to let the jury look behind the curtain.

