

THE FDA AND DEFERENCE LOST: A SELF- INFLICTED WOUND OR THE PRODUCT OF A WOUNDED AGENCY? A RESPONSE TO PROFESSOR O'REILLY

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INTRODUCTION

Professor James T. O'Reilly's article *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise* is a sweeping critique of the decline of the Food and Drug Administration (FDA), which until recently was considered one of the world's premier health and safety agencies.¹ According to Professor O'Reilly, the FDA's decline, resulting in what he contends is the diminishing judicial deference accorded to Agency determinations, is entirely the product of a self-inflicted wound—namely, the Bush Administration's politicization of the Agency at the expense of science.² To drive home his theory, Professor O'Reilly dissects two case illustrations: first, the Agency's unwarranted denial of approval for the over-the-counter sale to those under eighteen of the drug "Plan B," a postcoital contraceptive, to appease the Administration's anti-abortion constituency; and second, the Agency's complete about-face on its

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¹ 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 (2008) (describing the historical reputation of the Agency); see also Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, in FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY app. B, at B-7 (2007), http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_02_FDA%20Report%20Appendices%20A-K.pdf (reporting results of Harris Polls rating the public confidence in the FDA: during the 1970s, eighty percent of the public had confidence in the Agency; in 2000, sixty-one percent reported confidence in the Agency; by 2006, the percentage of the public having confidence in the Agency had dropped to thirty-six percent).

² See O'Reilly, *supra* note 1, *passim*.

preemption policy, giving drug companies the insulation from tort litigation they have long coveted but could not get from Congress.³

Professor O'Reilly does not mince words. In his view, the Agency has fallen victim to a classic case of regulatory capture.⁴ The FDA is a science-based agency and, according to Professor O'Reilly, has historically been faithful to that mandate.⁵ However, in Professor O'Reilly's view, the FDA has been subject to a hostile takeover by an Administration that cares more about outcomes that serve its constituency than its statutory mission.⁶ To achieve its political goals, the Administration has appointed like-minded conservatives to run health and safety agencies, including the FDA.⁷ The senior appointees at the FDA (many of whom have returned through the revolving door to represent the pharmaceutical industry) disregarded or marginalized the career scientists and policy experts who tried to get in their way.⁸ Key decisions, like those concerning Plan B and preemption, were made to benefit the Administration's constituents.⁹ Career Agency employees were then pushed to defend those decisions, often at the expense of science, agency morale, longstanding agency policy, and, ultimately, the Agency's credibility.¹⁰ The result, Professor O'Reilly claims, is that the Agency has squandered the respect that it had painstakingly earned from the courts, and thus the FDA will not receive the high level of deference that, in the past, virtually guaranteed judicial approval of its actions.¹¹

These are harsh claims to make. But Professor O'Reilly makes a convincing case, and his views command respect.¹² So, it is with some trepidation that I offer an amendment to Professor O'Reilly's self-inflicted wound theory. In my view, Professor O'Reilly is right that some of the blame for the decline in the FDA's prestige can properly be laid at the feet of the Bush Administration. I agree wholeheartedly with Professor O'Reilly that the Agency's policy reversal on preemption is

³ See *id.* at Parts XII, XIII.

⁴ *Id.* at Part XI; see, e.g., George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 11–13 (1971) (laying out the theory behind regulatory capture). See generally Symposium, *On Public Choice*, 74 VA. L. REV. 167 (1988) (compiling articles discussing public choice theory).

⁵ See O'Reilly, *supra* note 1, at Part V.

⁶ See *id.* at Part X.

⁷ See *id.*

⁸ See *id.*

⁹ See *id.* at Parts XII, XIII.

¹⁰ See *id.* at Part IX (describing the various forms of backlash against the FDA's shift towards an economics-driven view of policy).

¹¹ See *id.* at Part XV.

¹² Professor O'Reilly has been practicing food and drug law for over thirty years. He is the author of a leading treatise on the FDA, and has written scores of articles and essays on the FDA and administrative law. Curriculum Vitae, Professor James T. O'Reilly, <http://www.law.uc.edu/faculty/docs/oreilly.pdf>.

nothing short of an effort to give the pharmaceutical and medical device industry protection from tort litigation, and that the Plan B debacle, which was made to appease anti-abortion groups, was an insult to the FDA's scientific process. So we share common ground.

But we also part company in some important respects. I do not share Professor O'Reilly's view that the only reason for the Agency's decline and the declining deference it receives from courts is a handful of ill-considered, politically motivated decisions. Rather, the FDA's decline is inextricably tied to the slow erosion of the Agency's resources, coupled with a steady and unrelenting procession of new, congressionally imposed responsibilities.¹³ I agree that the FDA is a wounded agency, but I place much of the blame on Congress, which has simultaneously criticized the FDA for poor performance while also starving the Agency of the resources it needs to meet its burgeoning responsibilities. By 2001, if not before, the Agency did not have the necessary resources to fulfill its mission; it is the FDA's resource deficit, as much as regulatory capture, that is to blame for the string of regulatory failures that began then and have accelerated since. The FDA is chronically underfunded, overworked, incapable of effectively tackling the massive job Congress assigned it, and bereft of the leadership needed to defend itself in the court of public opinion. The decline of the FDA's prestige dovetails as much with its inability to safeguard the American people as it does with the Bush Administration's politicization of the Agency.

This Response presents three brief reflections on Professor O'Reilly's article. First, the most convincing argument for Professor O'Reilly's self-inflicted wound thesis is the Agency's ideological shift on preemption.¹⁴ Not only does it represent an instance in which this Administration repudiated the legal position taken by its predecessors—making the Bush Administration alone answerable for the consequences of its decision—but it is also a policy shift that, unlike Plan B, is not self-executing.¹⁵ Courts, and not the FDA, are the ultimate decision makers on preemption questions.¹⁶ Thus, for the FDA's new position on preemption to have operative effect, the Agency will have to persuade courts that its current position is legally sustainable. In deciding this question, courts will have to resolve whether the FDA's

¹³ See *infra* notes 44–53, 107–120 and accompanying text.

¹⁴ See generally *Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (Sept. 12, 2007) [hereinafter *Regulatory Preemption*] (statement of David C. Vladeck) (testifying on the FDA's new preemption policy); David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461 (2008) (offering an extended critique of the FDA's new position on preemption of drug claims).

¹⁵ See *infra* Part I.A.

¹⁶ See *infra* Part I.B.

new position warrants deference; thus far, courts are deeply split on the issue.

Second, the Agency's shift in position on preemption could not have come at a less propitious time. At the same time the FDA is contending that state tort law (and the discipline it places on the marketplace) should be eliminated, the Agency has faced an unprecedented torrent of regulatory failures.¹⁷ The American people, of course, get the worst of both worlds under the Agency's view—an FDA incapable of protecting them, and no tort system to provide compensation if they are injured. These regulatory failures support Professor O'Reilly's thesis, but they also support my claim that something more fundamental is to blame. The problems with drugs like Vioxx, Bextra, Celebrex, and Avandia, and with medical devices like Guidant defibrillators, Medtronic pacemakers, St. Jude Silzone heart valves, and Sulzer hip and knee prostheses, were likely to arise regardless of whether the Administration was placing political pressure on the FDA. These failures resulted from the Agency's structural weaknesses and resource limitations in its premarket approval and postapproval surveillance systems, not necessarily from regulatory capture.

Third, Professor O'Reilly worries that the Bush Administration's political shenanigans have squandered the respect that the Agency has earned from the courts through a century of reliable science, analytical rigor, and scrupulous political independence.¹⁸ Assuming that Professor O'Reilly's view of the FDA's history is correct, the more pressing query is what, if anything, the Agency can do to restore its preferred position in court. Here I end where I began. The Agency's basic problem is that it is ill-equipped to accomplish the Herculean mission assigned to it by Congress, and that regulatory failure, as much as regulatory capture, has wounded the Agency and will continue to undermine its credibility in court.¹⁹ That problem is likely to persist regardless of which political party occupies the White House. Congress's recent enactment of the Food and Drug Administration Amendments Act of 2007 (FDA Amendments Act) is an important but limited first step to shoring up the Agency's statutory authority.²⁰ But even that Act is emblematic of the FDA's lost luster: It imposes unprecedented transparency requirements on the Agency, which will enable Congress and the Agency's critics to second-guess FDA decisions as they are made.²¹ Until Congress gives the FDA the resources and political independence it needs to protect the public health, the

¹⁷ See *infra* Part II.

¹⁸ See O'Reilly, *supra* note 1, at Part XV.

¹⁹ See *infra* notes 44–53, 107–120 and accompanying text.

²⁰ Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (to be codified in scattered sections of 21 U.S.C.).

²¹ See *infra* notes 129–130.

Agency's image will remain tarnished and it will not regain the respect it was once deservedly given by the courts.

I

THE FDA'S SELF-INFLICTED WOUND OF PREEMPTION

Professor O'Reilly's most persuasive case for his self-inflicted wound theory is the Agency's policy reversal on the issue of preemption.²² This example helps prove Professor O'Reilly's point, but his account tells only part of the story. Professor O'Reilly focuses on how and why this about-face was accomplished, but he does not explain why the FDA's justifications for its policy reversal are so strained that many courts have given them little or no deference. I therefore begin where Professor O'Reilly left off, and explain why the FDA's justifications for its decision raise red flags. I then turn to the question of deference.

A. The FDA and Drug-Labeling Preemption

Prior to 2002, the FDA had consistently taken the position that its regulatory efforts could comfortably coexist with state failure-to-warn litigation brought by consumers injured by FDA-regulated drugs.²³ In the Agency's view, failure-to-warn litigation was an important additional tool that provided information to patients and physicians about a drug's risks—information that might not otherwise be available.²⁴ The FDA now maintains that failure-to-warn litigation threatens its ability to protect the public health.²⁵ According to the Agency, a judicial determination that an FDA-approved warning label fails adequately to warn of a drug's risks may force manufacturers to add warnings not approved by the FDA or even warnings that the FDA considered and rejected.²⁶ In order to prevent this, the FDA now asserts that its regulation preempts most failure-to-warn litigation.²⁷

²² See O'Reilly, *supra* note 1, at Part XIII.

²³ Kessler & Vladeck, *supra* note 14, at 463.

²⁴ *Id.*

²⁵ *Id.*; see, e.g., Brief for the United States as Amicus Curiae Supporting the Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court's Order Denying Partial Summary Judgment to Defendant-Appellee and Cross-Appellant at 23-24, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498) [hereinafter *Amicus Brief for the United States, Motus v. Pfizer*].

²⁶ Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) (effective June 30, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601); see also Kessler & Vladeck, *supra* note 14, at 463-64.

²⁷ See Kessler & Vladeck, *supra* note 14, at 474 (noting the FDA's argument that increased disclosure "'can erod[e], and disrupt[] the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.'") (quoting Requirements on Content and Format of Labeling, 71 Fed. Reg. at 3935).

There is no question that the FDA's new position on preemption represents a 180-degree shift. It is therefore worth asking why the Agency decided to reverse a position consistently held during past Administrations. All of the conventional justifications agencies cite when they reverse field can be quickly ruled out.²⁸ One cannot attribute the FDA's shift in position to an intervening Supreme Court ruling that might have cast doubt on the Agency's position, nor have there been any statutory changes that would have prompted Agency reconsideration. Although there has been a steady stream of failure-to-warn litigation (as well as complaints about the litigation from drug companies), Congress has not enacted a preemption provision shielding drug manufacturers from such liability.²⁹

Without a conventional justification at hand, the Agency could only argue that courts should find "implied" preemption, insofar as failure-to-warn cases challenge the FDA's determination that a drug's

²⁸ See, e.g., *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41-42 (1983) (noting that discretion can be refused if the agency's decision is "arbitrary, capricious, an abuse of discretion," or if it is inconsistent with prior practices); *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 814-15 (D.C. Cir. 1983) (discussing the nature of judicial review, as per *State Farm*, under the arbitrary and capricious standard). See generally Merrick B. Garland, *Deregulation and Judicial Review*, 98 HARV. L. REV. 507 (1985) (discussing judicial review of administrative agency decisions).

²⁹ The Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act), as originally enacted, contained no preemption provision. See Pub. L. 75-717, 52 Stat. 1040 (codified as amended in scattered sections of 21 U.S.C.). In the 1962 amendments to the FD&C Act, Congress included a clause expressly limiting the preemptive effect of the statute: "Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (codified as amended at 21 U.S.C. § 321 (2000)). When Congress revisited the Act in 2007, drug companies hoped that Congress would add an express preemption provision barring tort litigation; Congress did not do so. Cf. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) (noting, in the context of a different legal issue, that Congress tends to make clear when it wants state law to control). Instead, Congress adopted a "rule of construction." Pub. L. No. 110-85, § 901(a), 121 Stat. 823, 823 (to be codified at 21 U.S.C. § 355(o)(4)(I)). The rule of construction establishes that the FDA's new authority to order labeling changes does not alter manufacturers' preexisting obligations, such as the one set forth in 21 C.F.R. § 314.70, requiring manufacturers to amend labels to strengthen warnings and to add contra-indications as soon as safety information is available. There is no question that the House added this provision to "clarify that nothing in this legislation or in current law is intended to preempt remedies for consumers injured by dangerous drugs." H.R. REP. NO. 110-225, at 197 (2007); see also 153 CONG. REC. S11,831-84 (Sept. 20, 2007) (statement of Sen. Kennedy); *id.* at S11,834 (statement of Sen. Leahy); *id.* at S11,835 (statement of Sen. Durbin). Senator Allard expressed disappointment at Congress's failure to preempt drug claims by arguing that the new legislation would "open the floodgates" to litigation and would be "a definite boon to trial lawyers." *Id.* at S11,836-37. As one Washington, D.C., law firm put it, "Contrary to the expectations of many, the FDA Amendments Act of 2007 (FDAAA), signed into law by the President in late September, does not contain any provision expressly preempting state laws." Kimberly K. Egan & Alyson Russell Snow, *Does the FDA Amendments Act of 2007 Preempt State Law?* DLA PIPER, NEWS & INSIGHTS, Oct. 10, 2007, http://www.dlapiper.com/state_preemption/.

labeling was adequate. According to the Agency, warnings that overstate or exaggerate risks are no more helpful to physicians and patients than warnings that downplay those risks.³⁰ Striking the right balance takes expertise and judgment. Thus, the FDA now claims, failure-to-warn litigation threatens the Agency's control of drug labeling, and FDA decisions should not be subject to second-guessing by courts.³¹

The FDA's argument is misplaced for several reasons. First and foremost, the FDA did not address the "why now?" question. There was no reason for the FDA to change its position in 2002: failure-to-warn litigation has been a fixture for decades,³² but the Agency had never before claimed that such lawsuits threatened to undermine its regulatory efforts. So why does failure-to-warn litigation *now* stand as an obstacle to the FDA's performance of its duties? On that point, the Agency has no answer.

There is a reason for the FDA's silence.³³ Failure-to-warn litigation does not challenge the FDA's decision to approve a label for a new drug, or even the Agency's final say over the form and contents of drug labeling.³⁴ Instead, failure-to-warn litigation challenges the *company's* failure to revise its labeling to warn about risks unknown at the time of approval, or risks that turn out to be graver than the company (and the FDA) originally thought.³⁵ The FDA's own regulations impose a duty on drug manufactures to modify labeling without delay when hazards emerge and expressly authorize labeling changes without the Agency's advance approval.³⁶ Thus, the common law duty en-

³⁰ Requirements on Content and Format of Labeling, 71 Fed. Reg. at 3935 ("Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health.").

³¹ See Kessler & Vladeck, *supra* note 14, at 463–64.

³² See, e.g., *Stanton v. Astra Pharm. Prods., Inc.*, 718 F.2d 553, 563–69 (3d Cir. 1983); *Ezagui v. Dow Chem. Corp.*, 598 F.2d 727, 733 (2d Cir. 1979); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 141–42 (3d Cir. 1973); *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390, 1401 (8th Cir. 1969); *Orthopedic Equip. Co., Inc., v. Eutsler*, 276 F.2d 455 (4th Cir. 1960); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 660–64 (Cal. 1973); *Toole v. Richardson-Merrell, Inc.*, 60 Cal. Rptr. 398, 412–14 (Cal. App. 1967); *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 803–04 (Tex. 1978); see also *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1013 n.2, 1017 n.11 (2008) (Ginsburg, J., dissenting) (collecting cases).

³³ See Kessler & Vladeck, *supra* note 14, at 476 (developing the argument offered herein).

³⁴ See *id.*

³⁵ See *id.*

³⁶ See 21 C.F.R. §§ 314.70, 201.57(c)(6), 201.80(e) (2007); 44 Fed. Reg. 37,434, 37,447 (June 26, 1979) (codified at 21 C.F.R. pts. 201, 202) (noting that FDA labeling rules do not affect a manufacturer's duty to provide warnings to doctors and patients through labeling, advertising, or "Dear Doctor" letters, when the manufacturer discovers risks not clearly stated on the label). In a transparent effort to shore up its position in litigation, the FDA has now proposed to amend these rules to require FDA's prior approval on any label change. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2848–54 (Jan. 16, 2008) (to be codified at

forced in failure-to-warn litigation—namely a drug company’s duty to take all reasonable measures to alert physicians and patients to previously unknown hazards—is no different than the duty the FDA itself imposes on drug manufacturers. That is why the steady procession of failure-to-warn cases has not interfered with the Agency’s regulatory efforts for all of these years: the duties imposed by state and federal laws are parallel and mutually reinforcing.³⁷

For this reason, the FDA’s claim that recent lawsuits have “threatened the agency’s ability to regulate . . . risk information for prescription drugs” cannot withstand examination.³⁸ In fact, the handful of cases cited by the Agency undercut its interference claim. The chief case that the FDA relies on, *Dowhal v. SmithKline Beecham Consumer Healthcare*,³⁹ was not a product liability case, but an action to compel a drug company to add warnings required by a California law.⁴⁰ The California Supreme Court held that requiring warnings different from those the FDA required constituted an actual conflict between federal and state law, and thus state law had to yield.⁴¹ Two other cases the FDA cites also involved actions to compel changes to drug labeling; neither succeeded.⁴² Only a few of the FDA’s illustrative cases were failure-to-warn actions, and the FDA offered no expla-

21 C.F.R. pts. 314, 601, 814). As noted below, courts that have rejected the FDA’s preemption position often use these regulations to establish that manufacturers have wide leeway to add warnings to labels and then seek FDA approval. The proposed rule change aims at undercutting that argument. *See id.* at 2852–53.

³⁷ *See generally* *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496–97 (1996) (holding that a tort claim based on state law duties “equal to, or substantially identical to, requirements imposed” by federal law is not preempted) (citation omitted); *see also id.* at 513 (O’Connor, J., concurring in part and dissenting in part).

³⁸ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (effective June 30, 2006) (codified at 21 C.F.R. pts. 201, 314, 601); *see* Kessler & Vladeck, *supra* note 14, at 481–83 (developing the argument offered herein); *see also* Margaret Gilhooly, *Addressing Potential Drug Risks: The Limits of Testing, Risk Signals, Preemption, and the Drug Reform Legislation*, 59 S.C. L. REV. 347 (2008).

³⁹ 88 P.3d 1 (Cal. 2004); *see* Requirements on Content and Format of Labeling, 71 Fed. Reg. at 3934 n.7 (citing *Dowhal*, 88 P.3d 1).

⁴⁰ *See Dowhal*, 88 P.3d at 3.

⁴¹ *See id.* at 14–15.

⁴² *See* Requirements on Content and Format of Labeling, 71 Fed. Reg. at 3934 n.7 (citing *In re Paxil Litig. (In re Paxil I)*, No. CV-01-07937(MRP), 2002 WL 1940708 (C.D. Cal. Aug. 16, 2002); *Bernhardt v. Pfizer, Inc.*, Nos. 1:00CV04042(LMM), 1:00CV04379(LMM), 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000)). *In re Paxil* was a class action lawsuit brought against GlaxoSmithKline by users of Paxil, who sought to enjoin the company from advertising that “Paxil is non-habit forming.” *In re Paxil I*, 2002 WL 1940708, at *1. Although the court initially agreed to enter injunctive relief, it reversed that ruling two months later. *In re Paxil Litig. (In re Paxil II)*, No. CV-01-07937(MRP), 2002 WL 31375497, at *1 (C.D. Cal. Oct. 18, 2002). *Bernhardt v. Pfizer, Inc.* was an action seeking an order requiring Pfizer to send information about one of their drugs letter to users and physicians. 2000 WL 1738645, at *1. The court found that the plaintiffs lacked standing and that the FD&C Act preempted the injunctive relief sought. *See id.* at *1–3.

nation as to how these cases threatened the Agency's authority over drug labeling.⁴³ Not a single case sought to compel a labeling change, and none resulted in a labeling change. Thus, none of these cases support the FDA's claim that failure-to-warn litigation threatens its ability to protect the public's health and well-being.

More fundamentally, the FDA's preemption argument presupposes that the Agency has the resources to perform the monumental task of ensuring that the labeling of marketed drugs reflects current safety information.⁴⁴ It does not. According to the November 2007 report of a blue-ribbon panel appointed by the FDA Commissioner, "[t]he scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the . . . regulatory system, and hence the safety of the public."⁴⁵ The Institute of Medicine similarly reported in 2006 that the FDA "lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future."⁴⁶ The FDA regulates products that account for one-quarter of consumer spending in the United States,⁴⁷ amounting to \$1 trillion annually,⁴⁸ but has only nine thousand employees nationwide.⁴⁹ According to the most recent statistics, the FDA's Office of New Drugs, which reviews new drug applications, employs over one thousand physicians and scientists to review the approximately one hundred new drug applications it receives each year and to supervise postmarketing studies.⁵⁰ In contrast, the Agency's Office of Surveillance and Epidemiology, the unit charged with monitoring adverse events associated with over eleven thousand drugs currently on the market⁵¹ (including

⁴³ See Requirements on Content and Format of Labeling, 71 Fed. Reg. at 3934 n.7 (citing *In re Paxil I*, 2002 WL 1940708, *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085 (C.D. Cal. 2000), *aff'd*, 358 F.3d 659 (9th Cir. 2004), and *Bernhardt*, 2000 WL 1738645).

⁴⁴ See Kessler & Vladeck, *supra* note 14, at 484–86 (developing the argument offered herein).

⁴⁵ FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY § 1.1 (2007), http://www.fda.gov/ohrms/dockets/AC/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf [hereinafter FDA SCIENCE AND MISSION AT RISK].

⁴⁶ INSTITUTE OF MEDICINE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 193 (2007) [hereinafter INSTITUTE OF MEDICINE].

⁴⁷ U.S. Food and Drug Administration, FDA News: The Food and Drug Administration Celebrates 100 Years of Service to the Nation, <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01292.html> (last visited Apr. 9, 2008).

⁴⁸ FDA SCIENCE AND MISSION AT RISK, *supra* note 45, § 1.1.

⁴⁹ U.S. Food and Drug Administration, FDA Overview, www.fda.gov/oc/opacom/fda101/sld015.html (last visited Apr. 9, 2008); see also FDA SCIENCE AND MISSION AT RISK, *supra* note 45, § 2.1 (describing the Agency's core regulatory functions).

⁵⁰ See *Hearings on Ensuring Drug Safety: Where Do We Go From Here?: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 109th Cong. 42 (2005) (statement of Dr. Bruce M. Psaty).

⁵¹ *Regulatory Preemption*, *supra* note 14, at 11.

over three thousand prescription drugs),⁵² has about one hundred and thirty professional employees.⁵³ Congress recently enacted the FDA Amendments Act, which will bolster the Agency's statutory authority.⁵⁴ But as Senator Ted Kennedy, the Act's principal Senate sponsor, warned, even with added resources "[t]he resources of the drug industry to collect and analyze . . . safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does."⁵⁵

Nor can the FDA's new position square with the Agency's longstanding recognition that failure-to-warn litigation helps uncover and assess risks not apparent to the Agency during the drug approval process, and that this "feedback loop" enables the Agency to better do its job.⁵⁶ FDA approval of drugs is generally based on clinical trials that involve (at most) a few thousand patients and often last only a year.⁵⁷ These trials cannot detect risks that are relatively rare, have long latency periods, or affect vulnerable sub-populations.⁵⁸ For this reason, most serious adverse effects do not become evident until a drug is used in larger population groups for periods in excess of one year.⁵⁹ Time and again, failure-to-warn litigation has brought to light information that would otherwise not be available to the FDA, doctors, other health care providers, or consumers.⁶⁰ And failure-to-warn liti-

⁵² *Id.*

⁵³ See U.S. Food and Drug Administration, FDA Drug Safety Initiative: Fact Sheet, <http://www.fda.gov/oc/factsheets/initiative.html> (last visited Apr. 9, 2008) (reporting that since 2004 the Office of Surveillance and Epidemiology (formerly the Office of Drug Safety) "has increased the staffing dedicated to the post-marketing safety program by almost 25 percent (94 to 132 F[ull] T[ime] E[m]ployee[]s)").

⁵⁴ Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (to be codified in scattered sections of 21 U.S.C.).

⁵⁵ 153 CONG. REC. S11,832 (2007) (statement of Sen. Kennedy).

⁵⁶ See Kessler & Vladeck, *supra* note 14, at 463 (developing the argument offered herein); see also Prescription Drug Product Labeling: Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (effective June 1, 1999) (codified at 21 C.F.R. pts. 201, 208, 314, 601, 610) ("FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations."); Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997).

⁵⁷ See U.S. Food and Drug Administration, The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective, <http://www.fda.gov/fdac/special/testtubetopatent/drugreview.html> (last visited Apr. 9, 2008).

⁵⁸ Kessler & Vladeck, *supra* note 14, at 471.

⁵⁹ See, e.g., *Risk and Responsibility: The Roles of FDA and Pharmaceutical Companies in Ensuring Safety of Approved Drugs, Like Vioxx*, Hearing Before the H. Comm. on Government Reform, 109th Cong. 55 (2005) (testimony of Steven Galson, Acting Director, Center for Drug Evaluation and Research, United States Food and Drug Administration).

⁶⁰ See *infra* notes 87-93 and accompanying text (discussing the evidence uncovered during the Merck failure-to-warn litigation).

gation has often preceded and clearly influenced FDA decisions to modify labeling—and, at times, to withdraw drugs from the market.⁶¹

Congress is, of course, acutely aware of the shortcomings in the FDA's ability to police the marketplace on drug safety.⁶² The recent public health failures involving widely prescribed drugs like Vioxx, Bextra, Celebrex, and Avandia have driven home these shortcomings.⁶³ Indeed, the FDA Amendments Act reflects Congress's dissatisfaction with the FDA's performance.⁶⁴

It is precisely for these reasons that the FDA's critics have concluded that the Agency effected its dramatic change in position on preemption for political reasons, as opposed to scientific or public policy concerns.⁶⁵ The Agency's decision to announce its new position in an amicus brief filed in support of a drug company that was involved in private litigation fueled those suspicions.⁶⁶ And the substantive deficiencies in the FDA's justification cemented the conclusion that the Agency now aligned itself with the industry it was supposed to oversee.⁶⁷

In the past, the FDA generally submitted its decisions on preemption policy to the rulemaking process, thereby subjecting the decision to public comment and ultimately to judicial review.⁶⁸ The FDA is also required by Executive Order to give state and local governments notice and an opportunity to participate in any proceeding that may affect state or local law.⁶⁹ The FDA did none of this with its new preemption position. Not only did the Agency announce its policy shift in an amicus brief unsolicited by the court,⁷⁰ but thereafter the FDA's Chief Counsel publicly urged drug companies to request the Agency

⁶¹ See *Regulatory Preemption*, *supra* note 14, at 11; see, e.g., Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 309 (2007) (citing examples); Karen E. Lasser et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2217–18 (2002) (same).

⁶² *Regulatory Preemption*, *supra* note 14 (giving testimony before Congress regarding the FDA's shortcomings).

⁶³ *Id.* at 11.

⁶⁴ See *infra* note 130 and accompanying text.

⁶⁵ See, e.g., Hutt, *supra* note 1.

⁶⁶ See Amicus Brief for the United States, *Motus v. Pfizer*, *supra* note 25; see also Margaret H. Clune, *Stealth Tort Reform: How the Bush Administration's Aggressive Use of the Preemption Doctrine Hurts Consumers* 2–9 (Ctr. for Progressive Regulation, White Paper No. 403, 2004), available at <http://www.progressivereregulation.org/articles/preemption.pdf>.

⁶⁷ See *supra* note 31 and accompanying text.

⁶⁸ See, e.g., 21 C.F.R. § 808.1 (2007) (defining the scope of preemption under the 1976 Medical Device Amendments to the FD&C Act, 21 U.S.C. § 360(k)(A)–(B) (2000)).

⁶⁹ Exec. Order No. 13,132, 64 Fed. Reg. 43,255, 43,257 (Aug. 10, 1999) (“When an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.”).

⁷⁰ See Amicus Brief for the United States, *Motus v. Pfizer*, *supra* note 25.

to file amicus briefs supporting their preemption claims.⁷¹ When the Agency finally decided to formalize its position, it simply inserted its announcement into the preamble to a final rule—even though the preamble to the proposed rule said that it would *not* have a preemptive effect.⁷² Tactics like these clearly underscore the ad hoc nature of the Agency's action.⁷³

B. Deference and Drug Preemption Litigation

Professor O'Reilly cautiously predicts that, as a result of the clear political motivations driving the Agency's change in preemption policy, courts will give less deference to the FDA than they have in the past.⁷⁴ That is a risky prediction. The Supreme Court recently observed that agencies' judgments about the preemptive reach of their actions are entitled to judicial deference.⁷⁵ And, although Professor O'Reilly does not develop this point, the FDA's track record in judicial proceedings has been, until recently, the envy of other agencies. Until the 2000 ruling in *FDA v. Brown & Williamson Tobacco Corp.*,⁷⁶ the Agency had a stellar track record before the Court. In fact, the Court

⁷¹ See Daniel E. Troy, *FDA Involvement in Product Liability Lawsuits*, UPDATE: FOOD & DRUG LAW, REG., & EDUC. MAG., Jan./Feb. 2003, at 7–8.

⁷² See Prescription Drug Product Labeling, Medication Guide Requirements: Final Rule, 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998) (effective June 1, 1999) (codified at C.F.R. pts. 201, 208, 314, 601, 610) (“[T]he written patient medication information provided does not alter the duty, or set the standard of care for manufacturers”); *id.* (“FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations.”); see also *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M:05-1699(CRB), 2006 WL 2374742, at *8 (N.D. Cal. Aug. 16, 2006) (observing that “the FDA's current view of the preemptive effect of its labeling regulations is a 180-degree reversal of its prior position”). Professor Nina A. Mendelson has argued against granting presumptive deference to agency views of preemption. See Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737, 758 (2004).

⁷³ The fact that the FDA developed its position through such informal means is one factor that may bear on the degree of deference it receives in court. *Cf.* United States v. Mead Corp., 533 U.S. 218, 228 (2001) (noting that courts can consider “formality” when deciding whether Congress has impliedly delegated authority to the agency). Courts might also undercut the deference generally accorded if the agency's new position on preemption conflicts with its longstanding, contrary position. *Id.* See generally Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227 (2007) (outlining a perceived trend of judicial deference toward agency preemption interpretation).

⁷⁴ O'Reilly, *supra* note 1, at Part XVII.

⁷⁵ Indeed, in two of the most recent FDA preemption cases, the Court gave deference to the FDA's position. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996), the Court found the FDA's interpretation of its preemption regulation persuasive. And in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001), the Court followed the path laid out in an amicus brief filed on the FDA's behalf. See Brief for the United States as Amicus Curiae Supporting Petitioner, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768). And in another preemption case, this one involving the Department of Transportation, the Court deferred to an agency's views of the preemptive sweep of one of its regulations. See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000).

⁷⁶ 529 U.S. 120 (2000).

had previously gone out of its way to emphasize the deference owed to the FDA because of its scientific expertise and the complexity of its judgments.⁷⁷ And, in its most recent ruling involving the FDA, *Riegel v. Medtronic, Inc.*,⁷⁸ the Court, in finding tort claims against manufacturers of medical devices specifically approved by the FDA to be preempted, suggested that had it not found the preemption provision in the medical device statute to “speak[] clearly to the point at issue;” it may have accorded some degree of deference to the FDA’s position on the issue—even though the Agency’s earlier position was different.⁷⁹

Nonetheless, at least with respect to the FDA’s new position on preemption of drug claims, there is reason to believe that Professor O’Reilly’s prediction may be correct.⁸⁰ The *Riegel* Court went out of its way to stress that its decision—that the express preemption provision of the Medical Device Amendments bars tort claims challenging Agency-approved medical devices—does not bear on the drug provisions of the Act, which contain no preemption provision.⁸¹ Many courts that have examined the FDA’s position on failure-to-warn claims for pharmaceuticals, including the court handling the Vioxx multi-district litigation, have refused to accord the FDA’s preemption position any deference at all.⁸² Perhaps most importantly, the first—and, at this writing, only—appellate court decision on the issue, the Vermont Supreme Court’s decision in *Levine v. Wyeth*, resoundingly

⁷⁷ See, e.g., *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 982–83 (1986); *United States v. Rutherford*, 442 U.S. 544, 555 (1979).

⁷⁸ 128 S. Ct. 999 (2008).

⁷⁹ *Id.* at 1009. The Court reasoned that full-bore deference under *United States v. Mead Corp.*, 533 U.S. 218 (2001), might not be warranted given the Agency’s complete reversal of field on the question. The Court nonetheless thought that the Agency’s *current* position supporting preemption might be entitled to deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), because the view was a plausible one that was clearly articulated by the Agency. *Id.*

⁸⁰ See *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M:05-1699(CRB), 2006 WL 2374742, at *6–7 (N.D. Cal. Aug. 16, 2006); *Needleman v. Pfizer, Inc.*, No. 3:03-CV-3074-N, 2004 WL 1773697, at *4–5 (N.D. Tex. Aug. 6, 2004). *But see* *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 525 (E.D. Pa. 2006). When the FDA shifted its position on preemption of failure-to-warn claims for drugs, it also reversed field on the separate question of whether FDA premarket approval of medical devices preempts tort liability for defective design and failure-to-warn claims. The Supreme Court upheld the FDA’s position, although it did so on the ground that the statute explicitly preempted such claims. See *Riegel*, 128 S. Ct. at 1009–10. See generally David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95 (2005) (critiquing the FDA’s position on medical device preemption).

⁸¹ See *Riegel*, 128 S. Ct. at 1009–10.

⁸² See *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 786 (E.D. La. 2007); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 273 (E.D.N.Y. 2007); *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 730 (D. Minn. 2005); *Zikis v. Pfizer, Inc.*, No. 04-C-8104, 2005 WL 1126909, at *2–3 (N.D. Ill. May 9, 2005).

rejected the FDA's position and found it unworthy of deference.⁸³ This lack of deference represents a sharp break from tradition.⁸⁴ But the deference question will remain unresolved until the Supreme Court issues its ruling in *Levine*, which is not likely to come until late in 2008.

Although it is too early to tell whether this trend in the lower courts will persist, the preliminary evidence supports Professor O'Reilly's thesis. The trend against deference is good news for those unhappy with the Agency's new preemption position and who therefore are eager to see it rejected by the courts. However, for those who care more about the FDA's long-term ability to do its work without intrusive judicial oversight, these rulings may be the harbingers of a troubled future for the FDA.

II

PREEMPTION IN A TIME OF REGULATORY FAILURE

Even the staunchest defenders of the FDA's new pro-preemption position must concede that the Agency's timing could not have been worse: at about the same time it announced its shift in position, the Agency faced a flood of high-profile regulatory failures.⁸⁵ Most prominent, of course, have been the serious and unforeseen health risks that emerged with respect to drugs the FDA had recently approved, including new pain medicines like Vioxx, Celebrex, and Bextra, and the diabetes drug Avandia.⁸⁶

Failure-to-warn litigation involving these drugs has uncovered significant evidence that the manufacturers knew of the serious risks that these drugs posed but did not convey their findings promptly to the

⁸³ See *Levine v. Wyeth*, 2006 Vt. 107, ¶ 32 (Vt. 2006), cert. granted, 128 S. Ct. 1118 (2008) (mem.).

⁸⁴ See O'Reilly, *supra* note 1, at Part XV. One can infer from Professor O'Reilly's article that a court's views of deference will be outcome-determinative. Experience tends to prove that view correct: courts that defer to the FDA find preemption while courts that find the FDA's position does not warrant deference find no preemption. Compare, e.g., *Levine*, 2006 Vt. 107, at ¶ 32 (rejecting the argument that it should defer to the FDA's views on preemption and thereafter rejecting the drug company's preemption argument), with *Dobbs v. Wyeth Pharms.*, 530 F. Supp. 2d 1275, 1288–89 (W.D. Okla. 2008) (deferring to the FDA's view on preemption and thereafter holding in favor of the drug company on preemption grounds).

⁸⁵ The FDA first asserted its pro-preemption position in court in its amicus brief filed in *Motus v. Pfizer, Inc.* Amicus Brief for the United States, *Motus v. Pfizer*, *supra* note 25. Fallout from the Vioxx debacle began when Merck pulled the drug from the market on September 30, 2004. See, e.g., Barnaby J. Feder, *Vioxx Recall May Bring Flood of Suits to Merck*, N.Y. TIMES, Oct. 5, 2004, at C2; Linda Loyd, *Vioxx Fallout Hits Merck: Profit Falls; 300 Suits Filed*, PHILA. INQUIRER, Oct. 22, 2004, at C1. For a review of Vioxx's regulatory history, see Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941 (2007).

⁸⁶ See Bruce Japsen, *Meeting May Decide Diabetes Drugs' Fate; FDA Advisers Could Query Takeda's Acts*, CHI. TRIB., July 30, 2007, at C1.

FDA.⁸⁷ For instance, litigation has revealed that Merck, the manufacturer of Vioxx, was aware of the heart attack risk associated with the drug well before the company alerted the FDA.⁸⁸ Specifically, the plaintiffs' lawyers uncovered internal company memoranda and e-mails that Merck did not provide to the FDA.⁸⁹ One memorandum warned that, in a study designed to show that Vioxx decreased the risk of gastrointestinal bleeding, the test group should be limited to patients also taking aspirin; otherwise, there would be a "substantial chance that significantly higher rates" of cardiovascular disease would be revealed.⁹⁰ Similarly, an internal e-mail warned that if patients did not receive aspirin in addition to Vioxx, the patients "will get more thrombotic events and kill [the] drug."⁹¹ In response, a senior company doctor agreed that "the possibility of increased CV [cardiovascular] events is of great concern" and urged Merck to exclude potential subjects with a high risk of cardiovascular problems from the study so that cardiovascular problems "would not be evident."⁹² Evidence uncovered in litigation also revealed that Merck scientists considered combining Vioxx with other drugs to reduce the risk of heart attacks and strokes.⁹³

At the same time that the Agency was facing a string of regulatory failures with respect to drugs, it was experiencing a similar, or perhaps even worse, spate of problems with medical devices.⁹⁴ That is not necessarily surprising, for it is more difficult to test medical devices for safety and effectiveness than it is to test drugs.⁹⁵ This difficulty explains why the statutory standard for approving medical devices—a reasonable assurance of the device's safety and effectiveness—is lower than the standard for drugs, which may receive approval only if shown

⁸⁷ See Kessler & Vladeck, *supra* note 14, at 492–95 (offering a variety of examples of drug manufacturers' failure to disclose information to the Agency).

⁸⁸ See Anna Wilde Mathews & Barbara Martinez, *E-Mails Suggest Merck Knew Vioxx's Dangers at Early Stage*, WALL ST. J., Nov. 1, 2004, at A1.

⁸⁹ See *id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ Assoc. Press, *File Shows Merck Sought to Change Vioxx*, L.A. TIMES, June 23, 2005, at C3. Litigation also uncovered Merck-sponsored studies that found a high death rate among Alzheimer's patients taking Vioxx as compared to a placebo group. See Heather Won Tesoriero, *Attorneys Question Disclosure by Merck of Vioxx-Study Deaths*, WALL ST. J., Sept. 28, 2005, at D4.

⁹⁴ See *supra* notes 99–103.

⁹⁵ See generally Pamela S. Saha & Subrata Saha, *Clinical Trials of Medical Devices and Implants: Ethical Concerns*, IEEE ENGINEERING MED. & BIOLOGY MAG., June 1988, at 85 (stating the particular importance of clinical trial studies as regards the development of devices).

to be safe and effective for their intended use.⁹⁶ Ethical constraints limit the testing of experimental life-saving or life-sustaining medical devices on healthy subjects; thus, devices often receive approval on the basis of a single clinical trial.⁹⁷ For this reason, it is not uncommon for unforeseen risks to emerge after medical devices are approved for general marketing.⁹⁸ Nevertheless, the growing number of serious failures is cause for alarm. Just in the past few years there have been massive recalls of defibrillators,⁹⁹ pacemakers,¹⁰⁰ heart valves,¹⁰¹ hip and knee prostheses,¹⁰² and heart

⁹⁶ Compare 21 U.S.C. §§ 360c(a)(1), 360d(a)(2)(A) (2000) (providing the standard for medical devices), with 21 U.S.C. § 355(d) (2000 & Supp. V 2005) (providing the standard for drugs).

⁹⁷ See Saha & Saha, *supra* note 95, at 86 (“Trials on healthy subjects are condemned by the Nuremberg Code, the Tokyo Declaration, and the Helsinki Declaration of the World Medical Association.”).

⁹⁸ See *id.* at 85 (“Unless we decide to discontinue all innovative work and hold medicine to the [status quo], it is given that patients will be subject to some unforeseen risks in new treatments that come with the promise of improved care.”).

⁹⁹ Consider the case of the Guidant Prizm II defibrillators: even after Guidant learned of serious defects in these devices, and even after Guidant had developed a newer, safer model, the company kept selling the defective defibrillators until forced by adverse publicity (generated by the death of a twenty-one-year-old college student and the subsequent tort litigation) to recall the devices. By that time, more than 24,000 of the defective devices had been implanted in patients, who then faced the daunting decision of whether to have replacement surgery. See *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, No. 05-1708(DWF/AJB), 2007 WL 1725289, at *1–4 (D. Minn. June 12, 2007) (mem.); Barry Meier, *FDA Expanding Inquiry into Heart-Device Company*, N.Y. TIMES, Aug. 25, 2005, at C3.

¹⁰⁰ Although the FDA approved the Medtronic 4004M pacemaker, it was later determined to be defectively designed. Some patients died when the pacemaker’s lead failed, forcing many patients to undergo open-heart surgery to replace the defective part. See *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1368 (11th Cir. 1999).

¹⁰¹ The FDA approved the St. Jude Silzone heart valve on the basis of testing that involved only 792 human subjects. After St. Jude starting selling the valve, testing revealed that its silver coating not only did not protect against infection, but also caused the valves to leak. Litigation publicized the risk and forced St. Jude to recall the problem valves, but not until they had been implanted in over 36,000 patients. See *In re St. Jude, Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396 JRTFLN, 2004 WL 45503, at *1–2 (D. Minn. Jan. 5, 2004); see also *Bowling v. Pfizer, Inc.*, 143 F.R.D. 141, 170 (S.D. Ohio 1992) (approving settlement in a class action suit involving 55,000 patients who received defective heart valves).

¹⁰² The FDA granted approval to the Sulzer hip and knee implants, but it soon turned out that a manufacturing defect kept the implants from bonding properly with patients’ bones. See *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig. (In re Sulzer I)*, 455 F. Supp. 2d 709, 712 (N.D. Ohio 2006). Testimony in litigation exposed the fact that the problem was caused by unsanitary conditions at the manufacturing facility. See J. Scott Orr & Robert Cohen, *Messy Plant Made Faulty Hip Joints*, TIMES-PICTAYUNE (New Orleans), Aug. 13, 2002, at A-1. In December 2000, Sulzer finally notified the FDA that it recalled about 40,000 defective hip implants, 26,000 of which had been implanted in patients. See *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig. (In re Sulzer II)*, 268 F. Supp. 2d 907, 910–11 (N.D. Ohio 2003). Among the failed implants were approximately 6100 units that Sulzer, with the FDA’s permission, reprocessed and sold. See *id.* at 911. Many of the victims needed to undergo multiple additional surgeries to remove the faulty devices and replace them with more effective ones. See, e.g., Orr & Cohen, *supra* (describing the procedures

pumps¹⁰³—all of which have exacted a serious toll on the patients who face the daunting prospect of removal-and-replacement surgeries.

The combined effect of these regulatory failures has been a steady drumbeat of headlines critical of the Agency's performance.¹⁰⁴ Unsurprisingly, these press accounts have eroded the FDA's prestige to the point that only one-third of Americans claim confidence in the Agency.¹⁰⁵ Professor O'Reilly's account of the FDA's decline says little about the Agency's past failures; however, these regulatory failures have contributed far more to the erosion of the Agency's prestige than has regulatory capture.¹⁰⁶

The FDA has reached a critical point in its history: it has enormous and growing responsibilities, yet Congress has flat-lined its appropriations.¹⁰⁷ A report issued by an FDA panel describes in great

undergone by one plaintiff and also noting that many members of the class had similar experiences).

¹⁰³ See generally *Horn v. Thoratec Corp.*, 376 F.3d 163, 164–65, 167 (3d Cir. 2004) (finding a claim against the manufacturer of a heart pump preempted).

¹⁰⁴ Even Reader's Digest has recently run an article critical of the FDA's failure to safeguard consumers from dangerous drugs. See Alexis Jetter, *One Drug, Many Tragedies: A Doctor Blows the Whistle on a Dangerous New Drug that Wrongfully Received FDA Approval*, READER'S DIG., Apr. 2008, <http://www.rd.com/national-interest/consumer-safety/fda-approves-harmful-antibiotic/article.html>.

¹⁰⁵ See Hutt, *supra* note 1, at B-7. The social science literature drives home the impact of negative, trust-destroying events in the regulatory context. See generally Paul Slovic, *Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield*, 1997 U. CHI. LEGAL F. 59.

¹⁰⁶ Perhaps it can be argued that the two go hand-in-hand: a politicized agency is prone to make mistakes on scientific issues. For example, a 2006 survey found that significant numbers of the FDA's own physicians and scientists reported pressure to recommend that drugs be approved, even when they had reservations about the drug's safety and efficacy. See Union of Concerned Scientists, *News & Views: Scientific Integrity Update*, Sept. 2006, http://www.ucsusa.org/scientific_integrity/restoring/scientific-integrity-update-09-2006.html (last visited Apr. 9, 2008); see also OFFICE OF THE INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., *FDA'S REVIEW PROCESS FOR NEW DRUG APPLICATIONS: A MANAGEMENT REVIEW 12* (2003) (describing survey results indicating that twenty-one percent of FDA researchers felt unable to raise concerns regarding drug efficacy due to workplace pressures).

¹⁰⁷ For example, the FDA Amendments Act of 2007 promises the addition of only modest resources. During the Senate deliberations on the Act, Senator Kennedy estimated that the Act would bring an additional \$50 million to the Agency for its drug safety efforts. 153 CONG. REC. S11,831 (2007) (statement of Sen. Kennedy). The basis for Senator Kennedy's estimate is unclear: while the Act does increase user fees, only an increase in appropriations will add the financial resources that Senator Kennedy forecasts. However, whether additional appropriations will materialize is far from clear. Rep. Henry Waxman, one of the main House sponsors of the Act, expressed concern over funding. He noted that the "FDA will need a significant influx of resources to do what we are asking them to do in [the FDA Amendments Act]," and that, although the legislation "gives FDA the enhanced ability to dedicate user fee dollars to these activities, it will be critical for Congress to come forward with additional appropriated dollars. We simply have got to get FDA the funds it needs to do their job well." 153 CONG. REC. H7602 (2007); see also *id.* at H7606 (statement of Rep. Van Hollen) ("Congress must also significantly increase federal appropriations to FDA so that the agency is able to fulfill its most basic responsibilities.").

detail the dilemma the FDA faces.¹⁰⁸ “When the Federal Food, Drug, and Cosmetic Act was originally enacted in 1938, the regulatory and compliance issues faced by the FDA were comparatively simple.”¹⁰⁹ Then,

[t]hrough the enactment of a series of landmark statutes, beginning in the 1950s and extending through the 1970s, FDA was given a mandate by Congress to review and approve prior to marketing, the safety of color additives, human food additives and animal feed additives, as well as to review and approve the safety and effectiveness of new human drugs, new animal drugs, human biological products and medical devices for human use.¹¹⁰

As a result, “[t]oday no new pharmaceutical product or medical technology can be used in the US without FDA first determining that it is safe and effective for its intended use.”¹¹¹

The duties assigned to the FDA have, in recent years, expanded exponentially. According to the report, “[d]uring the past two decades Congress has enacted 125 statutes that directly impact FDA’s regulatory responsibilities—an average of more than six each year—in addition to the core provisions of the 1938 Act itself and its amendments from 1939 to 1987.”¹¹² These statutes require “the development of implementing regulations, guidance, or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some type of scientific knowledge or expertise for the agency adequately to address them,”¹¹³ and in some cases may require laboratory research. Despite Congress’s imposition of substantial additional responsibilities, “[n]one of these statutes is accompanied by an appropriation of new personnel and increased funding designed to allow adequate implementation.”¹¹⁴ In fact, during the past two decades, the Agency’s funding and staffing levels have remained static. From 1988 to 2007, the “FDA gained through appropriation only 646 new employees—an increase of 9 percent—and *lost* more than \$300 million [in annual appropriations] to inflation.”¹¹⁵

¹⁰⁸ See FDA SCIENCE AND MISSION AT RISK, *supra* note 45, §§ 3.0–3.3 (summarizing major findings that the FDA cannot fulfill its mission due to lack of scientific organizational structure, lack of workforce capacity, and weak information technology infrastructure).

¹⁰⁹ *Id.* § 2.1.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*; see also Hutt, *supra* note 1, at B-24–B-30 (listing statutes passed between 1988 and 2007 that increased the FDA’s responsibilities); *id.* at B-31–B-32 (listing statutes of general applicability passed from 1935 through 2002 that have a direct impact on the FDA); *id.* at B-33–B-34 (listing Executive Orders issued from 1969 to 2007 that have had a direct impact on the FDA).

¹¹³ Hutt, *supra* note 1, at B-4.

¹¹⁴ *Id.*

¹¹⁵ FDA SCIENCE AND MISSION AT RISK, *supra* note 45, § 2.1 (emphasis added).

In 2007, the FDA's budget was approximately \$1.6 billion, and it had roughly the same number of employees as it had fifteen years earlier.¹¹⁶ The report's conclusions are sobering: "This reality, combined with a burgeoning industry . . . has made it increasingly impossible for FDA to maintain its historic public health mission."¹¹⁷ The report also warns that, apart from the new drug approval process, which has gained support from user fees since 1992, the decline in resources available to the remainder of the FDA has been all the more severe.¹¹⁸ "Because these [user fee] funds are in addition to appropriated funds . . . the serious decline in appropriated support for other activities—many of which are core regulatory activities, but not covered by user fees—has not been generally appreciated by those who look only at bottom-line budget figures."¹¹⁹ The report's conclusions echo those that the prestigious National Academies of Science's Institute of Medicine reached a year earlier, which concluded that the FDA is ill-equipped to meet its public health mission.¹²⁰

The picture that emerges from these reports is alarming: the FDA has been weakened from within; it lacks the infrastructure, scientific resources, and expert personnel to do its job; and neither the Executive Branch nor Congress have shown a determination to shore up the Agency's flagging resources. There should be no wonder that the Agency, despite the best efforts of its dedicated staff, cannot keep pace with its growing responsibilities. It is this structural weakness, more than any other factor, that has triggered the decline of the FDA both in terms of its public prestige and the deference it garners from courts.

CONCLUSION

Professor O'Reilly and I agree that courts seem to be showing a greater willingness to second-guess the FDA's judgments, even if we disagree about the root cause of this trend. We also agree that, in the long run, probing judicial review will impede the Agency's ability to do its work swiftly and efficiently.

So the question becomes what, if anything, the Agency can do to restore its preferred position in courts. First and foremost, the Agency must renew its commitment to science. The FDA's ability to reach this goal depends heavily upon strict adherence to scientifically motivated decision making. Agency scientists should be insulated

¹¹⁶ *Id.* These figures exclude revenues brought in as user fees, which amounted to an additional \$352 million in 2007. See Hutt, *supra* note 1, at B-14.

¹¹⁷ FDA SCIENCE AND MISSION AT RISK, *supra* note 45, § 2.1.

¹¹⁸ See *id.*

¹¹⁹ *Id.*

¹²⁰ See INSTITUTE OF MEDICINE, *supra* note 46, at 90.

from political pressure when making decisions about which drugs and medical devices warrant approval and about which measures are appropriate when addressing unforeseen risks with drugs and devices that are already available. In short, politics and science should be separate at the FDA.

Second, the Agency must make its affirmative case to the public. Too often, there has been a leadership void at the FDA.¹²¹ Perhaps the FDA has been surprisingly quiet, rarely defending itself in the court of public opinion, because it has gone through long stretches without a Senate-confirmed Commissioner.¹²² Nor has the Bush Administration stepped in to defend the Agency.¹²³ This reticence has contributed to an adverse effect on public health, and consequently has eroded public confidence in the Agency.¹²⁴ Regulatory mishaps, especially highly publicized ones, occupy the attention of the press but obscure the full story of the FDA's overall performance.¹²⁵ For the most part, the FDA does a remarkable job keeping our drugs, medical devices, foods, biological products, and radiological products safe. The American public should judge the FDA on its excellent track record for safety, but those many successes are often overshadowed by public outcry over isolated but highly publicized failures.¹²⁶

Third, the Agency needs to rebuild a credible enforcement program. The FDA has drastically reduced its enforcement efforts, signaling to industry that the regulatory cop is off the beat and that

¹²¹ See FDA SCIENCE AND MISSION AT RISK, *supra* note 45, § 1.2.1 (noting the erosion of the Agency's organizational structure); see also U.S. Food and Drug Administration, Commissioners and Their Predecessors, <http://www.fda.gov/oc/commissioners/default.htm> (last visited Apr. 9, 2008) (listing the tenure of each FDA Commissioner).

¹²² *Hearings on the Nomination of Andrew Von Eschenbach and Paul DeCamp Before the Subcomm. on Health, Education, Labor, and Pensions*, 109th Cong. 2 (2006) (statement of Sen. Michael B. Enzi, Chairman, Committee on Health, Education, Labor, and Pensions) ("The FDA has been without a confirmed Commissioner for all but 18 months out of the last 5½ years.").

¹²³ See FDA SCIENCE AND MISSION AT RISK, *supra* note 45, § 4.1.1 ("President Bush stated that the current system must be fixed 'within available resources.' We can state unequivocally that the system cannot be fixed 'within available resources.'") (citation omitted).

¹²⁴ *Cf. id.* (noting the Agency's belief that the system could not "be fixed" under the approach of the current Administration).

¹²⁵ See Beth Herskovits, *Next FDA Head Faces Tough Road as Criticism Increases*, PR WEEK, Oct. 24, 2005, at 2.

¹²⁶ Even what I have referred to as the Agency's "regulatory failures" involved difficult and debatable questions of science. Consider the Vioxx controversy: the FDA welcomed the development of the so-called COX-2 inhibitors (Vioxx, Bextra, and Celebrex) because this new class of drugs held the promise of addressing a serious problem with the older generation of nonsteroidal anti-inflammatory drugs—namely, that they cause gastrointestinal bleeding in some patients, resulting in thousands of bleeding deaths a year. Thus, even recognizing the additional risk of heart attack and stroke from COX-2 drugs, that risk may be acceptable to patients prone to gastrointestinal bleeding. See generally *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 778–79 (E.D. La. 2007).

infractions will go unenforced.¹²⁷ The steep decline in enforcement efforts sends the wrong message both to the regulated industries and to the public. A weak FDA enforcement program inevitably leads to weak compliance, thus undermining the Agency's responsibility to safeguard the public health. The FDA must visibly enforce its governing statute to demonstrate to the industry that compliance is not optional and that failure to obey the law will result in swift and certain penalties.¹²⁸

Fourth, the Agency should reaffirm its commitment to making publicly accountable decisions. The Agency suffered criticism for its decision on preemption partly because it decided in a way that was neither transparent nor publicly accountable, and which marked a departure from past practices.¹²⁹ The FDA Amendments Act, which imposes unprecedented disclosure requirements on the FDA, is a response to what Congress perceived to be the Agency's lack of transparent decision making.¹³⁰ However, there is reason to worry that the disclosure requirements that Congress has imposed will consume scarce Agency resources and invite critics to second-guess Agency decisions.

One hopeful sign of increased transparency is that the Agency itself requested two independent audits of its capacity, the 2006 Institute of Medicine Report and the 2007 *FDA Science and Mission at Risk* Report of the Agency's Advisory Science Board.¹³¹ Both reports are exhaustive and highly critical assessments of the Agency's ability to fulfill its statutory duties; the Agency seems to be taking the reports seriously.¹³² Congress has adopted some of the Institute of Medicine's

¹²⁷ The drop in enforcement activities by the Agency is nothing short of stunning. In 1991 through 1993, the Agency brought a total of 468 civil seizure actions, 75 criminal injunction cases, and 121 criminal prosecutions. See Hutt, *supra* note 1, at B-22 to B-23. However, from 2004 to 2007, the Agency brought a total of only 53 civil seizure actions, 57 criminal injunction cases, and *no* criminal prosecutions. *Id.* at B-23. The decline in FDA warning letters is just as steep: from 1788 in 1993 to only 467 in 2007. *Id.* at B-23.

¹²⁸ See *id.* at B-23 ("A weakened FDA inevitably leads to weak compliance with the law."). Congress also showed concern over the steep drop in FDA enforcement efforts: the FDA Amendments Act provides the FDA with increased authority to impose civil penalties for violations of the Act, which may make it easier (if the Agency is so inclined) to rebuild its enforcement capacity. See Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 801(b)(2), 121 Stat. 823, 920 (to be codified at 21 U.S.C. § 331).

¹²⁹ See *supra* notes 68-73 and accompanying text; see also Mark Kaufman, *FDA Tries to Limit Drug Suits in State Courts*, WASH. POST, Jan. 19, 2006, at 1.

¹³⁰ See, e.g., 153 CONG. REC. S11,837 (2007) (statement of Sen. Dodd).

¹³¹ See U.S. DEPT. OF HEALTH AND HUMAN SERVICES, FDA, THE FUTURE OF DRUG SAFETY—PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC: FDA'S RESPONSE TO THE INSTITUTE OF MEDICINE'S 2006 REPORT (2007), <http://www.fda.gov/oc/reports/iom013007.pdf> [hereinafter FDA'S RESPONSE TO THE INSTITUTE OF MEDICINE]; FDA SCIENCE AND MISSION AT RISK, *supra* note 45.

¹³² See FDA'S RESPONSE TO THE INSTITUTE OF MEDICINE, *supra* note 131; FDA SCIENCE AND MISSION AT RISK, *supra* note 45.

recommendations in the FDA Amendments Act; the Agency is instituting other recommendations.¹³³ These are important first steps.

In reality, Congress, and not the FDA, ultimately will determine the Agency's fate. If the Agency continues to administer self-inflicted wounds, Congress will be powerless to heal it. But even with its house in order, the FDA will be unable to accomplish all of its statutory duties unless Congress provides the resources and political insulation the Agency needs to serve the American public.

¹³³ SEE FDA'S RESPONSE TO THE INSTITUTE OF MEDICINE, *supra* note 131, at 1-2.