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LOSING DEFERENCE IN THE FDA'S SECOND CENTURY: JUDICIAL REVIEW, POLITICS, AND A DIMINISHED LEGACY OF EXPERTISE

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INTRODUCTION

The Food and Drug Administration (FDA), created by the Federal Food and Drugs Act of 1906,[1] recently entered its second century.

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1 Although commentators often cite 1906—the year Teddy Roosevelt signed the Federal Food and Drugs Act—as the year of the FDA's birth, *see, e.g.*, *Food and Drug Administration, in* A HISTORICAL GUIDE TO THE U.S. GOVERNMENT 248, 250 (George T. Kurian et al. eds., 1998) (referring to the Act as the Pure Food and Drugs Act), the Secretaries of the Treasury, Agriculture, and Commerce and Labor combined to enforce the original Act. *See* Federal Food and Drugs Act of 1906, Pub. L. No. 384, § 3, 34 Stat. 768, 768-69, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 717, § 201(d), 52 Stat. 1040, 1040 (codified in scattered sections of 21 U.S.C.) (defining the Secretary of Agriculture as

With this new century comes new challenges, including the ever-increasing risk that the Agency will no longer enjoy the deference historically given to its policy decisions. The judicial deference given to the Agency is usually attributed to the FDA's century-long legacy of scientific expertise.[2] However, in recent years, the news media has disdained the Bush Administration's political manipulation of the FDA and has questioned the Agency's scientific integrity. This criticism of the Administration's political manipulations of the FDA (for the benefit of conservative political constituencies) may diminish the willingness of federal judges to defer to our nation's most distinguished regulatory Agency.[3] And if the FDA loses its legacy of deference, its ability to regulate efficiently will diminish significantly.

This Article discusses milestones in the FDA's legacy, explores the evolution of deference to the FDA (and its empowerment as a regulator during its first century), and notes the indications of diminished scientific independence at the hands of Bush Administration appointees serving powerful constituencies. This Article also discusses the growing attention to the politics underlying FDA decisions in recent years, and how that attention may diminish the FDA's carefully built aura of scientific integrity. Further, this Article analyzes how public recognition of the Bush Administration's political control over the FDA may erode federal judges' views of the Agency, making them less receptive to deference arguments. Finally, this Article explores the already-present consequences of a politicized FDA: by examining anti-abortion groups' influence over the approval process for the drug "Plan B" and also the political motivations behind the FDA's recent policy shift in favor of preemption, this Article concludes that political direction of the FDA—both overt and covert—has diminished the likelihood of future judicial deference to the Agency.

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the predominate head of the Agency). Various alternative dates are cited less frequently. *See, e.g.*, FRAN HAWTHORNE, INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT 31 (2005) ("Most people . . . date the agency to the Federal Food and Drug Act of 1906. Peter Barton Hutt, the FDA's chief counsel from 1971 to 1975 and its unofficial historian, prefers to [date the FDA to] 1862, when the newly created U.S. Department of Agriculture set up a laboratory to analyze food samples. It could also be argued that the modern FDA did not really take shape until the laws were revised in 1938 and 1962.").

2 As one commentator put it, "For almost a century, the FDA has been the *Good Housekeeping* seal of approval, the Nobel Prize, and Ivory soap (99 and 44/100 percent pure) combined." HAWTHORNE, *supra* note 1, at viii–ix.

3 *See* PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION, at xiv (2003) ("[The FDA] is the most known, watched, and imitated of regulatory bodies. . . . [I]t has also been described as the most important regulatory agency in the world.").

I
THE IMPORTANCE OF DEFERENCE

An administrative agency spends much of its time developing and enforcing regulations, conducting hearings, issuing licenses, and publishing advisory opinions.[4] The prudent federal agency official understands that all of the agency's grand rulemaking visions (or careful licensing decisions) would be wasted if a judge vacated the agency's actions when challenged in court.[5] Thus, it is in the agency's enlightened self-interest to avoid any threat to its continued success by encouraging judicial deference to its actions.[6]

One can loosely define deference as the willingness of a court to accept an agency's interpretations of a statute or policy over competing interpretations offered by regulated persons or public interest groups.[7] Once the agency decides the issue, a rigorous "hard look" by a federal court might overrule the agency's interpretation of the statute,[8] but a deferential review will likely accept the agency's interpretation—and with it, the agency's decision regarding issuing the license or rule.[9] Thus, the key to any agency's successful defense of its deci-

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4 *See generally* 2 AM. JUR. 2D *Admin. Law* § 48 (2004) (describing the bulk of an agency's purposes).

5 *See* 5 U.S.C. § 706 (2000) (defining the scope of judicial review when evaluating an administrative agency's decisions); *see also* JAMES T. O'REILLY, ADMINISTRATIVE RULEMAKING § 18:3 (2d ed. 2007) [hereinafter O'REILLY, RULEMAKING] (describing the levels of deference that the various agency actions may receive); Ronald M. Levin, *A Blackletter Statement of Federal Administrative Law*, 54 ADMIN. L. REV. 1, 37–39 (2002) (characterizing the various methodologies that courts employ under *Chevron* when evaluating an agency's interpretation of its organic statute).

6 *See, e.g.*, Timothy K. Armstrong, Chevron *Deference and Agency Self-Interest*, 13 CORNELL J.L. & PUB. POL'Y 203 (2004) (reviewing instances when courts have refused deference to an agency's self-interested legal interpretations).

7 *See* Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984) (defining the modern approach of judicial deference to agency statutory interpretations). For a useful synopsis of *Chevron* deference see Levin, *supra* note 5, at 37–39. *See also* O'REILLY, RULEMAKING, *supra* note 5, § 18:2; Ronald M. Levin, *The Anatomy of* Chevron*: Step Two Reconsidered*, 72 CHI.-KENT L. REV. 1253, 1267–68 (1997) (noting that "deference" is a means of recognizing legislative delegation of authority) (citation omitted); Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 513 (noting that *Chevron* represented the Court's decision to resolve the then-existing jurisprudential divide by sanctioning the deferential approach); Laurence H. Silberman, Chevron—*The Intersection of Law & Policy*, 58 GEO. WASH. L. REV. 821, 827–28 (1990) (arguing that judges must ask not if the agency's view is the best, but rather if it is reasonable); *cf.* Mark Seidenfeld, *A Syncopated* Chevron*: Emphasizing Reasoned Decisionmaking in Reviewing Agency Interpretations of Statutes*, 73 TEX. L. REV. 83, 128–30 (1994) (arguing that courts should employ a more rigorous approach to *Chevron*'s second step than traditional deference).

8 *See, e.g.*, Patrick M. Garry, *Judicial Review and the "Hard Look" Doctrine*, 7 NEV. L.J. 151, 155–59 (2006) (describing the evolution and application of hard look review).

9 *See, e.g.*, Auer v. Robbins, 519 U.S. 452, 457–59 (1997) (upholding as reasonable the Secretary of Labor's interpretive rule regarding existing regulation); *Chevron*, 467 U.S. at 863–64 (mandating judicial deference to an agency's reasonable construction of its organic statute). *But see* Gonzales v. Oregon, 546 U.S. 243, 255–69 (2006) (refusing to ex-

sions is the willingness of federal judges to give deference to its expertise. Indeed, agencies fervently seek deference to ensure the enforceability of their policy decisions.[10] If an agency does not receive consistent deference from the courts, regulated entities will likely deem the agency less potent; in turn, those entities will be less likely to respect agency decisions.[11]

As with any administrative agency, deference is a cornerstone of the FDA's effectiveness.[12] If it were not accorded deference, the many hours spent formulating and promulgating rules would amount to a waste.[13] A historic strength of the FDA has been the deference received from courts during enforcement actions; indeed, the FDA has long nurtured its aura of expertise in order to win the accommodating acceptance of judges.[14] In recent years, as the economic role of the FDA has become more overt,[15] FDA drug licensing decisions have been more controversial and more frequently litigated.[16] Therefore, deference, now more than ever, is central to the FDA's effectiveness as an administrative agency.

II
THE PARTICIPANTS IN THE DEFERENCE DEBATE

Given that deference is so important to the FDA's continuing efficacy, it may be surprising that the universe of individuals who control deference to the Agency is probably fewer than fifty: the federal judges likely to hear cases challenging the FDA will be those thirteen judges on the District of Columbia Circuit Court,[17] a small number of

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tend traditional deference to the Attorney General's interpretative rule when the interpreted regulation failed to define the authorizing statutory language in any meaningful way).

10 *See* O'REILLY, RULEMAKING, *supra* note 5, § 18:1. Although *Chevron* aids the agency in its quest for deference, it is not a total shift of power to agency decision makers. *See, e.g.*, Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 980–93 (1992) (demonstrating empirically that *Chevron* has not had a dramatic effect on the Court's deference jurisprudence).

11 *See* O'REILLY, RULEMAKING, *supra* note 5, § 18:1 (noting that the deferential approach announced in *Chevron* "is an important tool for agencies to defend their rules and their interpretations from challengers").

12 *See id.*; *see also id.* § 18:3 (describing the various agency functions that receive deference).

13 *See generally* 1 JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 4 (3d ed. 2007) (describing the FDA's rulemaking process) [hereinafter O'REILLY, FDA].

14 *See id.* § 2:7 (discussing the relationship between the FDA and the Judiciary).

15 *See infra* Part IX.

16 Litigation between the pharmaceutical industry and the FDA occurs particularly frequently. *See generally* 1 O'REILLY, FDA, *supra* note 13, §§ 14:1–14:3 (detailing the manifold opportunities for litigious interface between the FDA and the industry in the context of seeking approval of a new drug).

17 Court of Appeals for the District of Columbia: Roster of Presiding Judges, http://www.cadc.uscourts.gov/internet/home.nsf/content/judges (last visited Apr. 7, 2008); *cf.*

judges who sit as panel members on occasional review of the FDA cases heard in other circuits, and those few federal district judges who hear the relatively infrequent FDA lower court enforcement or injunction cases.[18]

Similarly, while FDA deference has truly global effects on the strength of regulatory protections, the actual players advocating and opposing deference are few. The individuals advocating deference are the civil appellate staff of the Justice Department and the attorneys in the FDA's Office of Chief Counsel.[19] These advocates are vastly outnumbered by the industry lawyers whose clients challenge FDA decisions.[20] Also, in recent years, numerous industry adversaries opposing FDA rules have funded the "think tank" and trade association entities who serve as stalking-horse plaintiffs against FDA rules.[21] Finally, a tiny handful of appellate lawyers work with nonprofit organizations that represent patients or consumers challenging FDA decisions.[22]

III
THE SUPREME COURT'S DEFERENCE TO THE FDA

The five peaks of modern judicial deference to the FDA were the Supreme Court decisions in the *Hynson*, *Rutherford*, *Chaney*, *Young*, and *Lohr* cases. These cases merit attention at the outset in order to adequately frame the remaining discussion on deference. The common element of these decisions was the Court's perception that the FDA was an expert agency, and thus should be allowed to exercise discretion within its areas of primary jurisdiction.

Christopher P. Banks, *The Politics of En Banc Review in the "Mini-Supreme Court,"* 13 J.L. & POL. 377, 379 (1997) (noting that the Circuit's "crucial role in deciding regulatory agency appeals[ ] have helped to institutionalize the D.C. Circuit as a [ ]'mini[ ] supreme court' in administrative law").

18 Perhaps fifty-nine would be a better number, given the Supreme Court's constitutional authority over all federal courts.

19 *See* U.S. Food and Drug Admin., Office of Chief Counsel, http://www.fda.gov/oc/occ/ (last visited Apr. 7, 2008).

20 The Administrative Law section of the ABA has over 7,000 professional members. Michael Asimow, Welcoming Remarks for the American Bar Association, Section of Administrative Law & Regulatory Practice, http://www.abanet.org/adminlaw/asimow-welcome.pdf.

21 For example, the Washington Legal Foundation has presented numerous challenges to the FDA's powers. *See* Washington Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000) (presenting the final outcome of a series of arguments against FDA control of pharmaceutical company "off-label" claim statements); *see also* Nancy Bradish Myers, *The Interactors*, *in* FDA: A CENTURY OF CONSUMER PROTECTION 94, 94–95 (Wayne L. Pines ed., 2006) [hereinafter CENTURY OF PROTECTION] (listing a wide range of industry trade associations and consumer organizations).

22 *See, e.g.*, Posting of Kerry Donahue to CARE TO LIVE, http://caretolive.com/2007-11-23/ (Nov. 23, 2007) (posting of the nonprofit's counsel, challenging the FDA's decision not to approve the immunotherapy drug Provenge).

Hynson was a landmark in administrative law history.[23] In that case, the Court showed remarkably broad deference to the FDA, giving the Agency virtually unreviewable authority to determine whether a product was (or was not) a "new drug" and thus within the FDA's regulatory jurisdiction.[24] After *Hynson*, the FDA had jurisdiction over every new drug, except for those new drugs that were "generally recognized" as effective.[25] However, courts would allow the FDA broad leeway to determine whether a new drug was generally recognized as safe and effective, and thus outside its area of regulatory control.[26] Given the lack of judicial scrutiny, this effectively gave the FDA an unchecked ability to determine its jurisdiction—a remarkable power for any agency.

Rutherford further confirmed the FDA's broad jurisdiction.[27] In that case, terminally ill patients sued the FDA for access to medications that the FDA had not yet approved, asserting that their status as terminally ill should exempt them from waiting for a drug to pass the FDA's efficacy proof process.[28] The Court upheld the FDA's authority to determine the effectiveness of all new drugs—even those for terminally ill patients—because the Court was "reluctant to disturb a long-standing administrative policy that comports with the plain language, history, and prophylactic purpose of the Act."[29] The confirmation of the FDA's authority, in the face of these strong equitable and moral arguments, was a clear victory for the Agency's extensive powers.

In *Chaney*, the Court allowed the FDA very broad prosecutorial discretion in determining which parties it would target with enforcement actions.[30] A group of inmates sentenced to death by lethal injection sought to compel the FDA to pursue enforcement actions against various states that, according to the inmates, were not using the lethal injection drugs for their FDA-approved purpose.[31] The Court permit-

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23 Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973); *see also* James O'Reilly, *Jurisdiction to Decide an Agency's Own Jurisdiction: The Forgotten Tale of the* Hynson *Quartet*, 58 ADMIN. L. REV. 829, 830 (2006) [hereinafter O'Reilly, *Jurisdiction to Decide*] (describing the historical significance of the case).

24 *See* Federal Food, Drug, and Cosmetic Act § 201(p)(1), 21 U.S.C. § 321(p)(1) (2000) (defining the term "new drug"); 25 AM. JUR. 2D *Drugs and Controlled Substances* § 111 (2004) (explaining the definition).

25 Federal Food, Drug, and Cosmetic Act § 201(p)(2), 21 U.S.C. § 321(p)(2) (excepting "generally recognized" drugs from the definition of "new drug").

26 *See* 25 AM. JUR. 2D *Drugs & Controlled Substances* § 112 (2004) (stating the requirements a drug must satisfy in order to achieve general recognition); O'Reilly, *Jurisdiction to Decide*, *supra* note 23, at 836–37 (noting the Court's blessing on the FDA to decide the minimum quantum of data necessary to support a finding of general recognition).

27 United States v. Rutherford, 442 U.S. 544 (1979).

28 *Id.* at 548.

29 *Id.* at 554.

30 *See* Heckler v. Chaney, 470 U.S. 821, 832 (1985).

31 *Id.* at 823–25.

ted the FDA discretion to decide whether or not to pursue enforcement for violation of the new drug approval requirements, thus limiting the scope of the Court's review over the FDA's decision not to pursue an enforcement action.[32] This was a key decision because the limited scope of judicial review over the FDA's enforcement decisions is a very important form of deference.

In *Young*, the Court gave deference to the FDA's decision not to promulgate a regulation that would set a safe tolerance level for a carcinogen found in some foods.[33] The FDA believed that the Federal Food, Drug, and Cosmetic Act (FD&C Act) gave it discretion in promulgating such standards, and the Court agreed.[34] The complexities of the FDA's statutory delegation led the Court to conclude that "we need not find that [an agency's interpretation of a statute] is the only permissible construction that [the agency] might have adopted but only that [the agency's] understanding of this very 'complex statute' is a sufficiently rational one to preclude a court from substituting its judgment for that of [the agency]."[35]

Finally, in *Lohr*, the Court deferred to the FDA's view of whether federal medical device law provisions preempted overlapping state law requirements.[36] Over a strong dissent,[37] the majority found the FDA "uniquely qualified" to interpret whether the FD&C Act preempted state law and thus deferred to the FDA's interpretation of the preemptive scope of the Act.[38]

IV
THE TYPES OF DEFERENCE ENJOYED BY THE FDA

The types of judicial deference to the FDA can be broadly classified into two separate categories. The first (and the earliest) form of deference sought by the Agency is deference to its decisions regarding which products it would pursue with enforcement actions;[39] indeed, it

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32 *Id.* Two Justices, though concurring in the judgment, disagreed as to the breadth of deference accorded to the FDA. *See id.* at 839 (Brennan, J., concurring); *id.* at 840–41 (Marshall, J., concurring).

33 Young v. Cmty. Nutrition Inst., 476 U.S. 974, 981 (1986).

34 *Id.* at 979–81.

35 *Id.* at 981 (quoting Chem. Mfrs. Ass'n v. Natural Res. Def. Council, Inc., 470 U.S. 116, 125 (1985)).

36 Medtronic, Inc. v. Lohr, 518 U.S. 470, 495-96 (1996) (deferring to the FDA's construction of the relevant statutory provision regarding the scope of preemption).

37 The split in the Court turned upon the degree to which courts should defer to several distinct levels of precision in the FDA's licensing of new medical devices. *See id.* at 513 (O'Connor, J., concurring in part and dissenting in part) (arguing for a broader preemptive scope than that adopted by the FDA and endorsed by the majority).

38 *See id.* at 496.

39 *See, e.g.*, Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594, 600 (1950) (holding that a district court "ha[s] no jurisdiction to review the [FDA's] determination" about whether it had probable cause to commence an enforcement action). *See generally* Edward

was critically important to the FDA that the courts would not lightly overturn its decisions regarding which regulated items to pursue with enforcement actions.[40] The consequences of not receiving deference in this area are illustrated by the experiences of the Consumer Product Safety Commission, an agency that was spun off from the FDA in 1972.[41] The Commission was denied deference in numerous appellate defeats;[42] because of its unsuccessful attempts to enforce its own standards, the Commission virtually ceased developing them.[43] However, unlike the failed Commission, the FDA was highly successful in achieving judicial deference to its enforcement decisions. This success is perhaps best illustrated by the 1985 *Chaney* decision, discussed above.[44] In discussing the FDA's enforcement decision, the *Chaney* Court showed maximum deference to the FDA's prosecutorial discretion:[45] the Court held that "an agency's decision not to take enforcement action should be presumed immune from judicial review . . . ."[46]

Although the FDA received deference to its enforcement decisions, that deference has been qualified in one very important respect. When the Agency brought enforcement cases in the district courts of the Fifth Circuit, the judges could hold food companies to a more stringent standard of food purity but could not be less stringent than the FDA in its view of food safety enforcement.[47] The Fifth Circuit's

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M. Basile & Melanie Gross, *The First Amendment and Federal Court Deference to the Food and Drug Administration: The Times They Are A-Changin'*, 59 FOOD & DRUG L.J. 31, 33–35 (2004) (describing several pre-*Chevron* cases in which the Court gave deference to the FDA's enforcement decisions).

40 *See supra* Part I.

41 In 1972, the FDA's Bureau of Product Safety folded into the new Consumer Product Safety Commission after adoption of the Consumer Product Safety Act, Pub. L. No. 92-573, § 4(a), 86 Stat. 1207, 1210 (1972) (codified as amended at 15 U.S.C. § 2053(a) (2000)). *See* Fred H. Degnan & Steven B. Seinborn, *Open Forum: Toys and Confectionary—A Legally Compatible Combination*, 53 FOOD DRUG L.J. 9, 14 n.28 (1998) ("After passage of the CPSA, the CPSC was formally established. A major component of the CPSC was [the] FDA's Bureau of Product Safety . . . .").

42 *See, e.g.*, Gulf S. Insulation v. U.S. Consumer Prod. Safety Comm'n, 701 F.2d 1137, 1140 (5th Cir. 1983); Southland Mower Co. v. Consumer Prod. Safety Comm'n, 619 F.2d 499, 527 (5th Cir. 1980) (denying deference to one part of the Commission's rule); Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n, 569 F.2d 831, 835 (5th Cir. 1978); D.D. Bean & Sons Co. v. Consumer Prod. Safety Comm'n, 574 F.2d 643, 653–54 (1st Cir. 1978).

43 *See* Anthony Sciascia, *Safe or Sorry: How the Precautionary Principle is Changing Europe's Consumer Safety Regulation Regime and How the United States' Consumer Product Safety Commission Must Take Notice*, 58 ADMIN. L. REV. 689, 693 (2006) (noting that the CSPC's emphasis on voluntary regulation has left the Agency "impotent and weak"); *see also* Elliot Klayman, *Standard Setting Under the Consumer Product Safety Amendments of 1981—A Shift in Regulatory Philosophy*, 51 GEO. WASH. L. REV. 96, 99–103 (1982) (same).

44 *See supra* note 30 and accompanying text.

45 Heckler v. Chaney, 470 U.S. 821, 832 (1985).

46 *Id.*

47 *See, e.g.*, United States v. Boston Farm Ctr., Inc., 590 F.2d 149, 151 (5th Cir. 1979) (considering whether the court should defer to the FDA's "action levels" and noting that it

statement regarding the level of the level of deference to be given to the FDA may be typical of the deference that the FDA received for decades:

> We remand the case to the District Court for it to determine under a correct reading of the statute whether the [regulated product] is adulterated. It may accept as a judicial standard the allowable tolerances now permitted by the Secretary . . . . A court may apply a stricter standard than the Secretary and hold a food substance adulterated though within the Secretary's tolerances. Considering the positive command of the statute, the power of the court to allow a greater departure from purity than the administrative tolerances is less certain.[48]

This one-way deference to enforcement had very practical consequences for the FDA: lawyers counseling companies regulated by the FDA would advise their clients to settle or to avoid enforcement because deference meant that the likelihood of judicial intervention to alter the FDA's established minimum levels was doubtful.[49]

The second type of deference is to Agency interpretations of its statutory delegation of authority over foods, drugs, medical devices, and related products.[50] Gaining deference over these matters fortified the FDA because it could then predict that courts would support new regulations.[51] Because of this, the FDA was able to regulate products that fell into the interstices between statutory categories, such as diagnostic products[52] and the labels disclosing the ingredients of cosmetics.[53]

The broad scope of deference given to FDA decisions reveals itself through examination of not only those instances in which the

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could use a more stringent standard of food purity, but ultimately deciding the matter on other grounds); United States v. 484 Bags, More or Less, 423 F.2d 839, 842 (5th Cir. 1970).

48 *484 Bags*, 423 F.2d at 842.

49 For example, 99.7% of seizures by the FDA in 1963 through 1973 were settled by consent or default. Peter Barton Hutt, *Philosophy of Regulation Under the Federal, Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L.J. 177, 186 (1973) [hereinafter Hutt, *Philosophy of Regulation*]; *see also* O'REILLY, FDA, *supra* note 13, § 7:3.

50 *See* O'REILLY, FDA, *supra* note 13, § 4:12.

51 *See, e.g.*, Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 883 (D.C. Cir. 2004) ("FDA interpretations of the FDCA receive deference, as do its interpretations of its own regulations.") (citations omitted); S.G. Loewendick & Sons, Inc. v. Reich, 70 F.3d 1291, 1294 (D.C. Cir. 1995) ("Well-known principles govern our review of agency interpretations of agency regulations. We owe 'substantial deference' to the agency's interpretation, which has 'controlling weight unless it is plainly erroneous or inconsistent with the regulation'") (quoting Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994)).

52 *See* United States v. Article of Drug . . . Bacto-Unidisk . . . , 394 U.S. 784, 797–98 (1969) (accepting the FDA's argument that Congress intended to include diagnostic devices under the term "drug").

53 *See* Indep. Cosmetic Mfrs. & Distribs., Inc. v. U.S. Dep't of Health, Educ. & Welfare, 574 F.2d 553, 557 (D.C. Cir. 1978) (finding against the plaintiff, on procedural grounds, in a case involving FDA regulation of cosmetics labels).

facts so strongly favored the FDA that the Agency would have prevailed on the factual record alone,[54] but also those cases in which the FDA made novel and broad interpretations of its jurisdiction over contaminants such that the Agency could only prevail if the court was willing to defer. It is in these latter cases where the degree of deference afforded the FDA is most impressive.[55] Thus, the twin pillars of enforcement deference and authority-delegation deference combined to support the belief that courts would accept FDA interpretations and applications of the FD&C Act.

V
How the FDA Earned Its Legacy of Deference

The FDA's historical roots are grounded in the pre-1900's populist reform movements of the Age of Trustbusters.[56] Teddy Roosevelt, the legendary trustbuster of the early twentieth century, saw the FDA's predecessor agencies as vehicles for populist control of an important aspect of the economy.[57] The 1906 Food and Drugs Act was, in fact, part of an institutional effort to constrain fraudulent practices by the trusts of the era.[58] The founders of the FDA sought to be passionate consumer advocates who used the power of a dispassionate scientific approach to address safety issues.[59] Through this aura of scientific expertise, the newly founded government agency quickly gained credibility.

The FDA's earliest enforcement efforts involved assembling evidence of problems through careful laboratory work. For example, at

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54 *See, e.g.*, United States v. Boston Farm Ctr., Inc., 590 F.2d 149, 151 (5th Cir. 1979) (declining to pass on the deference issue because the facts were "so one-sided that any finding [against the Agency] . . . would [be] clearly erroneous").

55 *See, e.g., supra* text accompanying notes 33–35.

56 *See generally* Richard M. Cooper, *The Struggle for the 1906 Act, in* Century of Protection, *supra* note 21, at 25 (providing a useful history of the FDA during the nineteenth century, up through the passage of the 1906 Federal Food and Drugs Act).

57 *See* Dennis R. Johnson, *The History of the 1906 Pure Food and Drugs Act and the Meat Inspection Act*, 37 Food Drug Cosm. L.J. 5, 8–9 (1982) (describing Roosevelt's role); Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Muckrakers and the Enactment of the First Federal Food and Drug Law in the United States*, 36 Food Drug Cosm. L.J. 647, 648–51 (1981) (same).

58 *See* Theodore Roosevelt, Message to Congress (Dec. 8, 1908), *in* Carl A. Auerbach, *Is Government the Problem or the Solution?*, 33 San Diego L. Rev. 495, 502 (1996) ("If this irresponsible outside power is to be controlled in the interest of the general public, it can be controlled in only one way—by giving adequate power of control to the one sovereignty capable of exercising such power—the National Government."); Cooper, *supra* note 56, at 28–29 (describing the unsafe industry practices existing before widespread regulation). *See generally* Joseph A. Levitt, *Keeping America's Food Supply Safe, in* Century of Protection, *supra* note 21, at 135 (discussing the food adulteration and misbranding crises that sparked the FDA's assent as America's protector of food).

59 *See* Cooper, *supra* note 56, at 45–46 (describing early Agency efforts to establish itself as science-oriented and nonpartisan).

the turn of the twentieth century, certain additives and food chemicals were suspected of causing negative health effects for consumers.[60] The earliest efforts of the Bureau of Chemistry, the forerunner of today's FDA, were to ensure food safety through the use of hands-on experiments with food ingredients.[61] The Bureau's founder, Dr. Harvey Wiley, paid volunteers to dine on high doses of selected additives in order to establish which of the additives were harmful at given doses.[62] Dr. Wiley's "Poison Squad" drew great publicity for the new agency.[63]

As originally conceived, the FDA was to use its scientific skill to protect the public from contamination and fraud.[64] The Agency would develop scientific evidence for federal prosecutors, thereby assisting those prosecutors in pursuing the snake-oil promoters who defrauded gullible consumers or adulterated common foods.[65] Federal trial courts of the early twentieth century were not likely to be aggressive consumer protectors, but more progressive judges gave deference to antifraud efforts of the new Agency; early on, the Agency won a number of important cases.[66]

Courts have been quick to give deference to the FDA because of its role as "gatekeeper" for new drug approvals.[67] This gatekeeper role eventually turned the FDA's approval of a new drug application into the international "gold standard" on product safety and effectiveness, as well as the final word on permission for a new drug's entry into the U.S. marketplace.[68] This confidence in the FDA exists because of the Agency's reputation for superior science and expertise—not for its doctrinal or political policies.

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60 *See id.*

61 *See* Suzanne White Junod, *The People Who Ate Poisons*, *in* CENTURY OF PROTECTION, *supra* note 21, at 52, 52.

62 *See id.*

63 *See* Cooper, *supra* note 56, at 53; Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 51–52 (1984).

64 *See* Cooper, *supra* note 56, at 66.

65 *See* Peter Barton Hutt, *FDA Comes of Age: A Century of Change*, *in* CENTURY OF PROTECTION, *supra* note 21, at 99, 115 (noting that the 1906 Act authorized criminal sanctions).

66 The breakthrough case for the FDA's predecessor, the Bureau of Chemistry, came when the Supreme Court held that the operative term "may" in the food adulteration prohibition was to be broadly construed—if the contaminant "may possibly injure the health" of consumers, it could be condemned. United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 411 (1914); *see also* Hutt & Hutt II, *supra* note 63, at 57 (noting the "paramount importance" of the opinion).

67 *See, e.g.*, *In re* Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817, 828 (3d Cir. 1998) ("[T]he FDA is a gatekeeper charged with the responsibility of protecting the public from unreasonable risks of injury . . . .").

68 *See* HAWTHORNE, *supra* note 1, at viii (noting that "poll after poll has always shown [that the FDA] is one of the most trusted arms of the entire government"); Susan F. Wood, *When Politics Defeats Science*, WASH. POST, Mar. 1, 2006, at A17.

The FDA grew into its gatekeeper role after the 1962 amendments to the FD&C Act, which expanded the statutory drug approval criteria from the traditional condition—that the drug be safe—to require that the drug be efficient in treating the medical condition for which it is prescribed.[69] The 1962 amendments are of an historic importance because they gave the FDA power to disapprove a drug that was deemed safe but was not fully proven to be effective, and to select which drugs had shown sufficient effectiveness to justify approval despite their potential safety risks.[70] Thus, because FDA approval was a requirement for market entry of all new drugs, the amendments imposed an expensive burden on sponsors to prove the clinical effectiveness of each new compound prior to market entry.[71] Judicial deference to this approval process was a critical concession in favor of the FDA.[72] Additionally, the *Hynson* and *Bentex* Courts gave the FDA enormous discretion to fix the norms for drug adequacy.[73] Receiving judicial deference to its ability to determine its own jurisdiction allowed the Agency to expand its scope with diminished judicial oversight—the ultimate in deferential review of agency powers.[74]

VI
How the FDA's Powers Evolved with Deference

The next phase of the FDA's history saw the Agency's decisions elevated to a rarified status, achieving a degree of judicial deference that rose to the highest degree possible, short of an express mandate from Congress. This deference caused the Agency's power to evolve in two important ways.

First, as in *Hynson*,[75] the Supreme Court gave deference to the FDA's decisions about which drugs were within its jurisdiction.[76] In the period after *Hynson*, the FDA began to treat its authorizing statute as a starting point for new regulations rather than a finite limit on

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69 *See* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 781 (codified as amended in scattered sections of 21 U.S.C.).

70 *See id.* § 102.

71 *See* Applications for FDA Approval to Market a New Drug, 21 C.F.R. § 314.80(c) (2007) (listing the post-marketing reporting requirements); O'Reilly, FDA, *supra* note 13, § 13:85 (discussing the post-marketing reporting requirements).

72 *See supra* Part I.

73 *See* Weinberger v. Bentex Pharm., Inc., 412 U.S. 645, 653–54 (1973) (holding that the determination of whether a drug is generally recognized as safe and effective is a determination "peculiarly suited to initial determination by the FDA"); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 627 (1973) (allowing the FDA to determine what drugs were within its control).

74 *See* O'Reilly, *Jurisdiction to Decide*, *supra* note 23, at 830 (discussing the *Hynson* quartet of cases and the grant of deference to the FDA).

75 *See supra* Part III.

76 *See Hynson*, 412 U.S. at 627 ("[The FDA's] jurisdiction to determine whether it has jurisdiction is as essential to its effective operation as is a court's like power").

them.[77] The former Chief Counsel once described the FD&C Act as a constitution, within which any acts not proscribed could be taken by the Agency.[78] This spirit of legal ingenuity, of finding ways to justify rules without secure legislative roots, led to a series of challenges in the courts; judicial deference was the special advantage that allowed the FDA to prevail.[79] Courts found that the FDA's determinations merited special deference because of what one judge called "latitude inherent in the statutory scheme" that favored the FDA.[80]

Second, the Court deferred to the FDA's assertions of its power to impose strict liability in enforcing the criminal provisions of the FD&C Act, even though criminal law is rarely deferential.[81] The public health purpose of the Act was the basis for such strict liability in the 1943 *Dotterweich* case;[82] the Court then expanded that deferential norm in its 1974 *Park* decision.[83] Courts thereafter applied strict criminal liability in multiple appellate cases, thereby augmenting the FDA's deterrence of violators.[84] This deference to the FDA's potential use of strict liability criminal enforcement is important because it likely directly deters misconduct by regulated firms, since any rational FDA-regulated entity's managers will always seek to avoid going to jail for their acts or omissions.[85] Further, this deference is noteworthy because imposition of individual strict liability for violations by a regulated entity, without proof of the individual's knowledge or guilt, occurs only rarely in American criminal law.[86]

The special judicial deference granted to the FDA also had important effects outside the judicial branch. Until 1994, the field offices of the FDA worked together with the Department of Justice to prosecute all civil and criminal cases.[87] As a result of this deference,

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77 *See* Hutt, *Philosophy of Regulation*, *supra* note 49, at 179 ("[T]he fact that Congress simply has not considered or spoken on a particular issue certainly is no bar to the Food and Drug Administration exerting initiative and leadership in the public interest.").

78 *See id.* at 178.

79 For example, the Court of Appeals for the District of Columbia Circuit accorded deference to the Agency's view of how its amended cosmetics-labeling regulations affected filing requirements. *See* Indep. Cosmetic Mfrs. & Distribs., Inc. v. U.S. Dep't of Health, Educ. & Welfare, 574 F.2d 553, 557-58 (D.C. Cir. 1978).

80 Monsanto Co. v. Kennedy, 613 F.2d 947, 954 (D.C. Cir. 1979).

81 United States v. Park, 421 U.S. 658, 676 (1975).

82 United States v. Dotterweich, 320 U.S. 277, 280–82 (1943) (citing health concerns as the reason for legislation "dispens[ing] with the conventional requirement for criminal conduct—awareness of some wrongdoing").

83 *See Park*, 421 U.S. at 671 (citing public health concerns as the basis for liability, even by means of a mere relationship to the offending corporation).

84 *See* O'REILLY, FDA, *supra* note 13, §§ 8:2–8:3.

85 *See Park*, 421 U.S. at 672 (discussing the deterrent effect that strict liability will have on the managers of regulated firms).

86 *See generally* 21 AM. JUR. 2D *Criminal Law* § 145 (1998).

87 *See* United States v. Gel Spice Co., 773 F.2d, 427, 429 (2d Cir. 1985) (describing how the FDA brings an enforcement action). The FDA launched its own independent

DOJ prosecutors routinely concurred with the FDA's enforcement decisions.[88] The FDA had developed a reputation for careful preparation of cases; as a result, the government's arguments prevailed in the vast majority of its civil and criminal enforcement cases.[89]

VII
EXCEPTIONS TO THE DEFERENCE NORMS

The general willingness of courts to grant deference to an agency's final regulations does have limits. Exceptions to a judicial grant of deference include situations where: (1) the regulation was not sufficiently definitive or final,[90] (2) there were fatal flaws in key evidence supporting the regulation,[91] (3) the agency lacked authority to make the decision or promulgate the regulation,[92] (4) the agency acted inconsistently in interpreting its regulation,[93] and (5) the agency changed its policy position with no notice to affected entities.[94]

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enforcement branch in 1994, the Office of Criminal Investigations. Office of Criminal Investigations, Food & Drug Admin., http://www.fda.gov/ora/hier/hfc300.html (last visited Apr. 7, 2008). The productivity of FDA criminal enforcement improved substantially after 1994. *See* OFFICE OF CRIMINAL INVESTIGATIONS, COMPARISON CHART (2004), http://www.fda.gov/ora/about/enf_story2004_archive/ch6/oci_charts.pdf.

88 The Department of Justice prosecutes approximately ninety percent of the cases referred by the FDA. *Cf.* Joel E. Hoffman, *Enforcement Trends Under the Federal Food, Drug and Cosmetic Act—A View from Outside*, 31 FOOD DRUG COSM. L.J. 338, 348 (1976) (noting that the Department of Justice declined to prosecute ten percent of those cases); Robert L. Rabin, *Agency Criminal Referrals in the Federal System: An Empirical Study of Prosecutorial Discretion*, 24 STAN. L. REV. 1036, 1091 (1972) (same).

89 For post-1994 conviction rates, see OFFICE OF CRIMINAL INVESTIGATIONS, *supra* note 87.

90 *See* United States v. Mead Corp., 533 U.S. 218, 234 (2001) (denying *Chevron* deference to a U.S. Customs Service tariff classification ruling).

91 *See* Almay, Inc. v. Califano, 569 F.2d 674, 682–83 (D.C. Cir. 1977) (refusing deference to the FDA's definition of "hypoallergenic" due to a lack of sufficient supporting evidence).

92 *See* Gonzales v. Oregon, 546 U.S. 243, 268 (2006) (holding that the Attorney General did not have the authority to issue an interpretive rule regarding medical policy); Nutritional Health Alliance v. Food & Drug Admin., 318 F.3d 92, 101, 104 (2d Cir. 2003) (holding "that the plain language of . . . the FDC Act" does not delegate certain regulatory authorities to the FDA and that the FDA's "proffered interpretation is not reasonable").

93 *See* Can Mfgs. Inst. v. U.S. Food & Drug Admin., Food Drug Cosm. L. Rep. (CCH) ¶ 38,354 (D.D.C. 1994) (refusing deference to the FDA's rule because of inconsistent requirements imposed and enjoining the FDA from enforcing the rule).

94 This is an infrequently used, but often-successful argument. *See* Nw. Tissue Ctr. v. Shalala, 1 F.3d 522, 531–32 (7th Cir. 1993) (acknowledging the standing of the plaintiffs because the FDA unexpectedly modified its interpretation of the relevant rule); *see also Mead Corp.*, 533 U.S. at 228 ("The fair measure of deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position."); Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 698 (1991) (noting a weaker commitment to deference when an agency changes position, but nonetheless deferring).

A comparison of two recent preambles to FDA regulation demonstrates that, over the course of six years, the Agency has shifted toward a view that its regulations should preempt conflicting state tort law.[95] However, the FDA's new view carries no grant of congressional authority, conflicts with the earlier preamble, and, in any event, was not codified in the existing regulation.[96]

VIII
WHY THE INDUSTRY SHIFTED TO FAVOR DEFERENCE

Deference to the FDA's decisions was anathema to the industries regulated by the FDA for virtually all of the Agency's first century.[97] When industry and the FDA clashed, the Agency used deference to its advantage over its challengers.[98] But, during the Bush Administration, money and power has shifted industry advocates from a staunch anti-deference position toward remarkable aggressiveness in favor of selective deference to the new leaders of the FDA.[99] This change in the industry position is due to the change in FDA management: outside critics of the FDA became its leaders, and they began efforts to reverse prior FDA policies.[100] The Bush Administration's political selection of Daniel Troy as the FDA Chief Counsel was a controversial choice: Troy had once litigated for the drug and tobacco industries against the FDA[101] and was appointed to replace Margaret Jane

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95 *Compare* Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (noting that the proposed rule would not preempt state law), *with* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3967–68 (Jan. 24, 2006) (effective June 30, 2006) (examining the same regulation but now arguing that it should preempt state law).

96 *Compare* sources cited *supra* note 95.

97 *Cf.* Basile & Gross, *supra* note 39, at 31–37 (explaining how the deference doctrine gave the FDA free reign to expand and enforce its regulations).

98 *See id.*

99 *See* Ralph Lindeman, *Federalism: Agencies Move to Override State Law As Part of Federal Rulemaking Process*, Daily Report for Executives (BNA) No. 66, at C-1 (Apr. 6, 2006) ("Industry is unlikely to mount a court challenge to the new rules, at least on the preemption issue, because it favors business interests.").

100 *See* Stacy Schultz, *Mr. Outside Moves Inside*, U.S. NEWS & WORLD REP., Mar. 24, 2003, at 63 (discussing how Daniel Troy, a lawyer who fought to curtail FDA regulatory schemes, became head of the FDA's legal division under the Bush Administration).

101 *See* Michael Kranish, *FDA Counsel's Rise Embodies U.S. Shift*, BOSTON SUNDAY GLOBE, Dec. 22, 2002, at A1 ("Troy's journey from relentless litigant against the FDA to its guiding legal star encapsulates the transformation of medical regulation under the Bush administration."); Schultz, *supra* note 100; Michael Steel, *FDA Signs Up an Opponent*, NATIONAL J., Sept. 22, 2001, at 2934 (noting the Senate Democratic Whip's statement that President Bush's selection for FDA Chief Counsel "has consistently been on the wrong side of consumer issues in his private practice"); *see also* Wash. Legal Found. v. Henney, 202 F.3d 331, 331–32 (D.C. Cir. 2000).

Porter, who disfavored federal preemption of tort cases.[102] Once in office, Troy publicly called upon industry advocates to suggest private tort cases into which the FDA could intervene on their behalf,[103] an unprecedented move for an FDA Chief Counsel.[104] Troy sought to make a new policy argument that drug approvals by the FDA should preempt all state tort remedies for consumers injured by prescription drugs.[105]

The pharmaceutical industry swiftly embraced Troy's new policy and supported the FDA's request for deference in numerous tort cases because preemption could shield industry tort defendants from the expense and uncertainty of products liability suits.[106] Advocates for the regulated firms became aggressive champions of deference to the FDA's new views of preemption in private civil tort cases.[107] It seemed an ironic about-face: longtime industry opponents of judicial deference had been converted by the Bush Administration's willingness to intervene in support of industry defendants.

The media coverage of this reversal was remarkably broad and consistently skeptical. For example, one journalist reported that "[t]he FDA's efforts on behalf of drug and medical-device makers is part of a broader Bush administration effort to curb lawsuits arising from personal injuries."[108] The stark political basis for the FDA policy reversal became transparent to the media, and perhaps even to the

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102 *See* Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 7–8 (1997) (noting the Agency's long-standing presumption against preemption).

103 *See* Daniel E. Troy, *FDA Involvement in Product Liability Lawsuits*, UPDATE: FOOD & DRUG LAW, REG., & EDUC. MAG., Jan./Feb. 2003, at 4; *see also* Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 589 n.5 (2005) (describing comments that Mr. Troy made at a legal education conference and noting that they were in favor of preemption).

104 *See* Struve, *supra* note 103, at 588–89 (describing Mr. Troy's actions as "controversial"). Clinton Administration appointees did take an occasional position in favor of the preemption position, but no prior FDA official had actively solicited preemption cases for FDA intervention. *See* Anne C. Mulkern, *Watchdogs or Lap Dogs? When Advocates Become Regulators*, DENVER POST, May 23, 2004, at 1A.

105 Rep. Maurice Hinchey criticized Troy's actions. *See* 150 CONG. REC. H5598–99 (2004) (statement of Rep. Hinchey) (requesting a $500,000 reduction in appropriations for the FDA Office of Chief Counsel in retaliation to Mr. Troy's preemption policy); Congressman Maurice Hinchey, FDA is Placing Corporations Above Public, http://www.house.gov/hinchey/issues/fda.shtml (last visited Apr. 7, 2008) (listing documents collected by Rep. Hinchey to support his anti-Troy position).

106 *See* Lindeman, *supra* note 99, at 7.

107 The January 2006 FDA preemption preamble followed amicus briefs, filed by Troy's office between 2003 and 2005, in support of pharmaceutical and medical-device company defendants. *See* Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, at N1.

108 Robert Cohen, *FDA Joins Suits on Side of Industry it Regulates*, SUNDAY STAR-LEDGER (Newark, N.J.), May 9, 2004, at 1; Kathleen Kerr, *Can FDA Seal be Broken?*, NEWSDAY (N.Y.), Aug. 11, 2004, at A26 ("Some legal experts say the government is using a back-door approach to achieve tort reform—a move to reduce huge payments to plaintiffs in liability

handful of judges to whom their arguments are being addressed.[109] For example, in a 2008 Supreme Court case, FDA pleas for deference were refused; both the majority and the dissent noted that the FDA should not receive the normal degree of deference because of its dramatic policy reversal.[110]

IX
HOW THE FDA'S INVOLVEMENT IN THE ECONOMICS OF DRUG APPROVAL EXPANDED

The development of a new drug is a high-stakes gamble.[111] Winners are rewarded with patent extensions and rights to exclusive sale, while marketers of the drug receive federal and state reimbursement for Medicare and Medicaid costs and for other federal drug program purchases.[112] The FDA's ability to select the winners from among those seeking approval makes the Agency the essential gatekeeper in the approval of drug products.[113] This gatekeeper role must be neu-

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cases."). *See generally* Thomas Ginsberg, *Litigation Inoculation: New FDA Policy Aims to Preempt Suits over Labels. A Judge Here Said It Was Right*, PHILA. INQUIRER, July 9, 2006, at E1.

109 *See, e.g.*, Mulkern, *supra* note 104 ("The president's political appointees are making or overseeing profound changes affecting drug laws, food policies, land use, clean-air regulations and other key issues."); Neil Steinberg, *Why Not Vaccinate the Right Against Wrong?*, CHI. SUN-TIMES, Mar. 13, 2006, at 24 ("The really jaw-dropping part is the administration's view of any medical advance that might lessen the wages of sin. . . . Lives would be saved by the vaccine [to prevent a common sexually transmitted disease], but the politicized Bush FDA will probably deny approval, as the disease—like all VD—is a handy ally to the Religious Right in its battle against sex."); Leonard Zehr, *Drug Approvals Seen Slowing*, GLOBE & MAIL (Canada), Dec. 10, 2001, at B3 ("The appointment of a new FDA commissioner has become highly politicized and is likely to result in the appointment of an 'ideal Republican' rather than an 'ideal commissioner.'").

110 *See* Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1008 (2008). The Court ultimately declined to decide whether the FDA should be accorded deference, instead ruling in favor of the industry defendant's claim of preemption because of express terms in the statute. *See id.* at 1009.

111 *See, e.g.*, Susan Todd, *Sunken Treasure: The Next Weapon in the Fight Against Cancer May Come from a Tiny Sea Creature Even Fish Don't Find Interesting*, STAR-LEDGER (Newark, N.J.), Oct. 24, 2002, at 49 (noting that "[i]n the high-stakes business of drug development, companies are under pressure to produce a steady stream of new medicines" and that the reward "could be worth billions of dollars").

112 FDA decisions directly impact $51 billion in costs of federal reimbursement for pharmaceuticals under Medicare and related federal programs. *See Allegations of Waste, Fraud, and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer: Hearing Before the H. Comm. On Oversight and Government Reform*, 110th Cong. 1 (Feb. 9, 2007) [hereinafter *Allegations of Waste*] (testimony of Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services) (estimating the Medicaid 2005 prescription-drug costs in 2005 at $41 billion and Medicare 2005 prescription-drug costs at $10 billion).

113 *See* HAWTHORNE, *supra* note 1, at ix ("If the FDA lets us down, we are not just personally disappointed, betrayed, and angry. We could be dead."); James T. O'Reilly, *Bombing Bureaucratic Complacency: Effects of Counter-Terrorism Pressures upon Medical Product Approvals*, 60 N.Y.U. ANN. SURV. AM. L. 329, 329 (2004) [hereinafter O'Reilly, *Bombing Bureaucratic Complacency*] ("This gatekeeper role allows the . . . FDA . . . to perform cost-

tral—and perceived to be so—in order to reassure those giving deference to the Agency that the approval process is based on scientific merit rather than possible economic benefits.[114]

Unlike other federal agencies that must seek adjudication by the courts to set precedential policy decisions,[115] the FDA has long enjoyed freedom from judicial interference with drug approval decisions.[116] This freedom from close judicial scrutiny, rooted in the *Hynson* and *Bentex* decisions discussed above,[117] had a liberating effect on the FDA's operations.[118] The FDA assumed that it had absolute gatekeeper power and could determine the fate of privately sponsored drugs without serious risk of judicial reversal.[119] Accordingly, it acted with great independence.

In the past, federal judges acquiesced to this independence by readily showing deference to the FDA's determinations of drug safety.[120] However, that was back in an era when the Agency declined to get involved in pricing and value-comparison issues for new drugs.[121] That era came to an end during the Bush Administration. Led by a former White House economic staff member, Mark McClellan, who was named Commissioner of the FDA in 2003, the FDA became a player in economic regulation.[122] Soon after his appointment, McClellan expressed his concern about rising drug prices, announcing that the FDA and other agencies "must do more to control healthcare costs" amid concerns about "rising spending on prescription

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benefit analysis and then reject or accept the consequences of the entry of new medical products into the American marketplace. Until recently, these choices were tradeoffs made carefully and based on the cautious balancing of medical, economic, and scientific interests.").

114 *See* O'Reilly, *Bombing Bureaucratic Complacency*, *supra* note 113, at 849–50 (explaining the negative implications of the FDA abandoning its "neutral gatekeeper" role in order to consider the economic concerns involved in drug approval).

115 The FDA and other administrative agencies make adjudicative licensing decisions. *See, e.g.*, 21 C.F.R. § 314 (2007) (setting standards for the FDA's approval of new drugs). However, only the federal courts can make certain adjudicative decisions, such as the agency's selection of defendants for court-enforcement cases in antitrust challenges under the Sherman Act. *See, e.g.*, 15 U.S.C. § 4 (2000) (vesting antitrust subject-matter jurisdiction in the federal courts).

116 *See supra* Part III.

117 *See id.*

118 *See* O'Reilly, *Jurisdiction to Decide*, *supra* note 23, at 835–36 (explaining that the *Hynson* case gave the FDA considerable freedom, which "allow[ed] the FDA's jurisdiction to reach more drug products[,] . . . to ignore the common marketplace experience of drug effectiveness[,] . . . [and] to decide subjectively what studies had or had not been adequately performed").

119 *See id.* at 838.

120 *See, e.g.*, United States v. Rutherford, 442 U.S. 544, 553–54 (1979).

121 *See* Alicia Ault, *McClellan's FDA: Boon to Industry, Consumers, or Both?*, 362 LANCET, Aug. 2, 2003, at 379 (noting that McClellan's tenure represents a transition to focusing on economic issues in drug development).

122 *Id.*

drugs."[123] But while McClellan's tenure marked a loss of Agency independence, it was not the beginning of deference's decline.

The credibility of the FDA as a neutral scientific gatekeeper for new drugs suffered several setbacks during the latter part of the Agency's first century. First, in 1984, Congress appeared to lessen the standards for drug product market entry, favoring economic advantages over detailed scientific evaluation of certain drugs.[124] Those amendments provided that generic alternative versions of new drugs need not demonstrate their scientific merits by controlled human clinical trials and could be marketed despite their lower effectiveness than the research-based product they sought to copy.[125] Second, in 1989, the FDA became engulfed in scandal when news broke that members of the Agency's generic drug approval staff had received bribes and gifts to expedite certain applications.[126] In response, Congress tightened the standards for filing generic drug approval applications.[127] Third, in 1992, the process of new drug approval became part of an express economic tradeoff in a new law, the Prescription Drug User Fee Act.[128] Reacting to the perception that the FDA was overly cautious in its review of drug applications, Congress commanded the Agency to meet strict time deadlines for drug approvals[129] and produced a system that commentators have criticized as rife with conflicts.[130] Finally, in 1994, Congress responded to the concern

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123 *See* Mark McClellan, *Remarks of the Commissioner of Food and Drugs*, 58 FOOD & DRUG L.J. 191, 192 (2003).

124 *See* Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (2000) (allowing the filing of, and stating the requirements for, an abbreviated application for the approval of a new drug).

125 A generic drug may be less effective in delivering the active ingredient to the target organ, so long as the FDA considers it "bioequivalent" to the delivery of the pioneer drug that it copies as determined by the test methods that the FDA sets under 21 C.F.R. § 320.23 (2007).

126 *See* Peter Barton Hutt, *Yes, Virginia, There Have Been Scandals*, *in* CENTURY OF PROTECTION, *supra* note 21, at 78, 79; Jeffrey Yorke, *FDA Ensures Equivalence of Generic Drugs*, FDA CONSUMER, Sept. 1992, at 11.

127 *See* Generic Drug Enforcement Act of 1992 § 2, 21 U.S.C. § 335a (preventing a person from filing a generic drug approval application if that person previously has been convicted of a felony in connection with a drug approval application).

128 Pub. L. 102-571, 106 Stat. 4491 (1992) (codified as amended in scattered sections of 21 U.S.C.).

129 *See id.* § 102(3) (citing 138 CONG. REC. H9099–H9100 (daily ed. Sept. 22, 1992) to require the FDA to approve breakthrough drugs within six months and all other drugs within twelve months). In order to meet these goals, Congress gave the FDA additional funds in the form of drug sponsor application fees. *See id.* § 736 (authorizing the FDA to receive fees in order to expedite the applications of drug applications). Additionally, the deadlines are enforceable statutory commands. *See* Sandoz, Inc. v. Leavitt, 427 F. Supp. 2d 29, 40–41 (D.D.C. 2006) (enforcing the Act against the FDA).

130 *See, e.g.*, HAWTHORNE, *supra* note 1, at 151–53 (noting that the Act was exposed to criticism from both industry groups and consumer advocates); Christopher-Paul Milne, *Exploring the Frontiers of Law and Science: FDAMA's Pediatric Studies Incentive*, 57 FOOD & DRUG

that irrational FDA bureaucrats would constrain the freedom of consumers to take their vitamins[131] by restricting the Agency's ability to regulate vitamin drugs marketed as "dietary supplements."[132] This legislation, which passed over the FDA's strong objections,[133] dramatically reduced the FDA's delegated authority in this product category.[134]

These setbacks have contributed to the FDA's recent evolution from a protector of safety to an evaluator of the new drug efficacy for consumers; additionally, it is now a facilitator to drug companies, allowing them to quickly realize the economic benefit of new therapies.[135] The latest impetus for this evolution is likely attributable to the economics that were introduced into the FDA when Mark McClellan took charge of the Agency.[136] The FDA took on a more express economic advisor's role regarding the selection of preferred patient therapies for federal reimbursement programs: efficacy approval by the FDA is now generally a prerequisite to federal benefit payment for the drug, vaccine, or medical device in use for Medicare patients' care.[137] The FDA approval policies therefore have an underlying importance within the federal healthcare payment system, directly im-

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L.J. 491, 512 (2002) (discussing "public criticism that user fees have compromised the agency's capacity to deal with industry at arm's length").

131 The FDA gave Congress plenty to concern itself about. *See, e.g.*, Letter from Mark V. Nadel, Assoc. Dir., Nat'l and Pub. Health Issues, to Senator Edward M. Kennedy, Chairman, Senate Comm. on Labor and Human Res.; Senator Nancy L. Kassebaum, Ranking Minority Member, Senate Comm. on Labor and Human Res.; Representative John D. Dingell, Chairman, House Comm. on Energy and Commerce; Representative Carlos J. Moorhead, Ranking Minority Member, House Comm. on Energy and Commerce (July 2, 1993) (on file with the United States General Accounting Office, B-252966) (noting the various actions that the FDA had taken against dietary supplements).

132 *See* Dietary Supplement Health and Education Act of 1994 § 4, 21 U.S.C. § 342 (placing the burden of proof on the government to prove that a dietary supplement is unsafe).

133 Peter Barton Hutt, *U.S. Government Regulation of Food with Claims for Special Psychological Value, in* ESSENTIALS OF FUNCTIONAL FOODS 339, 342 (Mary K. Schmidl & Theodore P. Labuza eds., 2000).

134 *See* 21 U.S.C. § 342 (creating a de novo standard of judicial review). *See generally* O'REILLY, FDA, *supra* note 13, § 10:46.

135 *See* HAWTHORNE, *supra* note 1, at 286–88 (comparing Commissioner Kessler, a Clinton appointee, who focused solely on the safety and effectiveness of drugs, to Commissioner McClellan, who concerned himself with the economic policy of drug approval); O'Reilly, *Jurisdiction to Decide*, *supra* note 23, at 347 (discussing the FDA's divergence from its traditional role as "gatekeeper of human safety").

136 *See supra* notes 122–23 and accompanying text. McClellan went on to become head of the Center for Medicare and Medicaid Services but resigned in 2006. President George W. Bush, President's Statement on Dr. Mark McClellan['s] Resignation as CMS Administrator (Sept. 5, 2006), http://www.whitehouse.gov/news/releases/2006/09/20060905-8.html.

137 42 C.F.R. §§ 419.64–66 (2007) (outlining the Agency approval requirements for drugs, biologicals, and medical devices, and indicating that approval is a prerequisite for payment).

pacting the approximately $51 billion cost of federal reimbursement for pharmaceuticals under Medicare and related federal programs.[138]

One result of the FDA's changed role has been lessened judicial deference toward the Agency in the cases challenging its approval of generic drugs. Federal judges have rejected approvals of abbreviated drug applications under the Drug Price Competition and Patent Term Restoration Act of 1984[139] more frequently than any prior set of decisions in the history of the FDA.[140] Clearly, deference was at risk when the FDA's decisions diverged from their classical safety orientation to a more economics-oriented approach to approving drugs.[141]

X
THE EXERCISE OF PRESIDENTIAL POLICY THROUGH APPOINTEES

While the FDA has historically enjoyed freedom to implement its policies without judicial interference,[142] the Agency has not always enjoyed the same independence from the Executive Branch. In light of the President's constitutional authority to ensure that the laws are "faithfully executed,"[143] it is questionable how much independence the FDA should expect to receive. Can anything other than its tradition of scientific probity[144] shield the FDA from the President's political agenda?

As George W. Bush once said, the President is "the decider."[145] The law permits the President to appoint a Secretary of Health and Human Services to his Cabinet; this Secretary has great autonomous discretion under the drug provisions of the FD&C Act to review drug approval applications and determine the safety and efficacy of any

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138 *Allegations of Waste*, *supra* note 112, at 1.

139 *See supra* notes 124–25 and accompanying text.

140 *See, e.g.*, Nutritional Health Alliance v. Food & Drug Admin., 318 F.3d 92, 101, 104 (2d Cir. 2003) (holding "that the plain language of . . . the FDC Act" does not delegate certain regulatory authorities to the FDA, and that the FDA's "proffered interpretation is not reasonable"); Mylan Pharms., Inc. v. Henney, 94 F. Supp. 2d 36, 58 (D.D.C. 2000) (declaring the FDA's interpretation contrary to the plain meaning of the statute and remanding "to the FDA for a permissible construction of the statute"), *vacated as moot sub nom.* Pharmachemie B.V. v. Barr Labs., Inc., 276 F.3d 627 (D.C. Cir. 2002), *vacated as moot sub nom.* Pharmachemie B.V. v. Barr Labs., Inc., 284 F.3d 125 (D.C. Cir. 2002) (per curiam).

141 *See, e.g.*, Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1284 (D.C. Cir. 2004) (according deference to the FDA's statutory interpretation because the Agency read the statute to preserve economic incentives for industry competitors).

142 *See supra* Part I.

143 U.S. CONST. art. II, § 3.

144 *See supra* Part VI.

145 *See* Jim VandeHei, *Bush Names a New Budget Director*, BOSTON GLOBE, Apr. 19, 2006, at A2 (quoting President Bush's public statements in defense of Secretary Donald Rumsfeld's remaining in the Cabinet).

drug.[146] As a Cabinet member, the Secretary's views of policy tend to be fully aligned with the President's.[147] The President also has the power, subject to confirmation by the Senate, to select FDA Commissioners, which occupy a position below that of the Secretary.[148] The new FDA Commissioners (and their handful of politically appointed colleagues, such as the legislative deputy commissioner) can be expected to change with each election cycle.[149] However, the Commissioners who have been appointed and confirmed since the Bush Administration arrived in 2001 have held the office for an average tenure of about one year after confirmation.[150] The appointees tend to pursue these jobs only in furtherance of their future careers, gaining appointment with the help of White House insiders who, in turn, seek those candidates most likely to implement the President's policies.[151] While such political favoritism may be common in the White

146 *See* U.S. CONST. art. II, § 2, cl. 2 (establishing the President's power to make Cabinet appointments); 21 U.S.C. § 355 (2000) (detailing the Secretary's powers to review new drug applications).

147 *See* President George W. Bush, Roster of the President's Cabinet, http://www.whitehouse.gov/government/cabinet.html (last visited Apr. 7, 2008) (listing President Bush's current Cabinet members and noting that "[o]ne of the principal purposes of the Cabinet . . . is to advise the President on any subject he may require relating to the duties of their respective offices").

148 21 U.S.C. §§ 393(d)(1)–(2).

149 *See* Brian Lawler, *Does Leadership Count at the FDA?*, THE MOTLEY FOOL, Dec. 31, 2007, http://www.fool.com/investing/high-growth/2007/12/31/does-leadership-count-at-the-fda.aspx (providing a detailed accounting of the five Commissioners that have served from January 2001 to December 2007); *see also* Struve, *supra* note 103, at 636 (explaining that "the FDA Commissioner serves at the pleasure of the . . . Secretary [of Health and Human Services] and, therefore, the President") (citation omitted).

150 Andrew von Eschenbach, Lester Crawford, and Mark McClellan have been the only Commissioners confirmed since the Bush Administration took office in January 2001. *See* U.S. Food and Drug Admin., Commissioners and Their Predecessors, http://www.fda.gov/oc/commissioners/default.htm (last visited Apr. 7, 2008) (showing every FDA Commissioner and the dates they served). Von Eschenbach, a friend of the Bush family, remains in office. *See id.*; *see also* Gardiner Harris, *Bush Picks F.D.A. Chief, but Vote is Unlikely Soon*, N.Y. TIMES, Mar. 16, 2006, at A18 (noting the family connection). Crawford, a career FDA official, served two months as Commissioner and later pled guilty to criminal ethics violations. *See* Matthew J. Seamon, *Plan B for the FDA: A Need for a Third Class of Drug Regulation in the United States Involving a "Pharmacist-Only" Class of Drugs*, 12 WM. & MARY J. WOMEN & L. 521, 535 (2006); David Stout, *Ex-F.D.A. Chief Pleads Guilty in Stock Case*, N.Y. TIMES, Oct. 18, 2006, at A21. McClellan, a former White House staff member, served sixteen months at the FDA before he was transferred to the Centers for Medicare and Medicaid Services. *See* Seamon, *supra*, at 535; U.S. Food and Drug Admin., *supra*.

151 For example, one of Bush's FDA Commissioner appointees, Mark McClellan, is the brother of the White House Press Secretary, and the son of a veteran Texas politician "with ties to the Bush family." HAWTHORNE, *supra* note 1, at 63. McClellan used his position as FDA Commissioner as a springboard to become Administrator for the Centers for Medicare and Medicaid Services. *See* Seamon, *supra* note 150, at 535. In fact, many FDA officials use their position as a springboard to more lucrative opportunities. *See* HAWTHORNE, *supra* note 1, at 150. According to the media, politics also motivated W. David Hager's appointment to the FDA Reproductive Health Drugs Advisory Committee. *See* Karen Tumulty, *Jesus and the FDA*, TIME, Oct. 14, 2002, at 26.

House, the Bush Administration has controlled the process more actively by appointing uncharacteristically aggressive appointees.[152]

White House policy staff members may be closer to "the decider," but no President has ever approved a new drug or medical device, and with good reason: the FDA is a highly complex administrative body with a detailed set of statutory requirements for each drug or medical device.[153] While the President and his staff should generally retain the power to make decisions that affect the Administration's foreign policy objectives,[154] the specialized nature of the FDA, coupled with its specific statutory delegation of powers,[155] suggests that decision making within the Agency should be restricted to its independent insiders. Former FDA Commissioner David Kessler reportedly achieved such independence from the White House staff during the Clinton Administration.[156]

When it comes to resisting political influence, the FDA is in a severe bind. Career officials within the FDA do have the advantage of experience and have learned to resist the desires of political appointees seeking to change FDA policies;[157] thus, the Agency can generally adapt to the winds of change from one administration to another. Inevitably, however, there are times when the visions of the incoming decider and the FDA career officials will diverge; in such situations, the career staffer's craftiness will only go so far. Moreover, Congress poses the additional threat of proposing budget cuts from any agency attempting to further an undesirable political agenda.[158] For example, a member of the House of Representatives recently proposed

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152 *See, e.g.*, Jeanne Lenzer, *FDA's Counsel Accused of Being Too Close to Drug Industry*, 329 BMJ 189, 189 (2004) (discussing charges against a Bush Appointee for subverting the public interest in favor of drug companies that provide substantial funding to the Administration); Rita Rubin, *FDA Commissioner's Post Could be Difficult to Fill: Observers say Politics Weighs Too Heavily*, USA TODAY, Sep. 26, 2005, at 7D (relaying insiders' beliefs that the position has become too politicized); Dan Zegart, *The Gutting of the Civil Service*, NATION, Nov. 20, 2006, at 24.

153 *See, e.g.*, 21 U.S.C. § 355.

154 For example, the President should rightly control decisions about negotiating a trade treaty with China.

155 *See* 21 U.S.C. § 393.

156 *See* Matthew Rees, *What Makes David Kessler Run?*, WKLY. STANDARD, June 3, 1996, at 25, 26 ("During the Bush years, Kessler succeeded in alienating numerous administration officials because of his antibusiness approach, his grandstanding, and his refusal to work with White House officials on FDA reform."); Sheryl Gay Stolberg, *Jane Ellen Henney: For F.D.A., an Old Hand*, N.Y. TIMES, June 24, 1998, at A16 (describing Kessler's tenure as "marked by . . . fights with Congressional Republicans who wanted . . . the agency to be more cooperative with the pharmaceutical industry . . .").

157 *See* HAWTHORNE, *supra* note 1, at 153–56 (describing precautions taken to limit drug reviewers' exposure to outside political influences).

158 *See id.* at 144 ("Congress controls the FDA's budget, and therefore, to FDA employees, a member of Congress carries the approximate authority of a god on Mount Olympus.").

amending an appropriations bill in order to reduce FDA funding as a response to one Agency official's undesirable policy of promoting preemption.[159] Given that the FDA can be buffeted on both sides by those with political motives, the Judiciary may not wish to maintain deference to the FDA's scientific choices.

XI
CRITICISM OF THE FDA'S DECISION PROCESSES INTENSIFIES

From 2005 to 2006, three books critical of the political control of the FDA were published in response to a seemingly unprecedented surge in industry lobbying at senior levels of Health and Human Services and the White House.[160] One author was scathing in her review of the politicized FDA, describing the Agency as a "political pawn":

> It would be bad enough if the only political pressures that the FDA had to withstand were from powerful drug and food companies with multimillion-dollar lobbying budgets, consumer groups that pounce every time a drug shows serious side effects, and consumer groups that want drugs for their disease approved *now*. But there is more. As a federal agency, run by a commissioner who must be confirmed by the Senate, who must go to Congress every year for money, and who must report to another political appointee . . . , the FDA also has to live in the hardcore world of Democrats and Republicans, Congress and the White House—the world of pure politics.[161]

The author was especially critical of former FDA Commissioner McClellan who, as the author noted, was "probably the most political commissioner the FDA had ever seen."[162] The conservative economist-physician's tenure "marked the first time any FDA commissioner had taken on drug prices as a specific, official issue . . . ."[163] The author noted speculation that McClellan's focus on drug prices was politically motivated.[164]

The second author explored the scientific community's response to multiple FDA decisions that were seemingly dictated by White

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159 House Representative Maurice Hinchey proposed a $500,000 budget cut from the FDA Chief Counsel's office as an amendment to a FDA appropriations bill. *See supra* note 105. The Bill, however, never made it out of the Senate. *See* H.R. 4766 [108th Congress]: Agriculture, Rural Development, Food & Drug Administration, and Related Agencies Appropriates Act, 2005, http://www.govtrack.us/congress/bill.xpd?bill=h108-4766 (last visited Apr. 7, 2008) (tracking the history of the Bill and demonstrating that it failed to pass through Congress).

160 *See* HAWTHORNE, *supra* note 1; CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE (2006); SETH SHULMAN, UNDERMINING SCIENCE: SUPPRESSION AND DISTORTION IN THE BUSH ADMINISTRATION (2006).

161 HAWTHORNE, *supra* note 1, at 209.

162 *Id.* at 215.

163 *Id.* at 287.

164 *See id.* at 288.

House sensitivity to its political constituencies, especially the FDA's ultimate rejection of over-the-counter sales of the Plan B contraceptive pill.[165] The third author examined the alleged politically motivated suppression of dissenting views among FDA scientists by partisan managers supportive of Bush Administration policies.[166]

While the merits of these authors' arguments are, of course, disputable, the books contain detailed and descriptive interviews that offer a remarkable chronicle of the trends within the FDA during the Bush Administration. These trends are symptomatic of the substantial problem of "regulatory capture,"[167] largely absent in the FDA's first century when the Agency, in accordance with its founders' goals, had been independent, impartial, fact-intensive, and archly scientific.[168] The controversy and criticism typifying the current FDA era form a colorful contrast to the Agency's stolid legacy of impartial objectivity.[169]

The above-mentioned books do not represent the only published criticism of the FDA in recent years. In September 2005, the *New England Journal of Medicine* ran an editorial entitled *A Sad Day for Science at the FDA*, which warned that "recent actions of the FDA leadership have made a mockery of the process of evaluating scientific evidence, . . . squandered the public trust, and tarnished the agency's image."[170] In the same month, press coverage of the controversies deepened.[171] A Republican Senator critical of the Bush Administration said that, "[i]n recent years the FDA has demonstrated a too-cozy relationship with the pharmaceutical industry and an attitude of shielding rather than disclosing information . . . ."[172] A Democratic Senator further decried "a crisis in leadership . . . . weak oversight, conflict of interest and poor management at the FDA."[173]

Perhaps the most damning criticism, however, has come from within the FDA's former ranks, as dozens of senior career officials

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165 *See infra* Part XII; *see also* HAWTHORNE, *supra* note 1, at 222–24 (describing how the political influences have distorted the science behind drug approvals); MOONEY, *supra* note 160, at 23, 217–18 (attacking a "catalogue of politicized interferences with science" and quoting former FDA Commissioner Donald Kennedy as saying the Plan B decision "was not a good call").

166 *See* SHULMAN, *supra* note 160, at 42–45.

167 "Regulatory capture" refers to the FDA's loss of perceived independence from the wishes of a regulated constituency to the detriment of the public at large.

168 *See supra* Parts I, V (discussing the FDA's history of scientific integrity).

169 *See id.*

170 Alastair J.J. Wood et al., *A Sad Day for Science at the FDA*, 353 NEW ENG. J. MED. 1197, 1199 (2005).

171 *See, e.g.*, Robert Pear & Andrew Pollack, *Leader of the F.D.A. Steps Down After a Short, Turbulent Tenure*, N. Y. TIMES, Sept. 24, 2005, at A1.

172 *Id.* (quoting Sen. Charles Grassley).

173 *Id.* (quoting Sen. Richard Durbin).

have departed or retired during the Bush Administration.[174] Several of these officials testified, and spoke to the media, as whistleblowers against the trends evident at the Agency.[175] Some described the officials departing as the "cream of the FDA's upper echelon, a group with much of the agency's accumulated know-how"[176] and attributed their departure in part to the changed atmosphere of the Agency's political climate, with its "steady erosion of influence by the career staff."[177] After leaving the FDA, former Assistant Commissioner Susan Wood expressed concern that federal health agencies were "increasingly unable to operate independently,"[178] while FDA scientist Dr. David Graham testified before Congress that FDA drug safety managers felt pressure to approve certain drugs, despite their substantial risks.[179] It seems likely that damage to the FDA's reputation for probity may be hard to repair, even if such individual allegations are proven false.

The Bush Administration appears to be blind to the possible impact of public criticism and the resulting loss of public acceptance that the FDA could suffer. Worse yet, as the public grows increasingly wary of the FDA's political motivations, those concerns may spread beyond advocacy groups and media critics and into the minds of the judges, who are asked to defer to the neutral, scientific impartiality of the FDA. Time will tell if the FDA's tarnished reputation for scientific impartiality will cost the Agency the judicial deference that it has so long relied upon.

XII
CASE STUDY: POLITICS AND "PLAN B"

The FDA's decision to delay the availability of the drug "Plan B" to younger women provides a case study in the Bush Administration's political influence over the FDA.[180] The drug, an emergency contraceptive, was developed under a cloud of political opposition that

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174 *See* Zegart, *supra* note 152, at 24 (estimating that fifty to one hundred senior management officials left the Agency between 2001 and 2006).

175 *See, e.g., FDA, Merck and Vioxx: Putting Patient Safety First?: Hearing Before the S. Comm. on Finance*, 108th Cong. 3 (2004) [hereinafter *Putting Patient Safety First*] (statement of Dr. David Graham, Assoc. Director for Science, Office of Drug Safety).

176 Zegart, *supra* note 152, at 24.

177 *Id.* at 26 (quoting former FDA Commissioner William Hubbard).

178 Susan F. Wood, *When Politics Defeats Science*, WASH. POST, Mar. 1, 2006, at A17.

179 *See Putting Patient Safety First*, *supra* note 175. Dr. Graham's testimony was widely reported in the press. *See, e.g.*, Gardiner Harris, *F.D.A. Failing in Drug Safety, Official Asserts*, N.Y. TIMES, Nov. 19, 2004, at A1.

180 *See, e.g.*, Ayelish McGarvey, *Plan B for Plan B*, NATION, July 18–25, 2005, at 8; William Saletan, *The Birds and the Plan B's*, WASH. POST, Apr. 2, 2006, at B3; Russell Shorto, *Contra-Contraception*, N.Y. TIMES, May 7, 2006, § 6 (Magazine), at 48.

called it the "abortion pill."[181] Opponents, citing moral objections, fought the approval and sale of the drug vigorously at both the federal and state levels.[182]

Normally, the FDA reviews new drug applications for scientific evidence indicating safety,[183] and the process attracts little or no public attention. However, given the politically charged nature of the drug and the possible moral implications of its use, Plan B faced strong opposition. Anti-abortion groups characterized this new drug as a license for promiscuity and an encouragement for teenagers to engage in sex without fear of pregnancy.[184] Because of the controversy, Plan B's approval process took a distinctly different path.[185] Ironically, this path to approval went through a form of politically driven alternative, "plan B."

The sponsor of the drug asked the FDA to allow Plan B to be sold without a prescription—a common enough request.[186] However, the time between when the sponsor made this petition and when the Agency granted it was extraordinarily long.[187] Further, the ultimate approval restricted the nonprescription use to women eighteen and over, and permitted women under eighteen to obtain the drug only by prescription.[188] This was an unprecedented restraint on the retail distribution of an approved drug product.[189]

The FDA has cleared new drugs for the nonprescription market in hundreds of cases since 1951, when Congress gave the Agency that power.[190] Reviewers make the discretion-laden choice of whether restricting the drug to prescription-only distribution is needed to protect the public health, i.e. whether physician oversight is so essential

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181 *See* Shorto, *supra* note 180, at 51.

182 *See, e.g., Lynne* Marie Kohm, *From* Eisenstadt *to Plan B: A Discussion of Conscientious Objections to Emergency Contraception*, 33 WM. MITCHELL L. REV. 787, 796–99 (2007) (discussing moral objections to emergency contraceptives).

183 21 U.S.C. § 355 (2000).

184 *See* Shorto, *supra* note 180, at 51–53.

185 *See* U.S. GOV'T ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL REQUESTERS: FDA: DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL, GAO-06-109, at 13–30 (Nov. 2005) [hereinafter GAO].

186 *See id.* at 5 (comparing the Plan B process to sixty-seven other proposed prescription-to-OTC switch decisions made by the FDA from 1994 to 2007).

187 The FDA received the request in April 16, 2003 and denied it May 6, 2004. *See id.* at 15–16.

188 *See* DURAMED PHARMS., PRESCRIBING INFORMATION 1, http://www.go2planb.com/PDF/PlanBPI.pdf (last visited Apr. 7, 2008).

189 *See* O'REILLY, FDA, *supra* note 13, §§ 13:77–132 (detailing the approval process for new drugs); *see also* GAO, *supra* note 185, at 5–6. Despite the contentious process, Plan B sold well. *See* David Crary, *Morning-After Pill Still Has Critics*, CINCINNATI ENQUIRER, Aug. 23, 2007, at A12.

190 *See* Humphrey-Durham Drug Prescriptions Act, Pub. L. No. 215, 65 Stat. 648 (1951) (codified at 21 U.S.C. § 353 (2000)).

that the drug cannot safely be sold over the counter to everyday purchasers.[191] The process includes a detailed review of a new drug's safety, consumer labeling awareness, and warning label adequacy; it is a technical process that involves the medical and scientific expertise of FDA reviewers.[192] Restricting Plan B's nonprescription use to women eighteen and over is not a scientifically or medically based distinction that would normally be made when determining whether a drug is safe for nonprescription use.[193]

The news media reported that the power of the anti-abortion constituency within the Bush Administration affected the approval process of Plan B.[194] The Center for Reproductive Rights, the plaintiffs in a pending suit against the FDA, also suggest that White House involvement overwhelmed the Agency's scientific decision-making process.[195] However, the extent to which White House interference caused the delays in Plan B's over-the-counter approval remains unclear even today. During the approval process, extensive sparring occurred between Congress, women's groups, appointed leaders of the FDA, drug review career staff at the FDA, and the White House policy staff.[196] Depositions of political officials show the degree of political control exercised by the White House staff.[197] The internal disagreements among the FDA staff concerning the Plan B controversy may have caused the most discord ever experienced within the FDA,[198] for the career professional staff's views on the safety of Plan B clashed with the Administration's policies of preserving the life of the unborn and of protecting family values.[199]

Reporting by the *New York Times* and other news media brought the details of the intense FDA-White House conflict into the general public's view.[200] Future FDA historians will probably have the benefit of further revelations from some of the current Agency managers; to-

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191 *See* 21 U.S.C. § 353(b)(3).

192 *See* 21 C.F.R. § 314.125 (2007).

193 *See* Shorto, *supra* note 180, at 51–53; *see also* HAWTHORNE, *supra* note 1, at 32 ("The FDA may need to consider, for the first time, the ethics of the drugs it evaluates, not just their safety and effectiveness. . . . Although the FDA may argue that its role is merely to decide whether the drugs work safely, politicians and religious leaders will turn any 'yes' or 'no' into a socio-political statement.").

194 *See* Shorto, *supra* note 180, at 51–53.

195 *See* Center for Reproductive Rights, Depositions Indicate Bush Administration Exerted Political Influence on FDA During Plan B Review Process: Center for Reproductive Rights Requests White House Subpoena, Aug. 3, 2006, http://www.reproductiverights.org/pr_06_0803FDADepositions.html [hereinafter Center for Reproductive Rights].

196 *See* Shorto, *supra* note 180.

197 *See* Center for Reproductive Rights, *supra* note 195 (making available excerpts of Mark McClellan's deposition).

198 *See, e.g.*, Shorto, *supra* note 180, at 53 (noting that Dr. Susan F. Wood, FDA's women's health official, resigned in protest over the controversy).

199 *See id.* at 51–53.

200 *See, e.g., id.*

day, however, these participants cannot publicly explain the pressures that the abortion issue brought to their labeling decisions. When the whole story emerges, it is likely to be unflattering to the White House, for the visible entanglement of Agency politics in a scientific decision does not appeal to the general public—though it may appease some constituents. The Plan B controversy may cause wider public skepticism about the newly politicized FDA and fuel its own "morning after" reluctance about judicial deference to other Agency decisions.

XIII
CASE STUDY: PREEMPTION OF STATE TORTS

The Plan B debacle may be a prime example of the FDA's recent politicization, but it is hardly the only one worth analyzing. As discussed earlier,[201] the use of implied preemption as a shield from tort liability has loomed large on the policy agenda of the Bush Administration's appointees.[202] Preemption is a constitutional doctrine, derived from the Supremacy Clause, of power sharing between federal, state, and local governments.[203] Preemption can be either expressly mandated by congressional statement or implied through a judicial evaluation of the conflicts between state actions and federal regulation.[204] Implied preemption means that the courts will assume Congress had an unstated but implied intention to bar states from local control of a certain class of products.[205] State tort claims attacking a drug or medical product's design suffer preclusion if preemption is expressly asserted by Congress in a statute or is implied by FDA approval.[206] If the court finds preemption, the defendant in a drug or medical products liability case can secure a dismissal of the state law claim on summary judgment through federal preemption without going through the time and expense of a trial.[207]

For nearly two decades, securing federal preemption of state tort claims has been a must-win, multi-million-dollar project for the advocates of FDA-regulated industries.[208] Beginning with the 1990 food

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201 *See supra* Part VIII.

202 *See* Allison M. Zieve & Brian Wolfman, *The FDA's Argument for Eradicating State Tort Law: Why It Is Wrong and Warrants No Deference*, 34 BUREAU FOR NAT'L AFFS.: PRODUCT SAFETY & LIABILITY REP., Mar. 27, 2006, at 308, 308.

203 U.S. CONST. art. VI, cl. 2.

204 *See* JAMES T. O'REILLY, FEDERAL PREEMPTION OF STATE AND LOCAL LAW: LEGISLATION, REGULATION AND LITIGATION § 8.1 (2006) [hereinafter O'REILLY, FEDERAL PREEMPTION] (discussing at length the roots of preemption law).

205 *Id.*

206 *See id.* §§ 8.1–8.8.

207 Because a cause of action cannot legally survive a finding of preemption, such a finding results in a dismissal under FED. R. CIV. P. 56. *See id.* § 9.1.

208 *See id.* §§ 10.3, 12.5. Congress has already given preemption by statute for nonprescription drugs and medical devices, among others, *see* 21 U.S.C. §§ 360k, 379r (2000), but

label statutes[209] and the 1997 cosmetic and nonprescription drug labeling amendments,[210] the FDA-regulated industries have vigorously pursued statutory preemption of state liability suits.[211] However, some members of Congress have been highly critical of the industries' efforts; thus, Congress has not granted express preemption for pharmaceutical drugs.[212] The industry lobbyists realized that Congress was unlikely to expressly preempt prescription drug tort law[213] or to revisit the oblique terms of the medical device preemption clause,[214] and that Congress had failed to adopt the parallel preemption of state power in food safety regulation.[215] Therefore, the Bush Administration appointees were remarkably aggressive in seeking out nonlegislative means to obtain preemption of state tort laws.[216] The industries believed that winning an FDA declaration of preemption, together with receiving judicial deference toward such a preemptive declaration, is the next best thing to the enactment of express preemption legislation.[217] These industries have expressed their newfound desire to preempt state tort remedies for prescription drug "failure to warn" claims in various amicus briefs.[218]

The Agency's amendments to the complex rules regarding prescription drug labeling vividly illustrate the FDA's shift in favor of preemption. When the FDA initially proposed the amendments in 2000, the preamble to the proposal expressly disavowed any intent to preempt state law tort actions.[219] But when the final rule was published in the Federal Register in January 2006, the FDA unexpectedly

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has not given preemption authority to the FDA for prescription drugs, *see* O'REILLY, FEDERAL PREEMPTION, *supra* note 204, § 12.5.

209 Nutrition Labeling and Education Act of 1990 § 6, 21 U.S.C. § 343-1.

210 Food and Drug Administration Modernization Act of 1997 § 412, 21 U.S.C. §§ 379r, 379s.

211 *See* O'REILLY, FEDERAL PREEMPTION, *supra* note 204, §§ 10.3, 12.5.

212 *See generally* Maurice Hinchey, *The Fight to Safeguard American Drug Safety in the Twenty-First Century*, 35 HOFSTRA L. REV. 685 (2006).

213 There are many opponents of the FDA preemption argument in powerful positions. *See id.*; *see also supra* note 105.

214 *See* 21 U.S.C. § 360k.

215 The latest effort at statutory preemption of state food enforcement failed. *See* National Uniformity for Food Act, H.R. 2699, 108th Cong. (2d Sess. 2004). The author was among the consultants used by the Association of Food and Drug Officials, which opposed the bill.

216 *See* David Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 123 (2005).

217 *See* O'REILLY, FEDERAL PREEMPTION, *supra* note 204, § 12.5 (describing the Agency's approach to preemption under the Federal Food, Drug, and Cosmetics Act).

218 See the extensive discussion of the pro-preemption arguments in Struve, *supra* note 103, at 589 n.5.

219 *See* Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (Dec. 22, 2000) (codified at 21 C.F.R. pt. 201) ("FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.").

changed its position to favor preemption.[220] Agency staff had worked for years on the highly detailed amendments, but the preemption statement seems to have been hastily added into the final text.[221] According to former FDA Chief Counsel Troy, the passage was added to the preamble "to signify that the agency endorsed the argument as 'official policy.'"[222]

The 2006 "preemption preamble" declaration was unusual in several respects. First, the public received no opportunity to comment against preemption because the proposed rule clearly stated that *no* preemption would arise from it.[223] Second, the absence of public comment meant that the usual norms for deference to an agency rule would not apply.[224] Finally, the rule to which the preamble was attached was a public agency's mandatory rule on the details of pharmaceutical labeling, a topic to which preemption is a tangential topic at best.[225]

The FDA's statement was the culmination of the Bush Administration's lobbying effort, illustrating "how a White House can use its administrative and legal powers to change the regulatory terrain without taking the often arduous course of asking Congress to change the law."[226] To be sure, the Bush Administration had long tried to free the pharmaceutical industry from tort liability through the implied preemption defense.[227] Contemporaneous press coverage of the pre-

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220 *See* 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) ("FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.").

221 The amendments were proposed six years before their final adoption. *Compare* Content and Format of Labeling for Human Prescription Drugs and Biologics, 65 Fed. Reg. 81,082 (proposing the rule), *with* Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. 3922 (promulgating the final rule). *See also* Lindeman, *supra* note 99, at 9 (quoting the author of this Article, who noted that "[i]f the FDA wanted to do the credible thing, they would have included the preemption language in the rule itself and put it out for public comment . . .").

222 Lindeman, *supra* note 99, at 8 (quoting Troy as stating that the preamble represented "official policy").

223 *See* Content and Format of Labeling for Human Prescription Drugs and Biologics, 65 Fed. Reg. at 81,103.

224 *See* United States v. Mead Corp., 533 U.S. 218, 231 (2001) (denying deference because, among other reasons, the agency ruling was "far removed . . . from notice-and-comment process").

225 Preemption was addressed in the 2000 preamble not as a main issue for comment, but as part of the analysis of impacts of the proposal. *See* Content and Format of Labeling for Human Prescription Drugs and Biologics, 65 Fed. Reg. at 81,103.

226 Kranish, *supra* note 101.

227 *See* Letter-Brief for The United States as Amicus Curiae Supporting Respondent at 26, Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004) (No. 02-4597) (arguing that FDA preemption was needed because tort awards "can harm the public health by retarding research and development and by encouraging 'defensive labeling' by manufacturers to

emption preamble highlighted how the FDA's strong pro-preemption statement related to similar efforts at other federal agencies under the Bush Administration.[228] However, the Administration's amicus briefs, arguing for preemption in appellate courts, had not gone as far as the preamble did in asserting immunity; in comparison, the preemption preamble seems tailored to most effectively aid a private entity's defensive litigation strategy[229]—and indeed, more defendants benefited from the preemption preamble than from the amicus briefs.[230] In retrospect, the 2006 preemption preamble appears to be the high-water mark of the Bush Administration's efforts to aid defendants in medical liability cases.[231]

Industry gloating over the achievement came rapidly after publication of the preemption preamble. For example, an industry advocacy group told members: "The key issue now is to take maximum advantage of the courts in these cases as forcefully as possible."[232] A veteran defense counsel told the media: "This is big. It opens a whole new front in pharmaceutical products-liability litigation that most people thought was moot. Now it becomes an issue in almost every case."[233] A *Philadelphia Inquirer* story reported: "Brandishing the preamble in recent months, drug companies have papered courtrooms nationwide with motions to dismiss failure-to-warn claims[,] [but] [m]ost of the motions have failed."[234] The gold rush of tort defenders had begun.

In 2008, the FDA went further, asserting that courts could not accept interpretations of FDA rules presented in tort cases by witnesses who were former FDA officials, since to accept these views would clash with its claim of preemptive power. The Missouri Court of Appeals had accepted a former FDA executive's view of the mean-

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avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments").

228 *See, e.g.*, Lindeman, *supra* note 99.

229 Bush Administration FDA appointees claimed industry labels cleared by the FDA should not be "second-guessed by state courts that don't have the same scientific knowledge." Marc Kaufman, *FDA Tries to Limit Drug Suits in State Courts*, WASH. POST, Jan. 19, 2006, at A2 (quoting Scott Gottlieb, the FDA's deputy commissioner for medical and scientific affairs).

230 In addition to the usual drug industry-protective rationales for preemption, the preamble also asserted medical malpractice protection for individual prescribing physicians as a rationale. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933 (Jan. 24, 2006) (effective June 30, 2006) (codified at 21 C.F.R. pts. 201, 314, 601).

231 *See generally* Lindeman, *supra* note 99 (recapping the multiple Bush Administration efforts).

232 *Id.* at 7 (quoting James Dabney Miller, Member, Washington Legal Foundation).

233 Lisa Brennan, *New FDA Rule's Preamble Stirs Up Bar on Both Sides*, LAW.COM, Feb. 1, 2006, http://www.law.com/jsp/ihc/PubArticleIHC.jsp?id=1138701910331 (quoting John Brenner, Esq.).

234 Ginsberg, *supra* note 108.

ing of a rule; the Agency supported the losing defendant with an amicus brief urging reversal.[235] A newsletter specializing in FDA law observed that excluding expert testimony was "a goal consistent with FDA's over-arching attempt to consolidate its legal authority" and that allowing juries to consider such testimony would make it "harder to assert . . . a ban on all tort suits involving FDA-regulated products."[236]

Express preemption by statute is constitutionally permissible under the Commerce Clause.[237] Indeed, Congress has expressly preempted states from labeling controls on medical devices,[238] cosmetics,[239] and nonprescription drugs,[240] and from design controls on certain approved medical devices.[241] However, Congress has remained silent on preempting state laws regarding prescription drugs. This silence significantly weakens the case for deference to the FDA's views on preemption. In *FDA v. Brown & Williamson Tobacco Corp.*, the Supreme Court rejected claims that the FDA could draw implicit authority from congressional silence.[242]

In 2008, the Court upheld express statutory preemption of medical device tort claims, but did not show much deference toward the FDA.[243] The Agency's change in position on deference undercut the potency of the FDA's briefs claiming that its policy choice should receive deference.[244]

A preamble that accompanies the publication of a final regulation is neither a rule nor a statute but a statement that, according to the FDA itself, has no more effect than an advisory opinion.[245] Therefore, a preamble is a slender reed on which to assert a claim to judicial deference. In the absence of legislation creating preemption, the FDA could have issued a notice-and-comment rule endorsing preemption[246] but did not do so. The best option the industry had was to insert a preamble statement that courts could later cite in tort cases, in

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235 Strong v. Am. Cyanamid Co., No. ED 87045, 2007 WL 2445938 (Mo. Ct. App. E.D. Aug. 28, 2007).

236 *FDA Doesn't Want Former Officials Testifying About Agency Regs*, FDA WEEK, Feb. 15, 2008.

237 U.S. CONST. art. I, § 8, cl. 3.

238 *See* 21 U.S.C. § 360k (2000).

239 *See id.* § 379s.

240 *See id.* § 379r.

241 *See id.* § 360k.

242 529 U.S. 120, 155–56 (2000) (denying deference to the FDA's interpretation of its jurisdiction to regulate tobacco in part because Congress was silent on whether FDA regulation preempted state tobacco regulation).

243 Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1008–09 (2008).

244 *See id.*

245 21 C.F.R. § 10.85(d)(1) (2007).

246 Such an interpretive rule on a nonstatutory issue may have received lessened (but still some) deference under *Chevron*.

the hope of allowing private defendants to win those cases through deferential acceptance.

XIV
PRESS COVERAGE OF THE FDA

Had the press stayed silent regarding the FDA's dramatic shift in position on preemption and the Bush Administration's political control over the Agency, courts would likely have given deference to the FDA's preemption preamble. However, the media focused significant public attention on the ways in which the White House's political choices dominated the FDA's scientific and enforcement choices.[247] For example, the media reported the vocal protests of consumer organizations against the FDA's claim of drug preemptive authority.[248] The former FDA Director of Women's Health, who had resigned in protest over the decisions made by the FDA in approving nonprescription use of Plan B, was featured in the *Boston Globe*:

> Today, FDA scientists are urged to be "team players," and to ignore any concerns they have about potential risks. The culture that disparages such disagreement at the FDA is dangerous and contributes to the agency's inability to recognize the early signals and safety concerns, and to its waning scientific credibility.[249]

Further, the Washington-based news media intensely covered the Bush Administration's control over the FDA on numerous issues, including the politicized Plan B approval.[250] The *Denver Post* also criticized Bush Administration appointees' efforts to change FDA policy, giving front-page coverage to former FDA Chief Counsel Dan Troy's attempt to preempt state tort cases.[251] *The Nation* vigorously criticized various political FDA appointees, including the lawyer named Chief

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247 *See, e.g.*, Ault, *supra* note 121, at 379–80; Pear, *supra* note 107.

248 *See, e.g.*, Stephen Pizzo, *Shielding Big Pharma*, TOMPAINE.COM, Jan. 25, 2006, http://www.tompaine.com/articles/2006/01/25/shielding_big_pharma.php (quoting Joan Claybrook, president of Public Citizen, as saying: "This is a sneak attack on consumer rights . . . . Bush is once again abusing his executive powers, this time in his attempt to protect the big pharmaceutical companies from the consequences of their actions. Thousands of people in this country have died or been seriously injured by drugs approved by the FDA, and this administration is saying it doesn't think people should have any recourse."). Of course, the media was not alone in its criticism: the National Conference of State Legislatures bluntly stated that unelected FDA officials had "usurped the authority of Congress, state legislatures and state courts." Nat'l Conference of State Legislatures, FDA Final Rule on Prescription Drug Labeling (Jan. 19, 2006), http://www.ncsl.org/statefed/health/FDArule.htm.

249 Susan F. Wood & David Michaels, Op-Ed, *Transparency, Strength at the FDA*, BOSTON GLOBE, Aug. 1, 2007, at A11.

250 *See, e.g.*, Marc Kaufman, *Safety of Drug Imports Questioned*, WASH. POST, Feb. 7, 2008, at A19; Mark McCarty, *Democrats Inquiring into FDA Restrictions on Label Changes*, MED. DEVICE DAILY, Jan. 28, 2008, at 3.

251 *See* Mulkern, *supra* note 104.

Counsel after Troy returned to private practice, whom the magazine called an "ultra-conservative" without relevant job experience.[252]

This appalling show of political control over the FDA's legal policy was a surprising change for the small number of veteran counsel who spent careers in the field of food and drug law.[253] In the past, the Agency's decision makers usually paid close heed to its career managers, and rarely attracted charges that their own political ambitions were driving the decisions of the Agency.[254] Two former FDA chief counsels observed that "pervasive political influence" had "not been the historical pattern" at the FDA.[255] However, the Bush Administration has changed the traditional role of the FDA, and turned the Agency into one driven by political agendas.

XV
GROWING DENIALS OF DEFERENCE DURING THE BUSH ADMINISTRATION

During the current decade, the FDA has frequently lost cases where deference previously would have aided the Agency.[256] For example, the 2006 *Abigail Alliance* decision rejected the FDA's restrictive authority over the distribution of experimental new drugs and found a novel constitutional right of patients to receive unapproved new drugs.[257] The panel considered deferring to the FDA's contrary position but rejected its argument in a split decision.[258] Though the *Abigail Alliance* panel was overturned en banc,[259] its decision suggests a recent hesitancy of federal courts to defer to the FDA.[260] Further, the

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252 Zegart, *supra* note 152, at 28.

253 *See, e.g.*, Wood, *supra* note 68.

254 For a history of prior FDA legal advisors, see Francis E. McKay, *Lawyers of the FDA—Yesterday and Today*, 30 FOOD DRUG COSM. L.J. 621, 627 (1975) (quoting former Assistant General Counsel for the Food and Drug Division, Peter Hutt, describing his regulatory philosophy: "The client will be the public through the FDA.").

255 PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 18 (3d ed. 2007). Hutt and Merrill both served as FDA Chief Counsel.

256 *See* Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1146–47 (2007) (noting that the FDA's efforts to obtain greater deference have been met with "limited success" and "significant skepticism"); *see also* HUTT, MERRILL & GROSSMAN, *supra* note 255, at 56 ("In recent years, however, FDA has not been as consistently successful [defending its policies] in court.").

257 Abigail Alliance for Better Access to Dev'l. Drugs v. Von Eschenbach (*Abigail Alliance I*), 445 F.3d 470, 486 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695, 712–14 (D.C. Cir. 2007).

258 *See Abigail Alliance I*, 445 F.3d at 485 n.26.

259 *See* Abigail Alliance for Better Access to Dev'l. Drugs v. Von Eschenbach (*Abigail Alliance II*), 495 F.3d at 714.

260 *Cf.* Davis, *supra* note 256, at 1139 ("The Court has been hesitant to permit an overly aggressive assessment of federal objectives to swamp the importance of longstanding tort principles).

same appellate court denied deference to the FDA's views regarding certain pharmaceutical patent issues, reasoning that the issues went beyond the Agency's statutory responsibilities.[261]

The FDA has also lost in three recent generic drug disputes. In *Ranbaxy Laboratories*, the D.C. Circuit declined deference to the FDA on its policy of conditioning the generic drug exclusivity period upon the applicant being sued for patent infringement.[262] In *Sandoz*, a district court rejected the FDA's request for deferential acceptance of its drug approval deadlines in an opinion that harshly criticized the FDA's disregard of statutory mandates,[263] holding that while "the agency's decision of how to allocate its resources is entitled to deference, . . . such deference yields when the statutory violation (here an excruciatingly long delay) is egregious and ceases to be reasonable."[264] And in *Purepac Pharmaceutical*, the D.C. Circuit declined to defer to the FDA on a determination of the coverage of a particular patent.[265]

The FDA has had similar trouble obtaining deference in other areas. In *Nutritional Health Alliance*, the Second Circuit decided that the FDA lacked the authority to regulate dosage packaging of dietary supplements for the purpose of poison prevention.[266] In denying deference, the court noted that norms of deference did not "obviate [the court's] responsibility to ensure that the regulatory authority exercised by the FDA is actually rooted in the statute."[267] And in *Medical Center Pharmacy*, the district court said it would give deference to the FDA but then rejected most of the Agency's constructions and interpretations of the amended FD&C Act.[268] As these examples indicate, since 2000 the FDA has had increased difficulty defending statutory interpretations of its regulatory authority.

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261 *See* Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1279 n.5 (D.C. Cir. 2004) (noting that "the court owes no deference to the FDA's interpretation of . . . a patent statute provision which the FDA is not charged with administering").

262 *See* Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 126 (D.C. Cir. 2006) (noting that "FDA may not . . . change the incentive structure adopted by the Congress.").

263 *See* Sandoz, Inc. v. Leavitt, 427 F. Supp. 2d 29, 31 (D.D.C. 2006) ("In essence, the defendant asks the court to excuse its delay, accept governmental mediocrity and vitiate the statute's mandatory language.").

264 *Id.* at 40 (citations omitted).

265 *See* Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 883–85 (D.C. Cir. 2004) (holding that an FDA determination as to the coverage of a patent was arbitrary and capricious).

266 *See* Nutrition Health Alliance v. Food & Drug Admin., 318 F.3d 92, 97 (2d Cir. 2003) ("[T]he FDC Act provisions relied upon by the FDA unambiguously fail to provide it with authority to prescribe its unit-dose packaging rule.").

267 *Id.* at 98.

268 *See* Med. Ctr. Pharm. v. Gonzales, 451 F. Supp. 2d 854, 858 n.1 (W.D. Tex. 2006) (explaining that although the court "afforded the appropriate deference" to the FDA, it had to reject the Agency's construction of the statutes at issue).

Federal courts have also refused to defer to the FDA's claims of its power, declared most vividly in its 2006 preemption preamble,[269] to preempt a broad range of state tort claims.[270] For example, a Minnesota district court rejected as "perverse" arguments by a drug maker that FDA decisions preempt state tort claims:

> [The] defendant's argument that it should not be exposed to fifty-one separate tort-law regimes also rings hollow. Most mass merchants in this nation's economy sustain this burden as a cost of doing business. If Congress intends to create a class of protected businesses, it has the means and ability to do so. The Court finds no proof that it has done so here.[271]

Furthermore, in the 2006 *DeSiano* case, the Second Circuit denied preemption and expressed mild disdain for the FDA preamble assertions, holding that the Agency could not supply "the clear legislative statement of intent required to overcome the presumption against preemption."[272] Also, in the June 2007 *In re Zyprexa* decision, the eminent Senior Judge Jack Weinstein rejected the claims of a defendant pharmaceutical company that the FDA's preemption preamble should receive deference, describing the FDA's representations of its preemption power as "self-motivated."[273] Given the clarity of the reasoning and the eminence of the author, future decisions are likely to follow the Weinstein opinion.[274]

Perhaps the most famous denial of deference to the FDA's interpretation of its own preemption power occurred in the Supreme Court's 5-4 split in *Brown & Williamson*.[275] The case arose out of the

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269 *See supra* Part XIII (discussing the preemption preamble).

270 *See, e.g.*, Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964, 966 (D. Neb. 2006) ("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 which would be valid in the absence of such amendments unless there is a direct and positive conflict . . . ." (quoting Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962); Peters v. Astrazeneca, LP, 417 F. Supp. 2d 1051, 1055–56 (W.D. Wis. 2006); Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 732 (D. Minn. 2005) ("Defendant's preemption argument ultimately fails because Congress has not expressed a specific intent to preempt state consumer-protection laws in the area of prescription-drug labeling."); McNellis v. Pfizer, Inc., No. Civ. 05-1286(JBS), 2005 WL 3752269, at *10 (D.N.J. Dec. 29, 2005); Zikis v. Pfizer, Inc., No. 04-C-8104, 2005 WL 1126909, at *2 (N.D. Ill. May 9, 2005); Cartwright v. Pfizer, Inc., 369 F. Supp. 2d 876, 881–87 (E.D. Tex. 2005).

271 *Witczak*, 377 F. Supp. 2d at 732.

272 DeSiano v. Warner-Lambert & Co., 467 F.3d 85, 97–98 n.9 (2d Cir. 2006), *aff'd sub nom.* Warner-Lambert Co. v. Kent, 128 S. Ct. 1168 (2008) (per curiam).

273 *See In re* Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 240–41, 275–78 (E.D.N.Y. 2007) (defending the "important regulatory role" of state tort claims).

274 *See* Thomas Adcock, *Judge Honored for Protecting Women, Children*, N.Y. L.J., Oct. 5, 2007, at 24 (describing Judge Weinstein as "known for his expertise in mass tort cases" and "likewise esteemed" for his involvement in civil rights litigation).

275 529 U.S. 120, 126 (2000) ("In this case, we believe that Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products.").

FDA's attempt to regulate cigarettes as medical devices that deliver nicotine,[276] an attempt that drew international attention and industry opposition so extensive as to garner "purportedly more [input] than any agency had ever received in a rulemaking proceeding."[277] Deference to the FDA's interpretation of the statutory terms at issue was crucial for the Agency to retain jurisdiction over cigarettes.[278] The majority rejected claims of deference to the FDA's definition of the statutory term "device," finding that years of conscious refusal to act by Congress were functionally equivalent to an implicit denial of the Agency's power to regulate cigarettes.[279] The majority concluded that, absent some congressional decision, FDA regulation could not derive from implied authority over the regulated item.[280] It was a dramatic decision that has had ripple effects on the law of deference to administrative rules.[281]

XVI
ARE COURTS INFLUENCED BY MEDIA PERCEPTIONS?

Regardless of media perceptions, the only opinions of the FDA that really matter are those of the small number of judges who decide whether to give deference to FDA action.[282] However, the media's negative portrayal of the politicized Agency may cast doubt on its legal arguments in the courtroom: judges are susceptible to the same human influences from past and current experiences and from information flows.

Two briefs sit before a federal judge, one favoring the FDA's position and one opposing, usually focused on ambiguous statutory language in a convoluted section of the FD&C Act.[283] The challenge

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276 Cigarettes and Smokeless Tobacco, 61 Fed. Reg. 44,616 (Aug. 28, 1996) (codified at 21 C.F.R. pt. 897).

277 William B. Schultz, *I Met the President Because of WordPerfect 6.1*, *in* CENTURY OF PROTECTION, *supra* note 21, at 111. Schultz is the former FDA Deputy Commissioner for Policy.

278 *See Brown & Williamson*, 529 U.S. at 159 ("In fact, the FDA contends that, were it to determine that tobacco products provide no 'reasonable assurance of safety,' it would have the authority to ban cigarettes and smokeless tobacco entirely.").

279 *See id.* at 144 ("Congress has created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA.").

280 *See id.* at 160 ("[W]e are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion.").

281 *See, e.g.*, Case Comment, *Review of Administrative Action, Limits on Agency Discretion:* Massachusetts v. EPA, 121 HARV. L. REV. 415, 421 (2007) (opining that *Brown & Williamson* indicated a step towards "a greater oversight role" for courts).

282 See *supra* Part II.

283 The 1938 Act has been amended more than 100 times. *See* HUTT, MERRILL & GROSSMAN, *supra* note 255, at 14. The Act has enormously complex ambiguities for the courts to interpret. *See* Guy v. Travenol Labs., Inc., 812 F.2d 911, 916 (4th Cir. 1987) ("[T]he Food, Drug, and Cosmetic Act establishes a complex enforcement scheme.").

does not reach the jurist in a vacuum. It would be incorrect to presume that judges are impervious to the media, and also incorrect to presume that judges do not pay attention to coverage of government agencies, such as the FDA, that affect them and their families. While no statistical sampling of federal judges' opinions can be performed for purposes of this Article, it is reasonable speculation federal judges on average are well read and cognizant of political forces, even long after their ascent to the bench.[284] News coverage of White House involvement in FDA decision making may undercut any presumption of detached, scientific objectivity that the Agency will plead in those briefs seeking deference, as can be seen by the recent rise in cases refusing deference to FDA decisions.[285]

The impact of losing one or more federal judges as deferential patrons of the FDA's policies would be extremely damaging to the Agency in its second century.[286] Doubt about the jurisprudential basis for claiming deference would disable the FDA's potent regulatory power of deterrence. Yet the possibility of judges abandoning their traditional deferential review of FDA decisions may already be becoming a reality in the courts. For example, consider Judge Weinstein's refusal to find preemption in *In re Zyprexa*.[287] Judge Weinstein may have set the definitive tone for the FDA's legal position when he quipped: "The FDA cannot be allowed to usher in such a sweeping change in substantive law through the back door."[288]

XVII
WOULD A LESS POLITICIZED FDA REGAIN DEFERENCE?

As a result of its defeats in the preemptive preamble dispute, the FDA has suffered a loss of legitimacy.[289] The Plan B fiasco has contributed to this loss by drawing media attention to insiders' perceptions that science was secondary to the assuaging of certain conservative constituencies.[290] What must the FDA do to reclaim its legitimacy in the eyes of the public— and, perhaps more importantly,

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284 *See* Linda Greenhouse, Essay, *Telling the Court's Story: Justice and Journalism at the Supreme Court*, 105 YALE L.J. 1537, 1555 (1996) (discussing an interplay between the Supreme Court and the media).

285 *See supra* Part XV.

286 Losing one judge's deferential position to the FDA would have a large impact because the actual number of judges that review FDA decisions is so few. *See supra* Part II.

287 *In re* Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 273 (E.D.N.Y. 2007).

288 *Id.* at 275.

289 *See supra* Part XIII (discussing the "preemption preamble" dispute); *see also* Christine H. Kim, *The Case for Preemption of Prescription Drug Failure-To-Warn Claims*, 62 FOOD & DRUG L.J. 399, 401 (2007) (noting "mounting charges of regulatory capture" of the FDA).

290 *See supra* Part XII (discussing the Plan B dispute); *see also* Wood et. al., *supra* note 170, at 1199 ("Will we ever again be able to believe in the FDA's independence?").

in the eyes of judges deciding whether to give deference to the Agency?

The FDA must reclaim its regulatory independence so that career scientists may make reasoned choices—even if those choices offend some voters or political action committee donors—without interference from the White House. Ideally, calls or e-mails from the White House staff would not impact product approvals;[291] the FDA would base policy decisions solely on elements listed in the statutory standards; it would evaluate product status on a scientific basis alone; label content decisions would emphasize medical rather than legal factors; FDA management would be selected for their nationally recognized scientific credentials rather than on political recommendations;[292] and the FDA career staff's work would be judged on its technical merits, making retention of skilled scientific employees easier.

Obtaining these ideals might remove the taint of recent political motivations behind FDA decisions and thus restore its reputation in the eyes of the judiciary. The Agency might thereby regain the deference it has historically been accorded.

CONCLUSIONS

Mark Twain once reportedly quipped: "The report of my death was an exaggeration."[293] As one who has studied the Food and Drug Administration intensely for thirty-five years, I hesitate to prematurely predict the "Death of Deference." Judicial acceptance of the FDA's prowess as a regulator has been a hardy phenomenon. However, the capture of the Agency's political leadership by agents of its regulated industries has been manifest in the visible policy shifts described above. I believe the tipping point of this regulatory capture has been reached in this, the second century of the FDA's existence.

If Dr. Wiley[294] were to study the FDA today, he would likely write excoriating editorials about the need for muckrakers to challenge the Agency's loss of stature as an independent consumer protector. Some of the FDA's most formidable career officials have been quite independent and assertive of the prerogative that the Agency has enjoyed,

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291 Ex parte contacts by persons outside the Agency during an adjudication of a new drug application are not unlawful because the prohibition in § 557(d) only applies to formal adjudications, and virtually all new drug licensure is done informally. *See* 5 U.S.C. §§ 557(a), (d) (2000). As a result, they should probably be permitted in most cases; in any event, they appear to be a fact of Agency life. *See* HAWTHORNE, *supra* note 1, at 153–56 (discussing the phone calls and letters from Congress that sometimes reach drug reviewers).

292 *See supra* note 151 (listing examples of politically motivated appointments).

293 N.Y. J., June 2, 1897.

294 For a thoughtful account of Dr. Wiley's contribution to food science, see U.S. Food & Drug Admin., *Harvey W. Wiley: Pioneer Consumer Activist*, FDA CONSUMER MAGAZINE, Jan./Feb. 2006, http://www.fda.gov/fdac/features/2006/106_wiley.html; *see also supra* Part V.

both with the public and the courts.[295] In a democratic system with co-equal branches of government, it is essential that an administrative agency earn and preserve the courts' respect and deference so that the agency's mission is not compromised by judicial review of its disputed rules, licenses, and enforcement actions. When an agency veers off course, charting an ultra vires direction for itself, it is the duty of the independent judiciary to hold it accountable for deviations from the statutory purpose for which it exists.[296] As Justice Scalia once noted, "Agencies may play the sorcerer's apprentice but not the sorcerer himself."[297] Regrettably, the efforts of the Bush Administration to practice alchemy with the Federal Food, Drug, and Cosmetic Act may deter courts from giving deference to this sorcerer's apprentice for years to come.

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295 *See* 151 CONG. REC. S10,249 (2005) (statement of Sen. Murray) (warning against using the FDA, "long admired around the world for its neutrality and professionalism," as a "political tool").

296 *See* 21 U.S.C. § 393(b)(2) (2000).

297 *In re* Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 273 (E.D.N.Y. 2007) (quoting Alexander v. Sandoval, 532 U.S. 275, 291 (2001)).