RULEMAKING WITHOUT RULES: AN EMPIRICAL STUDY OF DIRECT FINAL RULEMAKING

*Michael Kolber**

ABSTRACT

In an effort to improve efficiency, several administrative agencies have adopted a procedure known as "direct final rulemaking" (DFR). Some academics have debated whether DFR violates the Administrative Procedure Act (APA), but none have studied how DFR has functioned in practice. This paper, which examines the first decade of DFR at the Food and Drug Administration (FDA), is the first of this kind. The results are surprising, and suggest DFR deserves more attention than it has received. Intended for noncontroversial rules that are expected to receive no significant comments in a notice-and-comment rulemaking, the FDA has often used direct final rulemaking for the opposite: regulations that may be expected to be controversial. Far from generating few comments, forty percent of DFRs have had to be withdrawn due to significant opposition. These findings suggest greater limits should be placed on the use of direct final rulemaking and that its legality be re-evaluated in light of how the procedure is actually used. As it is presently practiced, direct final rulemaking could increase cynicism about government.

INTRODUCTION

Frustrated with the pace of even the most minor rulemaking, federal agencies have experimented with streamlined regulatory practices over the past several decades.[1] One such innovation,

* J.D., Harvard Law School, 2009; B.A., Yale College, 2002. I am grateful to Lewis Grossman, Peter Barton Hutt, Ronald Levin, Lars Noah, Matthew Stephenson, Elisabeth Theodore, and Daniel Troy for their comments on earlier drafts. All errors are, of course, my own.

[1] *See* Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1263–65 (2006) (describing Reagan-era effort to centralize regulatory oversight in White House Office of Management and Budget); Jeffrey S. Lubbers,

"direct final rulemaking," allows an agency to dispense with some amount of procedure for rules that it expects to be uncontroversial.[2] This paper is the first case study to evaluate the implications of direct final rulemaking in practice—an evaluation of direct final rulemaking by the FDA over the past decade. The FDA example raises real concerns about the value and wisdom of the innovation. The FDA has a remarkably poor record at predicting which of its regulations will truly be noncontroversial, and this study suggests that it has been classifying certain proposed regulations as "noncontroversial" in hopes, most frequently misplaced, that they will go unnoticed. Proponents of DFR argue that even if DFR is producing few efficiency gains, the possibility of such gains make DFR worthwhile because it is, at worst, harmless.[3] The experience of DFR at the FDA belies this view. Failed direct final rulemaking, as the practice at the FDA must be called, may reduce the efficiency of agency rulemaking, can cause confusion about the state of the currently effective law, and erodes public confidence in the rulemaking process.

Under the model of American administrative rulemaking predominant since the late twentieth century,[4] the FDA—or any other agency—has a straightforward path for enacting a regulation: it publishes a notice of proposed rulemaking in the *Federal Register*, solicits comments on the rule for a fixed period of time, and then publishes a final rule in the *Federal Register*, incorporating responses to all significant comments.[5] Nowhere in notice-and-comment informal rulemaking does the agency make a determination about whether a rule will be controversial or not. Whether or not an agency receives adverse comments in the rulemaking, it may still proceed to publish a final rule, as long as the final rule adequately responds to the comments.[6]

Approaches to Regulatory Reform in the United States: A Response to the Remarks of Professors Levin and Freeman, 83 WASH. U. L.Q. 1893, 1894–1903 (2005) (describing various regulatory reform efforts).

[2] *See* Ronald M. Levin, *Direct Final Rulemaking*, 64 GEO. WASH L. REV. 1, 1–2 (1995).

[3] *See id.* at 22–23.

[4] *See* Richard E. Levy & Sidney A. Shapiro, *Administrative Procedure and the Decline of the Trial*, 51 U. KAN. L. REV. 473, 484–87 (2003). Although the Administrative Procedure Act permits trial-like formal rulemakings, *see* 5 U.S.C. §§ 556, 557 (2006), "informal" notice-and-comment rulemaking, *see id.* § 553, has been the default mode since the 1970s. *See* Levy & Shapiro, *supra*, at 484–87.

[5] *See* 5 U.S.C. § 553. Notice-and-comment rulemaking is described in more detail in Part I.

[6] *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 57 (1983).

However, since 1997 the FDA has conducted abbreviated informal rulemaking, called "direct final rulemaking," which requires the agency to determine at the outset whether a rule is expected to be "noncontroversial" and thus unlikely to generate significant adverse comments.[7] If a rulemaking is expected to be noncontroversial, the FDA issues a proposed rule and a direct final rule on the same day. Both solicit comments, typically for a seventy-five-day comment period. If the FDA receives no significant adverse comments, as would be expected for a truly noncontroversial rule, then the direct final rule becomes effective, typically sixty days after the close of the comment period. If the agency receives even a single significant adverse comment, it withdraws the direct final rule, and—assuming it still wishes to promulgate the rule—issues a new final rule, on the basis of the comments and the proposed rule that was published the same day as the now-withdrawn direct final rule.[8]

DFR has received scant academic attention. The limited discussion has understandably focused on whether DFR amounts to a violation of the Administrative Procedure Act, or if it would prevent judicial review of agency action.[9] At the outset of DFR, academic inattention was anticipated. Professor Ronald Levin, who has written two of the three extant articles,[10] wrote in 1999: "frankly, I doubted that anyone would ever write another article about the subject."[11] Since he wrote those words, no one has. Professor Levin's vision of direct final rulemaking—relevant because he was a key player in its promotion—was that minor, ministerial changes could be made with less procedure than informal rulemaking requires.[12] Virtually all of these would sail through with no comments and those that received some would undergo a rulemaking process substantially identical to the one

[7] Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. 62,466, 62,466 (Nov. 21, 1997). The Environmental Protection Agency was the first agency to adopt direct final rulemaking in the early 1980s. *See* Levin, *supra* note 2, at 4.

[8] Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. at 62,468.

[9] *See* Levin, *supra* note 2, at 1; Ronald M. Levin, *More on Direct Final Rulemaking: Streamlining, Not Corner-Cutting*, 51 ADMIN. L. REV. 757, 757–58 (1999) [hereinafter Levin, *More on Direct Final Rulemaking*]; Lars Noah, *Doubts about Direct Final Rulemaking*, 51 ADMIN. L. REV. 402 (1999). Professor Noah does briefly mention that the first year of direct final rulemaking at the FDA did produce a lower "batting average" than other agencies, but does not consider why the FDA had a higher failure rate than the EPA and the Federal Aviation Administration (FAA). *Id.* at 411; *cf.* discussion *infra* Part III.A.

[10] Levin, *supra* note 2; Levin, *More on Direct Final Rulemaking*, *supra* note 9; Noah, *supra* note 9.

[11] Levin, *More on Direct Final Rulemaking*, *supra* note 9, at 757.

[12] Noah, *supra* note 9, at 406.

required by the APA. At the outset some expressed concern that substantial compliance with the APA was not good enough.[13] Perhaps assuaged by the belief that direct final rulemaking only affects noncontroversial rules, no court has considered the legality of direct final rulemaking.[14] Had direct final rulemaking played out as Professor Levin expected it to, there would be little reason to revisit the issue now.

But, it has not—at least not at the FDA. Since 1997, the FDA has proposed direct final rulemaking for thirty-eight rules.[15] Fifteen of these—or forty percent—received significant adverse comments that resulted in withdrawal of the direct final rule in part or in whole. In the abstract, this is a high number. Forty percent is not a rare outcome. But what limited reference points we have make the number startling. The EPA has used direct final rulemaking to approve state implementation plans since 1981.[16] In a trial period, the EPA needed to withdraw fewer than five percent of the ninety direct final rules it issued.[17] Other experiences with direct final rulemaking at the EPA, the Federal Aviation Administration and elsewhere have produced withdrawal rates of less than ten or twenty percent.[18] A withdrawal rate of forty percent is shocking. It suggests either the FDA is dramatically off when predicting which of its rules are likely to be controversial or the FDA is using direct final rulemaking for purposes it was not intended. An examination of the direct final rules that are being withdrawn suggests both

[13] *See id.* at 418–19 ("Simply providing an opportunity for the post-promulgation submission of adverse comments on a rule will not, without more, cure procedural errors such as initially dispensing with notice-and-comment procedures without good cause. . . . Beyond the allowance specified in the APA . . . there should be no common law doctrine accepting anything less than full compliance with this statute.").

[14] Only three federal cases available in Westlaw, all involving the Environmental Protection Agency, include the phrase "direct final rule." Sw. Pa. Growth Alliance v. Browner, 144 F.3d 984, 987 (6th Cir. 1998); Sierra Club v. U.S. Envtl. Prot. Agency, 99 F.3d 1551, 1554 (10th Cir. 1996); Sierra Club v. Whitman, No. 00-2206 (CKK/JMF), 2002 WL 393069, at *3 (D.D.C. Mar. 11, 2002). These cases discuss rules published via direct final rulemaking, without any discussion of the legality of the process.

[15] The numbers in this section, including a discussion of my methodology, are presented in greater detail in Part III. Summary data throughout this paper are based on my own compilation of FDA DFRs. A summary is provided in the Appendix.

[16] *See* Requirements for Preparation, Adoption, and Submittal of State Implementation Plans; New SIP Processing Procedures to Save Time and Resources, 47 Fed. Reg. 27,073 (June 23, 1982).

[17] Requirements for Preparation, Adoption, and Submittal of State Implementation Plans; New SIP Processing Procedures to Save Time and Resources, 47 Fed. Reg. at 27,074.

[18] *See* Noah, *supra* note 9, at 411.

factors are at play.

At the dawn of the administrative age, then-professor Felix Frankfurter warned against theorizing administrative law without reference to its practice: "[h]ere we must be especially wary against the danger of premature synthesis, of sterile generalization unnourished by the realities of 'law in action.'"[19] A similar wariness is appropriate about this new chapter in administrative law, direct final rulemaking, now no longer in its infancy but still quite unnoticed.

Part I briefly sketches the development of notice-and-comment rulemaking as the dominant mode of American regulation, laying the groundwork for why some believe direct final rulemaking is a useful innovation. Part II describes the development of direct final rulemaking in the United States and the particular characteristics of the procedure as it was implemented at the FDA. Part III describes the methodology of this study and its findings, including a categorization of the rules promulgated via direct final rulemaking and those withdrawn. Part IV discusses the implications of these findings and, given the experience at the FDA, challenges the wisdom of this procedural innovation.

I. THE SUCCESSES AND FAILURES OF NOTICE-AND-COMMENT RULEMAKING

Though regulatory activity was present in the "earliest days of the Republic,"[20] modern regulatory agencies typically trace their history to the late nineteenth century.[21] The period saw the rise of modern national corporations, and the spirit of the Progressive Era demanded that government, too, should grow to police the excesses of unchecked capitalism.[22] The Interstate Commerce Commission was the most visible regulatory agency of the era. The first half of the twentieth century, including the New Deal, saw a dramatic expansion of regulatory agencies and their involvement in nearly every aspect of American commerce.[23] The nation was unsatisfied

[19] Felix Frankfurter, *The Task of Administrative Law*, 75 U. PA. L. REV. 614, 619 (1927).

[20] *See* Richard J. Pierce, Jr., *Rulemaking and the Administrative Procedure Act*, 32 TULSA L.J. 185, 185 (1996) (describing President Washington issuing regulations for the provision of pensions to veterans).

[21] *See* William E. Forbath, *Politics, State-Building, and the Courts*, *1870–1920*, *in* 2 THE CAMBRIDGE HISTORY OF LAW IN AMERICA 643, 650–51, (Michael Grossberg & Christopher Tomlins eds., 2008).

[22] *Id.* at 651.

[23] *Id.* at 654.

with the laissez faire approach to regulating commerce that had preceded the New Deal.[24] Transportation, consumer products, communications, and other industries had become too complex and large for Congress to be able to address through specific legislation.[25] Instead, Congress created regulatory agencies and delegated to them broad legislative authority to regulate in the public interest. The delegations were so broad and so vague that America soon feared not the corporations, but the regulators who had been created to check those corporations.[26] After years of debate, Congress enacted the Administrative Procedure Act of 1946, the constitution of the administrative state.[27] The U.S. Constitution provides few real limits on administrative discretion.[28] Instead, the APA provides the most significant safeguard against an authoritarian bureaucracy.[29]

The APA divides all agency action into two categories, adjudication and rulemaking, and establishes particular procedures to govern each sort of action.[30] In the early years of the APA, adjudication and formal rulemaking—so formal that it shared many of the features of adjudication—were the predominant modes of regulatory action.[31] "The New Deal agencies viewed themselves as

---

[24] JAMES M. LANDIS, THE ADMINISTRATIVE PROCESS 8 (1938).

[25] *See id.* at 7–8.

[26] *See* PRESIDENT'S COMM. ON ADMIN. MGMT., REPORT OF THE COMMITTEE WITH STUDIES OF ADMINISTRATIVE MANAGEMENT IN THE FEDERAL GOVERNMENT 40 (1937); *see also* Universal Camera Corp. v. NLRB, 340 U.S. 474, 478–79 (1951) (describing protests against perceived administrative arbitrariness); *cf.* F.A. HAYEK, THE ROAD TO SERFDOM (1944) (warning that central planning in America and Britain may lead to authoritarian regimes).

[27] Administrative Procedure Act, ch. 324, 60 Stat. 237 (1946).

[28] The nondelegation doctrine is the most relevant constitutional restraint for this context. Article I, Section 1 of the Constitution vests all legislative power in Congress. *See* Thomas W. Merrill, *Rethinking Article I, Section 1: From Nondelegation to Exclusive Delegation*, 104 COLUM. L. REV. 2097, 2098 (2004). The Supreme Court has held that Congress may not delegate this power. *See id.* at 2099. Therefore, any statute that vests legislative power in an administrative agency is unconstitutional. *See id.* However, the Court has also devised countless ways to show Congressional grants of rulemaking authority to agencies are not truly delegations of legislative power and therefore has rarely struck down congressional enactments or regulatory action on nondelegation grounds. *See id.* (asserting that a judicial attitude of great deference towards congressional delegations of authority has made the nondelegation doctrine effectively unenforceable).

[29] Over the course of the second half of the twentieth century, the courts expanded and shrunk the amount of procedure that the APA imposed on agencies. Pierce, *supra* note 20, at 186–87. Rehashing this history is unnecessary for present purposes, but Pierce, *supra* note 20, at 187–95, provides a concise summary.

[30] Pierce, *supra* note 20, at 186–87.

[31] *Id.* at 187.

akin to special purpose courts."[32] But trial-like adjudication and formal rulemaking were slow and, in the case of adjudication, backward-looking.[33] They thus seemed not to harness the expertise of regulatory agencies to anticipate problems before they became "cases" or "controversies" suitable for judicial resolution.[34] A pair of Supreme Court decisions in the 1970s invigorated the remaining category of agency action under the APA—"informal rulemaking"—by explaining that the APA's minimal amount of procedure for informal rulemaking was all that was required to enact a legally binding regulation.[35] Informal rulemaking now far overshadows adjudication or formal rulemaking as a mode of agency regulation.[36] Professor Kenneth Culp Davis called rulemaking "one of the greatest inventions of modern government."[37]

Informal rulemaking, the now dominant mode of rulemaking, also known as notice-and-comment rulemaking, requires that an agency that seeks to enact a rule publish a notice in the *Federal Register* detailing "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[38] The agency must then give "interested persons an opportunity to participate in the rule making," although the agency may limit such participation to written submissions.[39] The agency must consider those comments from the public and then adopt a final rule that contains a "concise general statement of [its] basis and purpose."[40] Generally, agencies need not follow this procedure for rules involving military or foreign affairs or an agency's internal organization; for interpretative rules or general statements of policy; or when doing so would be "impracticable, unnecessary, or contrary to the public interest."[41] Courts may invalidate rules if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," contrary to the Constitution, or "in excess" of the agency's statutory

[32] *Id.*; *see also* Edward Rubin, *It's Time To Make the Administrative Procedure Act Administrative*, 89 CORNELL L. REV. 95, 111–12 (2003).

[33] Pierce, *supra* note 20, at 188.

[34] *Id.* at 187.

[35] Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc., 435 U.S. 519, 523–24 (1978); *see also* U.S. v. Allegheny-Ludlum Steel Corp., 406 U.S. 742, 758 (1972) (stating that since the statutory requirements were met, no more was required).

[36] *See* Levy & Shapiro, *supra* note 4, at 487–88.

[37] 1 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE § 6.1 (2d ed. 1978) (quoting 1 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE § 6.15 (1st ed. Supp. 1970)).

[38] Administrative Procedure Act, 5 U.S.C. § 553(b)(3) (2006).

[39] *Id.* § 553(c).

[40] *Id.*

[41] *Id.* § 553(a)–(b).

authority.[42]

Informal notice-and-comment rulemaking provides several interrelated benefits. It allows all stakeholders in a regulatory decision to be heard before a decision is made and ensures that the agency responds to relevant comments.[43] In comparison, adjudications tend to be bilateral confrontations between the agency and the regulated party. The courts narrowly define which interested parties have a right to be heard in adjudications.[44] Notice-and-comment ensures some level of political accountability because it gives visibility to internal agency deliberations that would otherwise be hidden both from the media and Congress.[45] Congress can intervene in rulemakings should they become particularly politically salient.[46] Finally, informal rulemaking provides a record upon which courts may evaluate the rulemaking process for compliance with the APA.[47] Though the administrative bureaucracy has been vulnerable to waves of criticism through the twentieth and twenty-first centuries, the procedural safeguards of informal rulemaking ensure that certain rule of law baselines are protected in our administrative regime, which is somewhat removed from the constitutional system of separation of powers.[48] Some have argued that informal notice-and-comment rulemaking is so successful at accomplishing these goals that it should be exported to non-American bureaucracies.[49]

Since the 1980s, however, widespread concern has developed over the "ossification" of even informal rulemaking.[50] Regulatory

---

[42] *Id.* § 706(2)(A)–(C).

[43] *See* Pierce, *supra* note 20, at 189.

[44] *Compare* Londoner v. Denver, 210 U.S. 373, 386 (1908) (finding that a small group of landowners, whose members were each exceptionally and individually affected by a cost-assessment determination, was entitled to a hearing on the issue), *with* Bi-Metallic Inv. Co. v. State Bd. of Equalization, 239 U.S. 441, 444–46 (1915) (upholding a determination that an individual landowner was not entitled to a hearing where all landowners in a wide area were equally affected by an order increasing property valuation).

[45] *See* Pierce, *supra* note 20, at 189.

[46] *Id.* at 197–99.

[47] *Cf.* Auto. Parts & Accessories Ass'n v. Boyd, 407 F.2d 330, 338 (D.C. Cir. 1968) (using the APA, as well as another act, to determine if an administrative agency carried out its duty in a proper manner).

[48] *See* Gary Lawson, *The Rise and Rise of the Administrative State*, 107 HARV. L. REV. 1231, 1248–49 (1994).

[49] *See* Francesca E. Bignami, *The Democratic Deficit in European Community Rulemaking: A Call for Notice and Comment in Comitology*, 40 HARV. INT'L L.J. 451 (1999).

[50] *See* Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 TEX. L. REV. 525 (1997); Thomas O. McGarity, *Some Thoughts on*

agencies, faced with increased procedural burdens imposed by all three constitutional branches, gradually ceased to enact new rules or repeal old ones.[51] The courts imposed new procedural burdens by granting broad standing to parties to seek judicial review of rulemakings,[52] demanding that agencies produce appropriate records upon which rulemakings could be reviewed,[53] and insisting that courts could overturn agency action if the agency had not adequately responded to reasonable comments.[54] The executive sought to exert greater control over the agencies by requiring that executive policy be coordinated through the White House Office of Management and Budget.[55] Finally, anti-regulatory Congresses imposed higher procedural burdens on particular agencies, such as requiring oral hearings in order to effectively end regulation of certain industries.[56]

One response to ossification has been to try to accomplish similar ends through even less formal means than notice-and-comment rulemaking, such as interpretive letters or policy statements.[57] Though these even-less-formal "rules" can be implemented with less procedure, courts are less likely to treat them as definitive statements of the law, and regulated parties thus lose the benefit of the certainty of having a rule. Furthermore, because these less formal documents are generated without notice or comment, industry and public alike lose the benefits of informal rulemaking—political accountability, public participation, information forcing, and an adequate record for judicial review. An alternate means of deossifying rulemaking has been to find methods that purport to fulfill the requirements of informal rulemaking but are less burdensome than informal rulemaking as it is currently practiced. The remainder of this paper describes direct final rulemaking, one of these attempts, and contrasts it with the values of informal

"Deossifying" the Rulemaking Process, 41 DUKE L.J. 1385, 1386 (1992); Richard J. Pierce Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59, 60–61 (1995).

[51] *See* Pierce, *supra* note 50, at 62.

[52] *See* Ass'n of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 154 (1970).

[53] Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 414 n.30, 420 (1971).

[54] *See* Pub. Citizen, Inc. v. FAA, 988 F.2d 186, 197 (D.C. Cir. 1993); *see also* Richard J. Pierce, Jr., *The APA and Regulatory Reform*, 10 ADMIN. L.J. AM. U. 81, 83 (1996).

[55] Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 19, 1981).

[56] *See generally* Jerry L. Mashaw, *Reinventing Government and Regulatory Reform: Studies in the Neglect and Abuse of Administrative Law*, 57 U. PITT. L. REV. 405, 417–20 (1996) (detailing congressional efforts to ossify the rulemaking process); Teresa M. Schwartz, *The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade*, 51 GEO. WASH. L. REV. 32, 58 n.178 (1982).

[57] *See, e.g.*, United States v. Mead Corp., 533 U.S. 218, 222–23 (2001).

notice-and-comment rulemaking just described.

II. ORIGINS OF DIRECT FINAL RULEMAKING

In 1995, at its last plenary session, the Administrative Conference of the United States[58] recommended that agencies adopt direct final rulemaking "for expediting the issuance of noncontroversial rules."[59] The goal of adopting DFR was to allow "the agency to issue the rule without having to go through the review process twice (i.e., at the proposed and final rule stages), while at the same time offering the public the opportunity to challenge the agency's view that the rule is noncontroversial."[60] Given the increasing procedural hurdles surrounding rulemaking, any procedure that would preserve public input while quickening the regulatory process would seem welcome. This part describes the procedural requirements that developed for direct final rulemaking at the FDA and other agencies and the existing scholarly views on the legality of the practice.

A. Preconditions and Requirements for Direct Final Rulemaking

The Administrative Conference recommended that agencies adopt direct final rulemaking "where an agency believes that [a] rule will be noncontroversial and adverse comments will not be received."[61] The agency would issue a direct final rule, indicating that the public has until a certain date to submit adverse comments.[62] If no significant adverse comments are received, the rule would go into effect no sooner than thirty days after the end of the comment period.[63] In the Administrative Conference recommendation, an agency may either issue a "confirmation notice" to indicate that no comments have been received, and allow the rule to go into effect, or remain silent and by its silence indicate the same.[64] As this bare

[58] The Administrative Conference, a forum for federal agencies to discuss and resolve their mutual problems, was dissolved by Congress in a budget-cutting effort. Although the agency had a miniscule budget, it also lacked any vocal constituents. *See* Toni M. Fine, *A Legislative Analysis of the Demise of the Administrative Conference of the United States*, 30 ARIZ. ST. L.J. 19, 23 (1998).

[59] Administrative Conference of the United States, Adoption of Recommendations, 60 Fed. Reg. 43,108, 43,110 (Aug. 18, 1995).

[60] *Id.* at 43,110–11 (footnote omitted).

[61] *Id.* at 43,110.

[62] *Id.* at 43,111.

[63] *Id.* at 43,110.

[64] *Id.* at 43,111.

outline indicates, how one defines "noncontroversial" and "significant adverse comment" and whether an agency decides to issue confirmation notices will play major roles in determining both the scale of efficiency gains from direct final rulemaking and the magnitude of the concerns about its legality.

The Administrative Conference offered few specifics in its definition of what sorts of rules would be noncontroversial enough to be suitable for direct final rulemaking. The Conference recommended agencies use direct final rulemaking for all rules that would otherwise fall under the "unnecessary" prong of the good cause exemption from notice-and-comment rulemaking.[65] But note that using direct final rulemaking in this context is indisputably acceptable—allowing an adverse comment to stop a rulemaking for which notice-and-comment is not required would be providing *more* procedure than the law requires.[66] The Conference also recommended direct final rulemaking for negotiated regulations, but otherwise provided little explanation for how an agency should predict whether a rule will be uncontroversial.[67] One must look to agency practice to get a real feel for what "noncontroversial" means.

The EPA was first to adopt DFR, predating the Administrative Conference's recommendation,[68] and still is the most frequent user of direct final rulemaking.[69] At first, the EPA limited direct rulemaking to certain programs it administers that involve many routine rulemakings that rarely generate comments: EPA approval of revisions to state implementation plans under the Clean Air Act and EPA promulgation of "significant new use rules" for chemicals under the Toxic Substances Control Act.[70] When it began issuing DFRs for each of those programs, the EPA issued a notice explaining its intent to do so because of the uniquely noncontroversial nature of the rulemaking in each case.[71] But since

---

[65] *Id.*; *see also* Administrative Procedure Act, 5 U.S.C. § 553(B) (2000).

[66] *See* Ellen R. Jordan, *The Administrative Procedure Act's "Good Cause" Exemption*, 36 ADMIN. L. REV. 113, 129–35 (1984).

[67] *See* Administrative Conference of the United States, Adoption of Recommendations, 60 Fed. Reg. at 43,111.

[68] *See* Levin, *supra* note 2, at 4.

[69] According to a LEXIS search, in the five years prior to March 31, 2008, 1,640 notices related to direct final rules have appeared in the *Federal Register* and 871 of those have been published by the EPA.

[70] Levin, *supra* note 2, at 4.

[71] Significant New Use Rules; General Provisions for New Chemical Follow-Up, 54 Fed. Reg. 31,298, 31,298 (July 27, 1989); Requirements for Preparation, Adoption, and Submittal of State Implementation Plans; Experimental State Implementation Plan Processing Techniques, 46 Fed. Reg. 44,476, 44,477 (Sept. 4, 1981).

the mid-1990s, the EPA has used DFRs in contexts outside these two programs, and without a prior policy statement of its intent to do so. Instead, each time the EPA issues a DFR, it explains that the subject of the rulemaking is expected to be noncontroversial and appropriate for direct final rulemaking.[72] The EPA has apparently never issued an across-the-board statement about how it determines a rule is expected to be noncontroversial.

On the other hand, the FDA did issue a policy statement in 1997 explaining how it intended to use direct final rulemaking for regulations about which it "does not anticipate receiving any significant adverse comment, or when a rule may qualify for exemption from notice-and-comment rulemaking."[73] As examples, the FDA said DFR would be appropriate "for minor, substantive changes to regulations; incorporation by reference of the latest edition of technical or industry standards; [and] . . . direct incorporations of mandates from new legislation . . . ."[74]

The Administrative Conference expected to withdraw the direct final rule if an agency received "'significant adverse' comment[s]," but noted that agencies have defined "'significant adverse' comment[s]" differently.[75] The Conference recommended that agencies withdraw DFRs if they received a comment

> where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, agencies should consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process.[76]

The FDA adopted this definition of "significant adverse comment."[77] The EPA appears to be somewhat more generous to commenters in that it will withdraw a DFR if it merely receives notification of an individual's intention to file adverse comments—a

---

[72] Levin, *supra* note 2, at 5.

[73] Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. 62,466, 62,468 (Nov. 21, 1997).

[74] *Id.* at 62,469.

[75] Administrative Conference of the United States, Adoption of Recommendations, 60 Fed. Reg. 43,108, 43,111 (Aug. 18, 1995).

[76] *Id.*

[77] Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. at 62,469.

commenter need not actually file a comment to have the DFR withdrawn.[78]

The EPA has chosen not to issue confirmations when a DFR has survived with no comments.[79] The initial DFR serves as the public's only notice that a rule is going into effect. The FDA has adopted the policy of publishing a confirmation stating that no significant comments have been received and that the rule will go into effect after the comment period ends and before the rule's effective date.[80] The FDA has generally followed this policy, although, as will be discussed below, on at least one occasion a DFR was neither withdrawn nor confirmed, which under the terms of the initial DFR meant the rule was effective.

B. The Legal Basis for Direct Final Rulemaking

Professor Levin, who as consultant to the Administrative Conference participated in drafting the DFR recommendation, described DFR as a "variation" on typical notice-and-comment rulemaking.[81] Even if DFR can be described as a variant of notice-and-comment rulemaking, it is not instantly obvious that the process can be squared with the APA requirements. Indeed, the Administrative Conference's report equivocates on whether DFR is legal: "Although direct final rulemaking is viewed by the Conference as permissible under the APA as currently written, Congress may wish to expressly authorize the process. Authorization would alleviate any uncertainty and reduce the potential for litigation."[82] Congress has not taken up this suggestion and it seems unlikely to be a high priority: despite the mountains of agency action challenged in court, no party has apparently ever sought to challenge the legality of a DFR because it was issued as a DFR.[83] Professor Levin offers two legal justifications for DFR. First, as the Administrative Conference's recommendation indicates, it may be used for rules that under Section 553(b) of the Administrative Procedure Act would otherwise be entirely exempt from "the usual

---

[78] Levin, *supra* note 2, at 5.

[79] *Id.*; *see, e.g.*, Approval and Promulgation of State Implementation Plans; State of Utah; Interstate Transport of Pollution and Other Revisions, 73 Fed. Reg. 16,543, 16,543 (Mar. 28, 2008).

[80] Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. at 62,468.

[81] Levin, *supra* note 2, at 1.

[82] Administrative Conference of the United States, Adoption of Recommendations, 60 Fed. Reg. 43,108, 43,111 (Aug. 18, 1995).

[83] *See supra* note 14 and accompanying text.

public participation requirements of the APA, because such participation would be 'unnecessary' within the meaning of the good cause exemption of Section 553(b)(B)."[84] Thus, DFR amounts to more procedure than the law requires, not less. Second, DFR amounts to "substantial compliance"[85] with Section 553, which requires publication of a notice of proposed rulemaking, an opportunity to comment on the rule, and then publication of a statement explaining the final rule in light of the comments.[86] Professor Levin argues, with some reason, that DFR can preserve all of these elements when no comments are received on the DFR because the initial publication serves as both proposed rule and final rule.[87] When comments are received, the initial publication serves as proposal and then a later final rule serves as the statement of basis and purpose.[88] "In short, direct final rulemaking appears to be in substantial compliance with the publication requirements of the APA, because members of the public receive the same information about the contents and rationale of the rule that they would receive in a typical rulemaking proceeding—only sooner."[89] Professor Levin later amended this second argument: although it is possible for DFR to comply substantially with Section 553, in certain circumstances it may not.[90] As the FDA experience described below demonstrates, failure to comply with 553 is a real possibility.

Professor Lars Noah offers the only full-throated attack of the DFR approach. He argues that under existing practice many rules contemplated as DFRs would not fit within the "unnecessary" exemption of Section 553(b) and that DFR does not fulfill the requirements for notice-and-comment rulemaking.[91] Those occasions when courts have permitted "substantial compliance" with Section 553 have involved smaller divergences from the prescribed practice.[92] Professor Noah adds a further objection: direct final rulemaking may not produce an adequate record upon which a

[84] Levin, *supra* note 2, at 11.
[85] *See id.* at 16.
[86] *See id.* at 16–17.
[87] *See id.* at 16.
[88] *Id.* at 15–18.
[89] *Id.* at 18.
[90] *See* Levin, *More on Direct Final Rulemaking*, *supra* note 9, at 762 n.20.
[91] Noah, *supra* note 9, at 412–17.
[92] *Id.* at 417–19.

reviewing court could determine whether the agency action was arbitrary and capricious.[93] Professor Levin responds that despite not looking like typical notice-and-comment rulemaking, direct final rulemaking does technically comply with Section 553 and, indeed, produces just as extensive an administrative record for review as notice-and-comment rulemaking would.[94] In the abstract, it appears that Professor Levin has the better argument: it is difficult to point to a provision of Section 553 that direct final rulemaking violates, and the procedure produces no smaller an administrative record than a notice-and-comment rulemaking in which no comments are received.[95] Still, I will revisit this debate after reviewing the FDA experience.

III. DIRECT FINAL RULEMAKING AT THE FDA

This part describes my methodology and then presents details of my findings. The methodology of this study is quite straightforward. I searched the *Federal Register* for every notice that contained both "Food and Drug Administration" in the caption and "direct final rule" anywhere in the notice. Of course, for any given rulemaking, one would anticipate finding at least three notices: a direct final rule, an identical proposed rule published on the same day, and then a confirmation or withdrawal at some later date. Therefore, merely reporting the total number of hits on this search—185—is not a reasonable proxy for the number of DFRs initiated by the FDA. By reading each of the filings, I have determined that as of April 2008, the FDA has proposed and confirmed or withdrawn thirty-eight direct final rules. Only a limited number of the FDA dockets are available online. I have examined those that are available related to DFR to confirm, when possible, the account of the rulemaking process as presented in the *Federal Register*.

---

[93] *Id.* at 426–28.

[94] Levin, *More on Direct Final Rulemaking*, *supra* note 9, at 758–63.

[95] Even if an agency receives significant non-adverse comments or insignificant adverse comments, it may finalize the rule in typical notice-and-comment rulemaking without responding to those comments, as long as those comments do not point to relevant factors that the agency failed to consider (which would make them significant and adverse). *See* Covad Commc'ns Co. v. Fed. Commc'ns Comm'n, 450 F.3d 528, 550 (D.C. Cir. 2006); Thompson v. Clark, 741 F.2d 401, 408–09 (D.C. Cir. 1984); Conference of State Bank Supervisors v. Office of Thrift Supervision, 792 F. Supp. 837, 846 (D.D.C. 1992).

A. The Record of Failure

As discussed in the Introduction, fifteen of the thirty-eight rules have been withdrawn in whole or in part.[96] As discussed above, this results in a withdrawal rate of forty percent, which is high both in the abstract and in comparison to studies of direct final rulemaking practice at other agencies. Yet direct final rulemaking has fared even more poorly than this record indicates.

First, three direct final rules were confirmed despite the fact that the FDA received comments on the direct final rule.[97] This can occur because under the FDA's final rulemaking policy, if the comments were seen as either not significant or not adverse, the rule need not be withdrawn. For example, the FDA received sixteen comments on a direct final rule revising the adverse event reporting regulations for medical devices to make the regulations easier to read.[98] Three of the comments supported the change and others suggested substantive changes to the reporting requirement, even though the rulemaking only concerned superficial changes to wording.[99] The FDA confirmed the rule because those comments were outside the scope of the rulemaking.[100] Although the Administrative Conference recognized that some direct final rules would be confirmed despite receiving comments, it clearly envisioned that virtually all confirmed direct final rules would be so uncontroversial that they would generate no comments, whether significant and adverse or not.[101] It is unclear whether these three direct final rules should be considered "failed" DFRs, despite their confirmation. My conservative count of fifteen withdrawn DFRs

[96] If the FDA determines that a rule is severable and receives significant adverse comments on only a portion of the rule, it may confirm those parts of the rule that it did not receive comments on, and then later issue a revised final rule for the remainder. *See, e.g.*, Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human), 65 Fed. Reg. 52,016 (Aug. 28, 2000); Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma, 66 Fed. Reg. 40,886 (Aug. 6, 2001).

[97] Medical Devices; Medical Device Reporting; Confirmation of Effective Date, 70 Fed. Reg. 34,652 (June 15, 2005); Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Confirmation of Effective Date and Technical Amendment, 73 Fed. Reg. 7,463 (Feb. 8, 2008); Revision of the Requirements for Live Vaccine Processing; Confirmation of Effective Date, 73 Fed. Reg. 12,262 (Mar. 7, 2008).

[98] *See* Medical Devices; Medical Device Reporting; Confirmation of Effective Date, 70 Fed. Reg. at 34,652.

[99] *See id.*

[100] *See id.*

[101] *See* Levin, *supra* note 2, at 16 ("[E]ven one objector can 'blackball' the rule.").

does not include these three. Nevertheless, at least for the August 16, 2007, direct final rule on biologics,[102] the case might equally be made for including it on the withdrawn side of the ledger: the agency received "several letters of comment" although the agency considered none significant and adverse.[103] Nevertheless, in confirming the rule, the agency responded in detail to those comments and made "two technical amendments" to the rule.[104] At least in this case, it is not clear whether there is any difference between direct final rulemaking and notice-and-comment rulemaking, either in efficiency or legal adequacy.

Second, not only does the FDA have to withdraw a surprisingly high number of its direct final rules because it receives adverse comments about them, but very frequently—more than half the time—those comments are so significant that not only does the FDA determine that direct final rulemaking is inappropriate, but that the proposed rule should be modified in response to the comments.[105] To understand why this is so surprising, consider a theoretical withdrawn DFR: the FDA would like to promulgate a rule that it believes is correct and, moreover, the FDA thinks it is so exquisitely correct that it is highly unlikely that anyone would object to the rule. Nevertheless, someone submits a significant adverse comment. One would not be surprised—one would even expect—that the FDA would withdraw the original DFR and then issue a substantially identical final rule after considering the comments. After all, the FDA began from a position of being so supremely confident in its original rule that it expected no significant adverse comments. Then someone objects. Fine, the FDA says, we concede you have some points, but we considered that

---

[102] Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma, 72 Fed. Reg. 45,883 (Aug. 16, 2007).

[103] Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Confirmation of Effective Date and Technical Amendment**,** 73 Fed. Reg. 7,463, 7,463 (Feb. 8, 2008).

[104] *Id.*

[105] For modified rules, see Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma, 66 Fed. Reg. 40,886 (Aug. 6, 2001); Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Confirmation of Effective Date and Technical Amendment, 73 Fed. Reg. at 7,463; Medical Devices; Humanitarian Use of Devices, 63 Fed. Reg. 59,217 (Nov. 3, 1998); Medical Devices; 30-Day Notices and 135-Day PMA Supplement Review, 63 Fed. Reg. 54,042 (Oct. 8, 1998); Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting, 65 Fed. Reg. 4,112 (Jan. 26, 2000); Administrative Practices and Procedures; Internal Review of Decisions, 63 Fed. Reg. 63,978 (Nov. 18, 1998). For rules withdrawn without subsequent revised final rules, see *infra* note 108.

and we still think our rule is better. This would be a perfectly reasonable response and depending on how the FDA explains its decision in its final rule, an identical rule is quite likely to survive "hard look" judicial review.[106] But that isn't what's happening. Of the fifteen DFRs withdrawn in whole or in part, six were reissued as a final rule *with modifications based on the comments*.[107] Two were withdrawn and never reissued.[108] In over half the cases in which the FDA underestimated how controversial a rule would be, it also then conceded that elements of its proposed rule were substantively wrong, by either modifying them in a final rule or not issuing a final rule altogether. Although authoritative data on how often proposed rules are modified is scant, this modification rate appears to be not significantly different from the rate for typical notice-and-comment rulemaking.[109]

---

[106] *Cf.* Matthew C. Stephenson, *A Costly Signaling Theory of "Hard Look" Judicial Review*, 58 ADMIN. L. REV. 753, 755 (2006) (suggesting that courts could use superficial qualities of an agency's explanation to evaluate the substance of rulemaking).

[107] *See* sources cited *supra* note 105.

[108] Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records; Withdrawal, 66 Fed. Reg. 20,401 (Apr. 23, 2001); Food Labeling: Ingredient Labeling of Dietary Supplements That Contain Botanicals; Withdrawal, 70 Fed. Reg. 76,684 (Dec. 28, 2005). The direct final rule on advisory committees, Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records, 66 Fed. Reg. 1,257 (Jan. 8, 2001), was a "midnight regulation" issued in the last two weeks of the Clinton administration. *See generally* Jack M. Beermann, *Presidential Power in Transitions*, 83 B.U. L. REV. 947 (2003) (discussing the frequency of presidential action at the end of a term). It was withdrawn by the Bush administration and never reissued. Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records; Withdrawal, 66 Fed. Reg. at 20,401. This failure to reissue appears to have more to do with the change in administration than the strength of comments; indeed, the comments were never addressed, perhaps raising questions about whether the withdrawal was even effective. *See* Noah, *supra* note 9, at 416; Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 (1983) (holding that rescission of a regulation, like promulgation of a regulation, may not be arbitrary and capricious). Still, since DFR is premised on the rule being noncontroversial, it is surprising and likely an indicator that the process was misused to see that a politically charged proposal was the subject of a DFR. Because a third DFR was withdrawn and not reissued two years ago, Current Good Manufacturing Practice Regulation and Investigational New Drugs; Withdrawal, 71 Fed. Reg. 25,747 (May 2, 2006), and a fourth was withdrawn even more recently, Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals; Withdrawal, 73 Fed. Reg. 18,440 (Apr. 4, 2008), it is too soon to conclude the FDA does not intend to reissue these as final rules.

[109] *Cf.* Mariano-Florentino Cuéllar, *Rethinking Regulatory Democracy*, 57 ADMIN. L. REV. 411, 414 (2005) (studying three representative notice-and-comment rulemakings and concluding that agencies change rules in response to comments, although "the sophistication with which a comment is written seems to affect the probability that the agency will accept suggestions in that comment").

B. Content of the Failed Rules

By examining the content of the DFRs, we begin to answer the puzzle of why this is happening. Direct final rules have been published about every subject matter that the FDA regulates, with the exception of radiological products and cosmetics. Since 1997, nine DFRs have been published that relate principally to biologics, eleven relate to medical devices, seven relate to human drugs, five relate to human food, and one relates to veterinary medicine.[110] The remaining five DFRs related to procedural issues or other concerns that span the agency's practice areas.[111]

A more interesting categorization of the agency's DFRs is according to the nature of the rules, not their subjects. I developed a classification scheme that largely follows the categories the FDA described in its policy on direct final rulemaking discussed in Part II.[112] I assigned each of the thirty-eight published direct final rules to one of six categories that more or less describes the nature of the principal change the regulation effects: inflation adjustment, regulatory simplification, "forced substantive" change, standards adjustment, change in a regulation as required by a statute, or an "unforced" substantive change at the agency's discretion. Some of the rules could have fit into more than one of these categories, and certainly at the margins there could be some argument about which label to affix to a particular rule. Still, the categories provide a useful device to summarize the work the agency has undertaken under its program of direct final rulemaking and begins to provide some answers as to why it has apparently been so unsuccessful.

Fifteen of the DFRs fit in the largest category, regulatory simplification. These tend to be rules to eliminate regulations to "be more consistent with current practices and to remove unnecessary or outdated requirements."[113] But it must be noted that there is some variation among these rules, so much that a different reader might have categorized some as a discretionary substantive change. There also seems to be a difference between regulations in this category between the Clinton and Bush administrations. The Clinton administration DFRs tend to describe the changes as

---

[110] *See infra* Appendix.

[111] *See id.*

[112] *See supra* note 74 and accompanying text.

[113] Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human), 64 Fed. Reg. 26,282, 26,282 (May 14, 1999).

eliminating regulations that simply are no longer effective or meaningful given technological change or other changed circumstances. Bush administration DFRs in this category tend to eliminate regulations that still have some effect but are judged too burdensome on industry given the small benefit from the rule.

A discussion of two representative rules will illustrate the distinction. In 1999, the Clinton-era FDA published a direct final rule that removed a little-used regulation listing veterinary and scientific journals available in the FDA library.[114] Typically when submitting a new drug application, an applicant is required to submit reprints or summaries of the published studies upon which the application relies.[115] Until 1968, human and animal drug applications were covered by the same regulation, which included a provision that permitted applicants to forego submitting copies of articles in journals on the list of journals in the FDA library.[116] In 1968, human and animal drug regulation was bifurcated and the exemption was dropped from the human rule.[117] However, the FDA continued to allow applicants submitting new animal drug applications to omit reprints for journals on the list.[118] Very few applicants ever used the exemption even though submitting reprints takes little effort and would seem to bolster an applicant's case, if only because it saves the FDA reviewer from having to retrieve the articles from the library herself.[119] Unsurprisingly, the direct final rule went into effect without significant adverse comments.[120]

The typical Bush administration DFR in this category has a somewhat different approach. In 2006, the FDA published a direct final rule removing the FDA regulations relating to blood vessels that are collected as part of organ harvesting for transplants.[121] Before the promulgation of the rule, both the FDA and the Health Resources and Services Administration—which regulates organ

---

[114] Removal of Designated Journals, 64 Fed. Reg. 69,188, 69,188 (Dec. 10, 1999).

[115] *See id.*

[116] *Id.*

[117] *Id.*

[118] *Id.*

[119] *Id.*

[120] Removal of Designated Journals; Confirmation of Effective Date, 65 Fed. Reg. 17,134 (Mar. 31, 2000).

[121] Blood Vessels Recovered with Organs and Intended for Use in Organ Transplantation, 71 Fed. Reg. 27,606, 27,606–07 (May 12, 2006).

transplants—had regulations relating to these blood vessels.[122] The FDA concluded that "having two Federal inspectional programs for such facilities without a medical or public health need for such dual oversight would be inefficient and burdensome."[123] Still, the regulation being eliminated here was not quite the nullity that the journals list was, and an argument could be made that there is real benefit to having one agency monitor the safety of tissues while another oversees the transplant network. Indeed, several comments were filed, including one that "stated that patients would be better protected under the existing regulatory scheme."[124] The FDA acknowledged there may be some dispute about the rule, but was undeterred by the comments and promulgated its original rule without modification.[125] While both the Clinton and Bush rules in this category sought to eliminate redundant or unnecessary regulations, the Bush rules as a whole shade more into substantive changes. To be sure, there are some Clinton-era rules that appear very substantive[126] and some Bush-era regulatory simplification that is utterly uncontroversial.[127] Still, as much as can be said from such a limited sample, it does appear that the Bush-era rules acting in the name of regulatory simplification promoted an anti-regulatory agenda, whereas the Clinton-era rules in this vein appear more purely animated by a desire to clarify existing rules. These regulatory simplification rules resemble the DFRs as a whole in their success rate: eight of the fifteen were confirmed with no significant adverse comments and seven were withdrawn in whole or in part due to comments.[128]

The next largest category is the twelve rules that were promulgated in order to insert in the *Code of Federal Regulations* changes that were made by a statute.[129] These seem to be the classic example of the ministerial function for which direct final

[122] *Id.* at 27,606.

[123] *Id.* at 27,608.

[124] Blood Vessels Recovered with Organs and Intended for Use in Organ Transplantation, 72 Fed. Reg. 10,922, 10,923 (Mar. 12, 2007).

[125] *Id.* at 10,923, 10,924.

[126] *See, e.g.,* Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records, 66 Fed. Reg. 1,257 (Jan. 8, 2001) (amending administrative regulations governing public disclosure of written background material for FDA advisory committee meetings).

[127] *See, e.g.,* Revocation of Status of Specific Products; Group A Streptococcus, 70 Fed. Reg. 72,197 (Dec. 2, 2005) (removing obsolete requirements for Group A streptococcus vaccines).

[128] *See infra* Appendix.

[129] *Id.*

rulemaking was intended. The bulk of them—ten enacted between April 1998 and January 1999—were promulgated in order to implement statutory commands of the Food and Drug Administration Modernization Act of 1997 (FDAMA), an omnibus reform bill.[130] For example, one element of the FDAMA repealed Section 507 of the Federal Food, Drug, and Cosmetic Act, under whose authority the FDA had regulated antibiotics—antibiotics are now regulated under Section 505 the general regulatory authority for new drugs.[131] In January 1999, the FDA issued a direct final rule eliminating its specific regulations for antibiotics because Congress had just withdrawn the FDA's authority to regulate them.[132] Unsurprisingly, the rule received no significant adverse comments and was confirmed.[133] Still, even in this most amenable of categories, five rules were withdrawn in response to significant adverse comments and four of those were modified in response to the comments when they were reissued as final rules.[134]

A related category is the two rules that I label as forced substantive rules.[135] These are rules promulgated in response to a mandate from Congress to issue a regulation on a certain subject by a certain date. It is surprising that the FDA would have expected these rulemakings to be so noncontroversial that they would not receive significant opposition, given that the issues they concerned were already so politically salient that Congress had been moved to force the agency's hand. The history of the two rules confirms this intuition. Both were Clinton administration rules and one was withdrawn in response to significant adverse comments. Following an earlier FDA rulemaking regarding water standards for bottled water,[136] the FDA had stayed the standards based on comments from industry that the standards would present an "undue economic burden."[137] Then Congress passed the Safe Drinking Water Act Amendments of 1996,[138] which required the FDA to issue bottled

[130] Pub. L. No. 105–115, 111 Stat. 2296 (1997).

[131] Conforming Regulations Regarding Removal of Section 507 of the Federal Food, Drug, and Cosmetic Act, 64 Fed. Reg. 396, 396 (Jan. 5, 1999).

[132] *Id.*

[133] Conforming Regulations Regarding Removal of Section 507 of the Federal Food, Drug, and Cosmetic Act; Confirmation of Effective Date, 64 Fed. Reg. 26,657, 26,657 (May 17, 1999).

[134] *See infra* Appendix.

[135] *Id.*

[136] Beverages: Bottled Water, 61 Fed. Reg. 13,258 (Mar. 26, 1996).

[137] Beverages: Bottled Water, 63 Fed. Reg. 25,764, 25,764 (May 11, 1998).

[138] Safe Drinking Water Act Amendments of 1996, Pub. L. No. 104–182, 110 Stat. 1613

water monitoring requirements within two years.[139] The rulemaking did not go well. The FDA received significant adverse comments on the direct final rule and was forced to withdraw it.[140] Moreover, the agency did not have time to promulgate a revised final rule before the statutory deadline and, so, under the terms of the Safe Drinking Water Act Amendments, the drinking water standards promulgated by the Environmental Protection Agency, which has primary responsibility for administering the Safe Drinking Water Act, became applicable to bottled water.[141] The second rule in this category implemented another part of the FDAMA, which called on the FDA to modify its approval process for food additives.[142] Although this rule was confirmed without significant comment,[143] it might initially be surprising that the rule was proposed via direct final rulemaking because it had been the subject of some prior public discussion.[144] However, the Administrative Conference did also recommend that the product of negotiated rulemaking be approved via direct final rulemaking.[145] Though the process here was not the formal negotiated process the Negotiated Rulemaking Act of 1990 prescribes,[146] the FDA can be seen as having undertaken an analogous process and thus may have felt some comfort in promulgating the rule as a DFR.

Three Bush administration rules amounted to minor substantive changes without any statutory mandate: permitting administrative law judges to serve as the presiding officer at a regulatory hearing,[147] revising the labeling requirements for over-the-counter skin protectant drug products,[148] and limiting the amount of information the agency would release in response to Freedom of

(1996) (codified as amended at 42 U.S.C. §§300f–300j (2000)).

[139] *See* Beverages: Bottled Water, 63 Fed. Reg. at 25,765.

[140] Bottled Water: Monitoring Requirements, 63 Fed. Reg. 42,199, 42,199 (Aug. 6, 1998).

[141] *Id.*

[142] National Environmental Policy Act; Food Contact Substance Notification System, 65 Fed. Reg. 30,352 (May 11, 2000).

[143] National Environmental Policy Act; Food Contact Substance Notification System; Confirmation of Effective Date, 65 Fed. Reg. 60,359 (Oct. 11, 2000).

[144] *See* National Environmental Policy Act; Food Contact Substance Notification System, 65 Fed. Reg. at 30,353.

[145] Administrative Conference of the United States, Adoption of Recommendations, 60 Fed. Reg. 43,108, 43,111 (Aug. 18, 1995).

[146] *See* 5 U.S.C. §§ 561–570a (2000).

[147] Presiding Officers at Regulatory Hearings, 67 Fed. Reg. 53,305 (Aug. 15, 2002).

[148] Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Monograph; Direct Final Rule, 68 Fed. Reg. 35,290 (June 13, 2003).

Information Act[149] (FOIA) requests.[150] No obvious characteristic divides these rules from run of the mill regulations suitable for notice-and-comment rulemaking. These appear to have been published as direct final rules merely based on a subjective determination that a rule would be noncontroversial. The agency was correct for the first two rules, which were confirmed without objection.[151] The public information regulation did generate significant adverse comment, but the FDA ultimately published a final rule identical to the initial direct final rule.[152] This was not a surprising outcome, given that the restrictions on information were consistent with FOIA—the FDA had not previously incorporated certain exemptions under FOIA into its own regulations—and were undertaken due to a post-September 11 executive order that instructed the Secretary of Health and Human Services to limit disclosures of sensitive information.[153] Although the FDA clearly was within its right to promulgate the rule, the context indicates that a reasonable observer might have seen the rule as potentially controversial at the outset and inappropriate for a direct final rulemaking. In this case at least, there were no obvious efficiency gains from DFR.

Five rules effect standards adjustments, when the FDA incorporates into its regulations new standards promulgated by other groups such as the EPA or the American National Standards Institute.[154] These would seem to be quite rightly labeled uncontroversial and, indeed, among this group the FDA has a much better than average track record, withdrawing only one of the five.[155] The withdrawn regulation was to have incorporated by reference more recent editions of two reference books into the rule that defines botanical ingredients in dietary supplements.[156] The

[149] 5 U.S.C.A. § 552 (West 2007 & Supp. 2008).

[150] Public Information Regulations, 69 Fed. Reg. 53,615 (Sept. 2, 2004).

[151] Presiding Officers at Regulatory Hearings; Confirmation of Effective Date, 67 Fed. Reg. 71,461 (Dec. 2, 2002); Skin Protectant Drug Products for Over-the-Counter Human Use; Astringent Drug Products; Final Monograph; Direct Final Rule; Confirmation of Effective Date, 68 Fed. Reg. 58,273 (Oct. 9, 2003).

[152] Public Information Regulations, 70 Fed. Reg. 41,956–57 (July 21, 2005).

[153] *Id.* at 41,956.

[154] *See infra* Appendix.

[155] *Id.*

[156] Food Labeling: Ingredient Labeling of Dietary Supplements that Contain Botanicals, 68 Fed. Reg. 51,693 (Aug. 28, 2003).

rule was withdrawn in December 2005,[157] and has not yet been issued as a revised final rule, although such a delay is not unusual, as will be discussed below in the last section of this Part.

Inflation adjustment is straightforward and is a category that contains only a single rule—a direct final rule that adjusted a dollar value in a regulation related to sample collection that had not been indexed for inflation.[158] The rule is included in my tally of rules confirmed without any significant adverse comments, but with one wrinkle: it is the only "confirmed" DFR that appears not to have a confirmation in its name. After the initial direct final rule was published, no further mention of it was made in the *Federal Register*. Given that the initial rule said, "[t]his rule is effective February 8, 1999,"[159] in the absence of a withdrawal or confirmation, the rule became effective. Checking the current *Code of Federal Regulations* indicates that the change promulgated in the DFR was, indeed, effective.[160] Clearly the practice of publishing confirmations is a useful means of alerting the public that direct final rules—which are final in name alone[161]—truly become effective.

[157] Food Labeling: Ingredient Labeling of Dietary Supplements that Contain Botanicals; Withdrawal, 70 Fed. Reg. 76,684 (Dec. 28, 2005).

[158] Amendment to Examination and Investigation Sample Requirements, 63 Fed. Reg. 51,297 (Sept. 25, 1998).

[159] *Id.*

[160] *Compare id.* at 51,299, *with* 21 C.F.R. § 2.10(b)(2) (2008).

[161] *See* Levin, *supra* note 2, at 17 ("The word 'final' that is used in the published notice is in the end only a word; any connotation of irrevocability is belied by the underlying dynamics of the context in which it appears.").

Table 1: Classification of Direct Final Rules, by Nature of Rules

	Number published	Number withdrawn, in whole or in part
Regulatory Simplification	15	7
Forced Substantive Change	2	1
Unforced Substantive Change	3	1
Codification of Statutory Changes	12	5
Standards Adjustment	5	1
Inflation Adjustment	1	0

C. Timing Issues

Because efficiency is direct final rulemaking's main selling point and inadequate notice a potential drawback, it will also be useful to provide some data about the timing of rulemaking. Of the fifteen withdrawn DFRs, five have never been issued as revised final rules. Two of the fifteen, somewhat alarmingly, were revised based on comments, but never formally withdrawn. Both were rules implementing provisions of the Food and Drug Administration Modernization Act of 1997.[162] Because the two revised final rules were published after the effective date of the direct final rules,[163] this means that for some period of time a rule was in effect that the FDA intended to withdraw—one for only a month, the other for more than a year. And in both of these cases, the FDA later determined the rule should be modified in response to the

[162] Medical Devices; 30-Day Notices and 135-Day PMA Supplement Review, 63 Fed. Reg. 20,530, 20,530 (Apr. 27, 1998); Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting, 63 Fed. Reg. 26,069, 26,069 (May 12, 1998).

[163] Medical Devices; 30-Day Notices and 135-Day PMA Supplement Review, 63 Fed. Reg. 54,042, 54,042 (Oct. 8, 1998); Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting, 65 Fed. Reg. 4,112, 4,112 (Jan. 26, 2000).

comments.[164] For these two rules it would be hard to say there was even substantial compliance with the APA: a proposed rule was issued, comments (later determined to be significant and adverse were submitted), and yet the rule nevertheless became effective even though the FDA had not yet responded to the comments.

Putting aside the five withdrawals that did not lead to a revised final rule and the two revised final rules without prior withdrawals, there are seven direct final rules that were both withdrawn and subsequently reissued as a revised final rule.[165] For these seven, the average time between withdrawal of the direct final rule and issuance of the revised final rule was 365 days.[166] The longest took 1,672 days; the shortest took fifty-two.[167]

IV. REAPPRAISAL OF DIRECT FINAL RULEMAKING IN LIGHT OF THE FDA EXPERIENCE

The FDA's experience over the past decade raises troubling questions about direct final rulemaking. A surprising percentage of direct final rulemakings do not perform as expected. Because the FDA has attempted so few direct final rulemakings, these unexpected results could be due to random variation. However, both because the outcome is so different here than in prior tests of direct final rulemaking and because the subjects of some rulemakings seem so unsuitable for DFR, a reasonable conclusion to draw would be that the FDA is misusing the process. This experience suggests that the FDA and other agencies should rethink their commitment to direct final rulemaking, both because it may be stretching the limits of the Administrative Procedure Act and because as it has been implemented, it is not obvious that any efficiency gains are being made. As I argue in this part, though the efficiency gains of direct final rulemaking are questionable, the harm DFR imposes on an agency's credibility is not. The practice has the potential to increase cynicism about government. There is some reason to think that the FDA may be an outlier among agencies that have adopted direct final rulemaking. Still, this paper suggests further study of direct final rulemaking could be useful

[164] *See* Medical Devices; 30-Day Notices and 135-Day PMA Supplement Review, 63 Fed. Reg. at 54,042–43; Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting, 65 Fed. Reg. at 4,113–14.

[165] *See infra* Appendix.

[166] *Id.*

[167] *Id.*

and recommends modification to the practice at the FDA.

This paper began with the realization that the FDA has withdrawn forty percent of the DFRs it attempts to promulgate and the belief that this withdrawal rate is troubling. An alternative narrative of the FDA experience could credit the agency for its high withdrawal rate, praising an agency scrupulously withdrawing rules that it had anticipated being noncontroversial, but which turned out to generate some comments. Indeed, under this positive story of DFR, the FDA has *too low* a withdrawal rate: the agencies should be pushing more rules into DFR, because any withdrawal rate lower than 100 percent represents an improvement over typical notice-and-comment rulemaking. That is, each successful direct final rulemaking results in efficiency gain at an insignificant cost.

In either of these competing narratives of the FDA experience, however, the high number of withdrawals can only be explained by some combination of only three scenarios. Scenario One: Because it believes any rule that is approved by direct final rulemaking represents an efficiency gain at essentially no cost, the FDA is not attempting to determine which rules are controversial. Instead, it is putting as many rules into DFR as possible and letting the public at large decide which rules are controversial.[168] Scenario Two: the agency is actively proposing direct final rulemaking for regulations it knows will be controversial and hopes no one notices, in order to circumvent hostile public comment. Scenario Three: the agency is making a good-faith effort to use direct final rulemaking only for rules it believes to be noncontroversial, but is unsuccessful at predicting which rules will be controversial.

Regardless of which of these three scenarios is true, any one of them undermines the justification for direct final rulemaking. The well-considered legal and policy justifications of DFR were predicated on the belief that agencies would only use the process for noncontroversial rulemaking and that agencies are able to predict

[168] At one point, this was at least partially true. Daniel E. Troy, former chief counsel of the FDA, commenting on an earlier version of this paper, wrote that in his experience, the FDA "consistently underestimates the controversy . . . of its rules" and "often tries a DFR as a flier, hoping for the best and preparing for the worst." Troy believed there was no harm to trying a DFR except "the harm in credibility and some people may think that the FDA is trying to sneak something by. But people inside don't care about that; they just want to do anything that could make the regulatory process less burdensome." Email from Daniel E. Troy to Ronald Levin, Professor of Law, Washington University Law School (Apr. 16, 2008) (on file with author).

with some accuracy which rules are controversial or not.[169] FDA practice upturns this premise—the agency cannot tell which rules will be controversial or does not care. One can conclude that the negative narrative of DFR is correct: the FDA withdrawal rate is problematic because it lacks a sound legal or policy explanation. As practiced at the FDA, direct final rulemaking is legally questionable and unappealing as a policy choice.

Recall that the legal basis of DFR relied on two theories: that the practice would be either used for rulemakings where notice-and-comment rulemaking was unnecessary under the APA or, if notice-and-comment was necessary, DFR would represent substantial compliance with the APA.[170] Yet these theories are premised on a DFR regime in which an agency is successful at determining which rules will be noncontroversial and in which withdrawals are rare. It might be appropriate to say that some of the rules I label as presumptively noncontroversial are rules for which the "good cause" exception to notice-and-comment rulemaking applies.[171] But the FDA experience demonstrates that direct final rulemaking is not easily cabined to those sorts of rules, and quickly encroaches on just those rules that notice-and-comment rulemaking was designed for—for example, the FDA DFRs I labeled as substantive regulations. When notice-and-comment is necessary, some of the criticisms that Professor Noah raised,[172] which seemed overly cautious in the abstract, appear quite prescient. At least in isolated occurrences, such as when direct final rules were withdrawn after they had already gone into effect, the agency did not substantially comply with the APA. Furthermore, DFR creates a cloud of uncertainty around comment periods, which undermines any attempt to portray DFR as merely condensed notice-and-comment. Some commenters may be confused or discouraged about filing a comment, believing the rule is already truly "final." By the time interested parties learn that the agency intends to respond to comments in the rulemaking—when the DFR is withdrawn—it is too late to file comments.[173] When direct final rulemaking is used for patently

[169] *See* Levin, *supra* note 2, at 2.

[170] *See supra* Part II.B.

[171] *See* Jordan, *supra* note 66, at 129–35.

[172] Noah, *supra* note 9.

[173] Remember that the comment period, at least in FDA practice, begins when the DFR and a notice of proposed rulemaking are published in the *Federal Register* on the same day. If the agency receives significant adverse comments, it withdraws the DFR and then later publishes a final rule based on the original significant adverse comments.

controversial rulemaking, such as the bottled water regulation in the Clinton administration,[174] a midnight regulation in the waning days of the Clinton administration,[175] and the public information rule in the aftermath of the September 11 terrorist attacks,[176] it is rightly read as an attempt to undermine notice-and-comment rulemaking, not substantially comply with it.

Even if direct final rulemaking survives legal challenge, as currently practiced—at least by the FDA—it undermines confidence in the agency's commitment to openness in government. Professors David Barron and Elena Kagan have described notice-and-comment rulemaking as a "charade," with heightened judicial review forcing agencies to make their final regulatory decisions before any comments have been solicited.[177] Seen from this vantage point, direct final rulemaking may have a salutary effect: it allows agencies to be more open about their disregard for public comments. This conclusion, however, relies on a faulty premise. As this study and others have shown,[178] agencies do respond to comments, even if they may not want to. If the goal of these rulemakings was to keep a controversial debate off the public radar, the volume of comments received on many rules demonstrates the effort was unsuccessful. Still, these variations from standard rulemaking practice do create real problems for regulated industry and the general public. There is something disingenuous about an agency publishing a "final rule," with the knowledge that it has a good chance of being quickly withdrawn.[179] A careless lawyer might errantly rely on a "final rule," not realizing it was only a "direct final rule" that had been replaced by a true final rule. Furthermore, when, as was the case at least twice, a final rule is withdrawn after the effective date, even

[174] Beverages: Bottled Water, 63 Fed. Reg. 25,764, 25,764 (May 11, 1998).

[175] Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records, 66 Fed. Reg. 1,257 (Jan. 8, 2001).

[176] Public Information Regulations, 69 Fed. Reg. 53,615 (Sept. 2, 2004).

[177] *See* David J. Barron & Elena Kagan, *Chevron's Nondelegation Doctrine*, 2001 SUP. CT. REV. 201, 231–32.

[178] *See, e.g.*, Cuéllar, *supra* note 109, at 414.

[179] Professor Levin points to a different hazard in the FDA practice of publishing concurrent direct final rules and notices of proposed rulemaking: interest groups that might have commented during a traditional rulemaking might be dissuaded from commenting on the DFR, believing the rule is unlikely to change at this point. *See* Levin, *supra* note 2, at 25–26. It is conceivable that interest groups who favor the proposed rule might not comment and then feel blind-sided should the rule be altered in response to adverse comments. Yet the data reported here indicates that attempts at direct final rulemaking have not done much to dissuade commenters.

the most diligent lawyer would have difficulty advising a client about the current status of the rule. When withdrawals are as common as they have become at the FDA, these are real problems.

Without compiling similar data from its sister agencies, one can only speculate about whether the FDA's experience with direct final rulemaking is unique. Still, there is some reason to think it may be so. Professor Todd Rakoff has speculated that, because the FDA so pervasively regulates its industries and because all parties to FDA regulation are repeat players, relationships between the FDA and industry may be a more powerful force than the "law" as it can be enforced in court.[180] Regulated parties, more concerned about maintaining those relationships, may thus avoid litigation with the FDA, particularly over a matter such as direct final rulemaking, which is easily characterized as a technicality. The FDA, in turn, might be more willing to stretch the definition of "noncontroversial," knowing regulated parties are unlikely to sue over this issue. It is well known that parties who are not presently in litigation will adjust their behavior based on the consequences their actions would generate in litigation.[181] When the FDA faces minimal risk of being sued over direct final rulemaking, it is unsurprising that it may be less than scrupulous in practice. Other agencies that tend to have less pervasive influence over the industries they regulate might be more vulnerable to lawsuit and, thus, more likely to take steps to prevent litigation, such as limiting use of direct final rulemaking.

Though this study suggests that the FDA ought to limit the use of direct final rulemaking, my survey of FDA practice indicates there are several types of regulations that may be appropriate for direct final rulemaking. The discussion in Part III suggests several presumptions that an agency could adopt to determine ex ante whether a rule will be controversial. Rules that merely incorporate statutory commands, such as those deleting or inserting statutory language into regulations, presumptively can be seen as noncontroversial. Rules that adjust existing regulations to keep pace with inflation or to incorporate modern standards developed by

---

[180] Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 169–70 (2000).

[181] *See* Issachar Rosen-Zvi & Talia Fisher, *Overcoming Procedural Boundaries*, 94 VA. L. REV. 79, 105–06 (2008); Robert H. Mnookin & Lewis Kornhauser, *Bargaining in the Shadow of the Law: The Case of Divorce*, 88 YALE L.J. 950, 956 (1979). Professor Owen Fiss has noted that the much-discussed decline of the trial in America may result in less equitable settlements, a similar dynamic as the one described here. *See* Owen M. Fiss, *Against Settlement*, 93 YALE L.J. 1073, 1075 (1984).

another agency or scientific group also are likely to be suitable for direct final rulemaking. Although even these categories of rules had higher withdrawal rates than one might expect, it would be difficult to attribute any improper motive to the FDA for seeking to promulgate these rules via DFR.

Several other categories ought to be seen as presumptively controversial: First, those that are undertaken at the direct command of Congress or have otherwise been the subject of prior public debate.[182] These would seem to be obvious indicators that a rule will be controversial, and yet several times the FDA has sought to promulgate DFRs under these circumstances. Second, agencies should avoid promulgating discretionary substantive changes to rules. The FDA said it limits itself to "minor, substantive changes,"[183] yet nowhere defines what a "minor" change is. In other contexts, agencies tend to define rules as minor or major based on the expected economic impact of the rule,[184] but given that an FDA rule may have a significant impact on health and safety without having a significant economic cost, it does not seem like economic impact would be a good indicator of whether a rule will be controversial. Instead, agencies should avoid using DFRs for substantive changes unless there is some objective indicator that the rule will be noncontroversial, such as inflation adjustment, incorporation of third-party standards, or codification of statutory mandates.

The prevalence of rules in the category that I now label presumptively controversial among the thirty-eight DFRs that the FDA published over the last decade suggests misuse of the

[182] On May 14, 1999, the FDA published one of several direct final rules that were part of an agency effort to reform the way it regulated blood products. Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human), 64 Fed. Reg. 26,282 (May 14, 1999). The FDA had spent the previous five years soliciting comments on various proposals related to blood products, including a public meeting on January 26, 1995. *Id.* at 26,283. Reports on the subject were issued by a subcommittee of the U.S. House of Representatives, the General Accounting Office, and the Institute of Medicine. *Id.* Although there certainly had been no shortage of opportunity for public participation, it is confusing, to say the least, why the FDA would have thought the proposal would be noncontroversial with little likelihood of further comment. *See id.* at 26,282. The FDA did receive significant adverse comments on the rule and withdrew it, although the agency eventually published a final rule identical to the initial direct final rule. *See* Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human), 65 Fed. Reg. 52,016 (Aug. 28, 2000).

[183] Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. 62,466, 62,469 (Nov. 21, 1997).

[184] *See, e.g.,* Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,738 (Sept. 30, 1993).

procedure. The FDA experience also suggests that efficiency gains—the ostensible motivation for direct final rulemaking—are scarce, and there are significant costs to the agency's legitimacy, both legal and political. The ostensible motivation for direct final rulemaking is that it avoids the cumbersome review of a rule that happens twice under typical notice-and-comment rulemaking: first when the rule is proposed and a second time when the final rule is published.[185] In addition to the internal agency review, rules that are expected to have more than $100 million in economic impact need approval by the White House Office of Management and Budget.[186] Depending on the rule, other interagency review may also be necessary.[187] But as even proponents of direct final rulemaking concede, the rules that would be proposed as DFRs would typically be so inconsequential that even as notice-and-comment rules they still would not have gone through OMB or other external reviews.[188] So the real benefit, then, is avoiding the second internal agency review before publishing a final review: for agencies where the practice is not to publish a confirmation, the rulemaking work is finished once the comment period ends with no comments. For agencies like the FDA, a low-level employee can publish a confirmation once the confirmation period ends with no comments. If comments are submitted, then the second review process occurs to produce a final rule, and—in the view of proponents of DFR—the agency is at least no worse off than if it had started off in notice-and-comment.

However, this model assumes that comments are rare on DFRs and that virtually any comment automatically leads to the withdrawal of the DFR. The experience at the FDA shows that neither assumption holds: the FDA receives comments on a significant portion of its DFRs and occasionally declines to withdraw a DFR on that basis, because it believes the comments are not both significant and adverse. That means the efficiency gains from direct final rulemaking are greatly diminished: for a significant plurality of DFRs the agency must still carefully consider comments and determine whether they are significant and adverse.

---

[185] Levin, *supra* note 2, at 2.

[186] *See* Exec. Order No. 12,866, 58 Fed. Reg. at 51,738.

[187] *See generally* THOMAS O. MCGARITY, REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY 17–25 (1991) (summarizing the evolution of the regulatory analysis program and detailing analytical requirements established by the Executive and Legislative branches).

[188] *See* Levin, *More on Direct Final Rulemaking*, *supra* note 9, at 767.

If the FDA decides they are, the agency must then publish a withdrawal and then finally a revised final rule incorporating responses to the comments and perhaps changes to the proposed rule. In these circumstances, direct final rulemaking could be seen as a greater burden on agency resources than straight notice-and-comment rulemaking, particularly when withdrawal is as common an occurrence as it is at the FDA.

CONCLUSION

With the American administrative state so frequently the object of scorn, agencies and academics are well counseled to seek innovation where possible. Apparently cumbersome notice-and-comment rulemaking for insignificant rules would appear to be a good place to start. Recognizing that Section 553(b) already provides exemptions from notice-and-comment for rules where comments would truly be "unnecessary," direct final rulemaking can provide an additional simplified rulemaking process for uncontroversial rules. Yet, as currently practiced, direct final rulemaking is too open to misuse. The FDA and other agencies that use direct final rulemaking should promulgate new guidances that limit direct final rulemaking to those rules that can objectively be called noncontroversial. It would also be suitable for OMB to issue an executive-branch wide bulletin describing best practices for using direct final rulemaking, as OMB recently did for guidances.[189]

This study also provides further evidence that legal debates are shaped as much by facts as law. Academic debates need not remain academic: there often is an answer. While it would be unfair to say that FDA practice proves that direct final rulemaking is illegal, studying the experience at this one agency demonstrates real problems with the practice that would otherwise remain obscure.

[189] Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3,432 (Jan. 25, 2007).

APPENDIX

Summary of FDA Direct Final Rulemakings

Date DFR Published	**Subject**	**Cite**	**Nature**	**Outcome**
4/17/98	Devices: Humanitarian Use	63 FR 19196	Codification of statutory change	W
4/20/98	Biologics	63 FR 19431	Regulatory simplification	P
4/27/98	Devices: PMA procedure modification	63 FR 20558	Codification of statutory change	W
5/11/98	Food: Bottled water standards	63 FR 25789	Forced substantive change	P
5/12/98	Devices: Adverse Event Reporting	63 FR 26129	Codification of statutory change	W
5/12/98	Drugs: Certification of Antibiotics	63 FR 26127	Codification of statutory change	C
5/13/98	Drugs: Insulin	63 FR 26690	Codification of statutory change	C
6/16/98	Procedure: Scientific Review	63 FR 32772	Codification of statutory change	W
8/7/98	Devices: Removing Reporting Requirements	63 FR 42300	Codification of statutory change	C
9/25/98	Procedure: Sample Collection	63 FR 51322	Inflation adjustment	C
9/29/98	Devices: Registration requirements	53 FR 51874	Codification of statutory change	C
12/14/98	Drugs: IND procedure	63 FR 68710	Codification of statutory change	C
1/5/99	Drugs: Certification of Antibiotics	64 FR 448	Codification of statutory change	C
5/14/99	Biologics	64 FR 26344	Regulatory simplification	P
6/17/99	Devices:	64 FR	Codification of	C

	Mammography	32443	statutory change	
8/19/99	Biologics	64 FR 45375	Regulatory simplification	P
11/3/99	Devices: Hearing Aids	64 FR 59695	Standards adjustment	C
12/10/99	Animal Drugs: Listed Journals	64 FR 69209	Regulatory simplification	C
1/24/00	Devices	65 FR 3627	Standards adjustment	C
5/11/00	Food: Environmental Impact	65 FR 30366	Forced substantive change	C
12/12/00	Biologics	65 FR 77532	Regulatory simplification	C
1/8/01	Procedure: Advisory Committees	66 FR 1276	Regulatory simplification	W
3/28/01	Food: Bottled water standards	66 FR 16884	Standards adjustment	C
8/15/02	Procedure: ALJs	67 FR 53324	Unforced substantive change	C
3/3/03	Food: Bottled water standards	68 FR 9955	Standards adjustment	C
6/13/03	Drugs: Labeling of OTC Skin Protectants	68 FR 35346	Unforced substantive change	C
8/28/03	Food: Dietary Supplements	68 FR 51738	Standards adjustment	W
12/30/03	Biologics	68 FR 75179	Regulatory simplification	C
9/2/04	Procedure: Public Information	69 FR 53662	Unforced substantive change	W
2/28/05	Devices: Adverse Event Reporting	70 FR 9558	Regulatory simplification	C
12/2/05	Biologics: Strep organism	70 FR 72257	Regulatory simplification	C
1/17/06	Drugs: GMP for IND	71 FR 2494	Regulatory simplification	W

5/12/06	Biologics: Organ transplants'	71 FR 27649	Regulatory simplification	W
9/25/06	Devices: Single-use devices	71 FR 55748	Codification of statutory change	W
12/7/06	Devices: Ozone depleting	71 FR 70912	Regulatory simplification	C
8/16/07	Biologics	72 FR 45993	Regulatory simplification	C
10/18/07	Biologics: Live vaccine	72 FR 59041	Regulatory simplification	C
12/4/07	Drugs: GMP	72 FR 68113	Regulatory simplification	W

Outcome codes:

C: Confirmed without significant adverse comments

P: Partially confirmed, partially withdrawn due to significant adverse comments

W: Withdrawn due to significant adverse comments