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Abstract

In an effort to improve efficiency, several administrative agencies, including the Food and Drug Administration, have adopted a procedure known as “direct final rulemaking” (DFR). Some academics have debated whether DFR violates the Administrative Procedure Act, but none have studied how DFR has functioned in practice. This paper, which examines the first decade of DFR at the FDA, is the first of this kind. The results are surprising, and suggest DFR deserves more study than it has received. Intended for noncontroversial rules that are expected to receive no significant comments in a notice-and-comment rulemaking, 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 Far from generating few comments, forty percent of DFRs have had to be withdrawn due to significant opposition.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 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.

Introduction

Frustrated with the pace of even the most minor rulemaking, federal agencies have experimented with streamlined regulatory practices over the past several decades. One such innovation, “direct final rulemaking,” allows an agency to dispense with some amount of procedure for rules that it expects to be uncontroversial. This paper is the first case study to evaluate the implications of direct final rulemaking in practice — here an evaluation of direct final rulemaking by the Food and Drug Administration (FDA) over the past decade. The FDA example raises real concerns about the value and wisdom of the innovation. FDA has a remarkably poor record at predicting which of its regulations will truly be noncontroversial, and this study suggests FDA has been classifying certain proposed regulations as “noncontroversial” in hopes, most frequently misplaced, that they will slip under the radar screen.

But why does the FDA need to decide what rules are “noncontroversial”? Under the model of American administrative rulemaking predominant since the late 20th century,¹ the FDA has a straightforward path for enacting a regulation: it publishes a notice of proposed rulemaking in the *Federal Register*, it solicits comments on the rule for a fixed period of time, and then it publishes a final rule in the *Federal Register*, incorporating responses to all significant comments.² 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.³

However, since 1997 FDA has conducted abbreviated informal rulemaking, called “direct final rulemaking” (DFR), that does require the agency to determine at the outset whether a rule is expected to be “noncontroversial” and thus unlikely to generate significant adverse comments.⁴ 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 75-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 60 days after the close of the comment period. If the agency receives even a single significant adverse comment, it withdraws the final direct rule, and — assuming it still wishes to promulgate the rule — issues a

¹ Although the Administrative Procedure Act permits trial-like formal rulemakings, *see* 5 U.S.C. § 556, 557 (2000), “informal” notice-and-comment rulemaking, *see* 5 U.S.C. § 553 (2000), has been the default mode since the 1970s. *See* Richard E. Levy & Sidney A. Shapiro, *Administrative Procedure and the Decline of the Trial*, 51 U. KAN. L. REV. 473, 487 (2003).

² *See* Administrative Procedure Act, 5 U.S.C. § 553 (2000).

³ *See* *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Ins.*, 463 U.S. 29, 57 (1983).

⁴ *Guidance for FDA and Industry: Direct Final Rule Procedures*, 62 Fed. Reg. 62,466 (Nov. 21, 1997).

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.⁵

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 would prevent judicial review of agency action.⁶ At the outset of DFR, academic inattention was anticipated. Professor Ronald Levin, who has written two of the three extant articles, wrote in 1999, “[F]rankly, I doubted that anyone would ever write another article about the subject.”⁷ 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. 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 required by the Administrative Procedure Act. There was some concern that substantial compliance with the APA was not good enough.⁸ Perhaps assuaged by the belief that direct final rulemaking only affects noncontroversial rules, no court

⁵ *Id.* at 62,468.

⁶ See Ronald M. Levin, *Direct Final Rulemaking*, 64 GEO. WASH. L. REV. 1 (1995); Ronald M. Levin, *More on Direct Final Rulemaking: Streamlining, Not Corner-Cutting*, 51 ADMIN. L. REV. 757 (1999) [hereinafter *Direct Final Rulemaking*]; Lars Noah, *Doubts About Direct Final Rulemaking*, 51 ADMIN. L. REV. 401 (1999). Professor Noah does briefly mention that the first year of direct final rulemaking at FDA did produce a lower “batting average” than other agencies, Noah, *supra*, at 411, but does not consider why FDA had a higher failure rate than EPA and FAA. *Cf. infra* Part II.

⁷ Levin, *More on Direct Final Rulemaking*, *supra* note 6, at 757.

⁸ See Noah, *supra* note 6, at 418-49 (“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.”)

has considered the legality of direct final rulemaking.⁹ Had direct final rulemaking played out as Professor Levin expected it to there would be little reason to revisit the issue now.

It hasn't – at least not at the FDA. Since 1997, the FDA has completed direct final rulemaking procedures for thirty-eight rules.¹⁰ Fifteen of these — 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 Environmental Protection Agency has used direct final rulemaking to approve state implementation plans since 1981. In a trial period, the EPA needed to withdraw fewer than five percent of the ninety direct final rules it issued.¹¹ Other experiences with direct final rulemaking at EPA, the Federal Aviation Administration and elsewhere have produced withdrawal rates of less than ten or twenty percent.¹² A withdrawal rate of forty percent is shocking. It suggests either FDA is dramatically off when predicting which of its rules are likely to be controversial or 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 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. “Here we must be especially

⁹ 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. E envtl. Prot. Agency*, 99 F.3d 1551, 1554 (10th Cir. 1996); *Sierra Club v. Whitman*, 32 *Envtl. L. Rep.* 20,538, 2002 WL 393,069, at *3 (D.D.C. March 11, 2002). These cases discuss rules published via direct final rulemaking, without any discussion of the legality of the process.

¹⁰ The numbers in this section, including a discussion of my methodology, are presented in greater detail in Part II. Summary data throughout this paper are based on my own compilation of FDA DFRs. A summary is provided in the Appendix.

¹¹ 47 *Fed. Reg.* 27,073, 27,074 (1982).

¹² *See Noah, supra* note 6, at 411.

wary against the danger of premature synthesis, of sterile generalization unnourished by the realities of ‘law in action.’”¹³ 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 describes in greater detail the development of direct final rulemaking in the United States and the particular characteristics of the procedure as it was implemented at FDA. Part II describes the methodology of this study and its findings, including a categorization of the rules promulgated via direct final rulemaking and those withdrawn. Part III discusses the implications of these findings and, given the experience at FDA, challenges the wisdom of this procedural innovation.

I. Origins of Direct Final Rulemaking

In 1995, at its last plenary session, the Administrative Conference of the United States¹⁴ recommended that agencies adopt direct final rulemaking “for expediting the issuance of noncontroversial rules.”¹⁵ 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.”¹⁶ Given the increasing procedural hurdles surrounding

¹³ Felix Frankfurter, *The Task of Administrative Law*, 75 U. PA. L. REV. 614, 619 (1927).

¹⁴ 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).

¹⁵ Administrative Conference of the United States, *Adoption of Recommendations*, 60 Fed. Reg. 43,108, 43,110 (Aug. 18, 1995).

¹⁶ *Id.* at 43,110-11 (footnote omitted).

rulemaking, commonly referred to as “ossification,”¹⁷ any procedure that would preserve public input while quickening the regulatory process would seem welcome.

The Administrative Conference recommended that agencies adopt direct final rulemaking: when an agency believes a rule will be “noncontroversial and adverse comments will not be received,”¹⁸ it should issue a direct final rule, indicating that the public has until a certain date to submit adverse comments. If no significant adverse comments are received, the rule will go into effect no sooner than 30 days after the end of the comment period. In the Administrative Conference recommendation, agencies may either issue a “confirmation notice” to indicate that no comments have been received and allow the rule to go into effect or may remain silent and by its silence indicate the same.¹⁹ As this bare outline indicates, depending on how one defines “noncontroversial” and “significant adverse” and whether an agency decides to issue confirmation notices will play a major role in determining both the scale of efficiency gains from direct final rulemaking and the magnitude of the concerns for 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 that direct final rulemaking for all rules that would otherwise fall under the “unnecessary” prong of the good cause exemption from notice-and-comment

¹⁷ 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 “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385 (1992). Judicial review of agency action under the “arbitrary and capricious” standard is most commonly identified as the largest force in ossification of rulemaking, see, e.g., Richard J. Pierce, Jr., *The APA and Regulatory Reform*, 10 ADMIN. L. REV. 81, 83 (1996). A more recent development that has contributed to ossification is White House review of economically significant rules. See Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993).

¹⁸ Administrative Conference of the United States, *Adoption of Recommendations*, 60 Fed. Reg. at 43,110.

¹⁹ *Id.* at 43,111.

rulemaking.²⁰ 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.²¹ 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.²² One must look to agency practice to get a real feel for what “noncontroversial” means. EPA was first to adopt DFR, predating the Administrative Conference’s recommendation,²³ and still is the most frequent user of direct final rulemaking.²⁴ At first, 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.²⁵ When it began issuing DFRs for each of those programs, EPA issued a notice explaining its intent to do so because of the uniquely noncontroversial nature of the rulemaking in each case.²⁶ But since the mid-1990s EPA has used DFRs in contexts outside these two programs, and without an prior policy statement of its intent to do so. Instead, each time EPA issues a DFR it explains that the subject of the rulemaking is expected to be noncontroversial and appropriate

²⁰ *Id.*; see Administrative Procedure Act, 5 U.S.C. § 553(b) (2000).

²¹ See Ellen R. Jordan, *The Administrative Procedure Act’s “Good Cause” Exemption*, 36 ADMIN. L. REV. 113, 129-35 (1984).

²² See Administrative Conference of the United States, *Adoption of Recommendations*, 60 Fed. Reg. at 43,111.

²³ See Levin, *Direct Final Rulemaking*, *supra* note 6, at 4.

²⁴ 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.

²⁵ Levin, *Direct Final Rulemaking*, *supra* note 6, at 4.

²⁶ Requirements for Preparation, Adoption, and Submittal of State Implementation Plans; Experimental State Implementation Plan Processing Techniques, 46 Fed. Reg. 44,476 (Sept. 4, 1981); Significant New Use Rules; General Provisions for New Chemical Follow-up, 54 Fed. Reg. 31,298 (July 27, 1989).

for direct final rulemaking.²⁷ EPA has apparently never issued an across-the-board statement about how it determines a rule is expected to be noncontroversial. FDA, however, 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.”²⁸ As examples, FDA said DFR would be appropriate for “minor, substantive changes to regulations; incorporation by reference of the latest edition of technical and industry standards; extensions of compliance dates[; and] direct incorporations of mandates from new legislation.”²⁹

The Administrative Conference expected that if an agency receives “significant adverse” comments it would withdraw the direct final rule, but noted that agencies have defined “significant adverse” differently.³⁰ The Conference recommended that agencies withdraw DFRs if they receive 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.”³¹ FDA adopted this definition of “significant adverse.”³² EPA appears to be somewhat more generous to commenters in that it will withdraw a DFR if it merely receives notification of

²⁷ Levin, *Direct Final Rulemaking*, *supra* note 6, at 5.

²⁸ Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. 62,46, 26,468 (Nov. 21, 1997).

²⁹ Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. at 62,469.

³⁰ Administrative Conference of the United States, *Adoption of Recommendations*, 60 Fed. Reg. at 43,111.

³¹ *Id.*

³² Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. at 62,469.

an individual's intention to file adverse comments – a commenter need not actually file a comment to have the DFR withdrawn.³³

EPA has chosen not to issue confirmations when a DFR has survived with no comments.³⁴ The initial DFR serves as the public's only notice that a rule is going into effect. FDA has adopted the policy of publishing a confirmation that no significant comments have been received and that the rule will go into effect after the comment period ends and before the effective date.³⁵ 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.

Professor Levin, who as consultant to the Administrative Conference drafted the DFR recommendation, described DFR as a "variation" on typical notice-and-comment rulemaking.³⁶ It would not be too outrageous to call it instead an abrogation of notice-and-comment rulemaking as required by the Administrative Procedure Act. Indeed, the Administrative Conference's report equivocates on whether direct final rulemaking 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."³⁷ 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 direct final rule because it was

³³ Levin, *Direct Final Rulemaking*, *supra* note 6, at 5.

³⁴ *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).

³⁵ Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. at 62,468.

³⁶ Levin, *Direct Final Rulemaking*, *supra* note 6, at 1.

³⁷ Administrative Conference of the United States, Adoption of Recommendations, 60 Fed. Reg. at 43,111.

issued as a direct final rule.³⁸ Professor Levin offers two explanations for how DFR may be legal: first, as the Administrative Conference recommendation indicates, it may be used for rules that under section 553(b) of the Administrative Procedure Act would otherwise be entirely exempt from notice-and-comment rulemaking.³⁹ Thus, DFR amounts to more procedure than the law requires, not less. Second, DFR amounts to “substantial compliance” 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. Professor Levin argues, with some reason, that DFR preserves all of these elements: when no comments are received on the DFR, the initial publication serves as both proposed rule and final rule. When comments are received, the initial publication serves as proposal and then a later final rule serves as the statement of basis and purpose.⁴⁰ “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.”⁴¹

Professor Lars Noah offers the only full-throated attack of the DFR approach. He argues that the under existing practice many rules contemplated as DFRs would not fit within the “unnecessary” exemption of section 553(b) and that direct final rulemaking does not fulfill the requirements for notice-and-comment rulemaking – those occasions when courts have permitted “substantial compliance” with section 553 have involved smaller divergences from the prescribed practice.⁴² Professor Noah adds a further objection: direct final rulemaking may not

³⁸ See *supra* note 9.

³⁹ Levin, *Direct Final Rulemaking*, *supra* note 6, at 11-15.

⁴⁰ *Id.* at 15-18.

⁴¹ *Id.* at 18.

⁴² Noah, *supra* note 6, at 412-19.

produce an adequate record upon which a reviewing court could determine whether the agency action was arbitrary and capricious.⁴³ Professor Levin responds that despite not looking like typical notice-and-comment rulemaking, directly 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.⁴⁴ In the abstract, it appears that Professor Levin has the better of the 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.⁴⁵ Still, I will revisit this debate after reviewing the FDA experience with the practice.

II. Direct Final Rulemaking at the FDA

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 and 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 FDA. By reading each of the filings, I have determined that as of April 2008, the

⁴³ *Id.* at 426-28.

⁴⁴ Levin, *More on Direct Final Rulemaking*, *supra* note 6, at 758-63,

⁴⁵ 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 Communications Co. v. Fed. Communications Comm’n, 450 F.3d 528, 550 (D.C. Cir. 2006); *Thompson v. Clark*, 741 F.2d 401, 408-10 (D.C. Cir. 1984); *Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F. Supp. 837, 846-47 (D.D.C. 1992).

FDA has proposed and confirmed or withdrawn thirty eight direct final rules. Only a limited number of FDA dockets are available online. I have examined those that are available related to direct final rulemaking to confirm when possible the account of the rulemaking process as presented in the *Federal Register*.

As discussed in the Introduction, fifteen of these thirty eight rules have been withdrawn in whole or in part – if 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.⁴⁶ 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 FDA received comments on the direct final rule.⁴⁷ This can occur because under FDA's final rulemaking policy if the comments were seen as either not significant or not adverse or neither, the rule need not be withdrawn. For example, 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. 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

⁴⁶ 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).

⁴⁷ 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).

wording. The FDA confirmed the rule because those comments were outside the scope of the rulemaking.⁴⁸ 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.⁴⁹ It is unclear whether these three direct final rules should be considered “failed” DFRs, despite their confirmation. My conservative count of fifteen withdrawn DFRs does not include these three. Nevertheless, at least for the August 16, 2007, direct final rule on biologics⁵⁰ 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.⁵¹ Nevertheless, the agency in confirming the rule, the agency responded in detail to those comments and made “two technical amendments” to the rule.⁵² 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 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 FDA determine direct final rulemaking is inappropriate, but that the proposed rule should be modified in response to the

⁴⁸ See *Medical Devices; Medical Device Reporting; Confirmation of Effective Date*, 70 Fed. Reg. at 34,652.

⁴⁹ See Levin, *Direct Final Rulemaking*, *supra* note 6, at 16 (“[E]ven one objector can ‘blackball’ a rule.”).

⁵⁰ *Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma*, 72 Fed. Reg. 45,883 (Aug. 16, 2007).

⁵¹ *Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Confirmation of Effective Date and Technical Amendment*, 73 Fed. Reg. 7463, 7463 (Feb. 8, 2008).

⁵² *Id.*

comments.⁵³ To understand why this is so surprising, consider a theoretical withdrawn DFR: FDA would like to promulgate a rule that it believes is correct and moreover 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 FDA would withdraw the original DFR and then issue a substantially identical final rule after considering the comments. After all, FDA began from a position of being supremely confident in its original rule. Then someone objects. Fine, FDA says, we concede you have some points, but we considered that and we still think our rule is better. This would be a perfectly reasonable response and depending on how FDA explains its decision in its final rule, an identical rule is quite likely to survive “hard look” judicial review.⁵⁴ 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*.⁵⁵ Two were withdrawn and never reissued.⁵⁶ In over

⁵³ 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. 7,463 (Feb. 8, 2008); 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. 4112 (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 56.

⁵⁴ Cf. Matthew C. Stephenson, *A Costly Signaling Theory of “Hard Look” Judicial Review*, 58 ADMIN. L. REV. 753 (2006) (suggesting that courts could use superficial qualities of an agency’s explanation to evaluate the substance of rulemaking).

⁵⁵ See sources cited *supra* note 53.

⁵⁶ 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, 66 Fed. Reg. 1257 (Jan. 8, 2001), was a “midnight regulation” issued in the last two weeks of the Clinton Administration. See generally Jack M. Beerman, *Presidential Power in Transitions*, 83 B.U. L. REV. 947 (2003). It was withdrawn by the Bush Administration, 66 Fed. Reg. 20,401

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, this modification rate appears to be not significantly different from the rate for typical notice-and-comment rulemaking.⁵⁷ 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 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. The remaining six DFRs related to procedural issues or other concerns that span the agency's practice areas.

A more interesting categorization of the agency's DFRs is according to the nature of the rule, not its subject. I developed a classification scheme that largely follows the categories the FDA described in its policy on direct final rulemaking discussed in Part I. I assigned each of the

(Apr. 23, 2001), and never reissued. 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 6, 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 less than 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 Re regulations for Finished Pharmaceuticals; Withdrawal, 73 Fed. Reg. 18,440 (Apr. 4, 2008), it is too soon to conclude FDA does not intend to reissue these as final rules.

⁵⁷ *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 the comment is written seems to affect the probability that the agency will accept suggestions in that comment”).

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.”⁵⁸ 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 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 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

⁵⁸ 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).

veterinary and scientific journals available in the FDA library.⁵⁹ 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. 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. In 1968, human and animal drug regulation was bifurcated and the exemption was dropped from the human rule. However, FDA continued to allow applicants submitting new animal drug applications to omit reprints for journals on the list.⁶⁰ Very few applicants ever used the exemption – 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. Unsurprisingly, the direct final rule went into effect without significant adverse comments.⁶¹

The typical Bush Administration DFR in this category has a somewhat different approach. In 2006, FDA published a direct final rule removing FDA regulations relating to blood vessels that are harvested as part of organ harvesting for transplants.⁶² Before the promulgation of the rule, both FDA and the Health Resources and Services Administration — which regulates organ transplants — had regulations relating to these blood vessels. 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.”⁶³ Still, the

⁵⁹ Removal of Designated Journals, 64 Fed. Reg. 69,188 (Dec. 10, 1999).

⁶⁰ *Id.* at 69,188.

⁶¹ Removal of Designated Journals; Confirmation of Effective Date, 65 Fed. Reg. 17,134 (Mar. 31, 2000).

⁶² Blood Vessels Recovered with Organs and Intended for Use in Organ Transplantation, 71 Fed. Reg. 27,606 (May 12, 2006).

⁶³ *Id.* at 27,608.

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.”⁶⁴ FDA acknowledged there may be some dispute about the rule, but was undeterred by the comments and promulgated its original rule without modification.⁶⁵ 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 substantive⁶⁶ and Bush-era regulatory simplification that is utterly uncontroversial.⁶⁷ 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.

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

⁶⁴ Blood Vessels Recovered with Organs and Intended for Use in Organ Transplantation, 72 Fed. Reg. 10,922, 10,923 (Mar. 12, 2007).

⁶⁵ *Id.* at 10,924.

⁶⁶ *See, e.g.*, Title, 66 Fed. Reg. 1257 (Jan. 8, 2001).

⁶⁷ *See, e.g.*, Title, 70 Fed. Reg. 72,197 (Dec. 2, 2005).

1997⁶⁸ (FDAMA), an omnibus reform bill. For example, one element of FDAMA repealed section 507 of the Federal Food, Drug and Cosmetic Act, under whose authority FDA had regulated antibiotics – antibiotics are now regulated under section 505 the general regulatory authority for new drugs.⁶⁹ In January 1999, FDA issued a direct final rule eliminating its specific regulations for antibiotics because Congress had just withdrawn FDA’s authority to regulate them.⁷⁰ Unsurprisingly, the rule received no significant adverse comments and was confirmed.⁷¹ 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.

A related category are the two rules that I label as forced substantive rules. 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 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,⁷² FDA had stayed the standards based on comments from industry that the standards would present an “undue economic

⁶⁸ Pub. L. No. 105-115, 111 Stat. 2296 (1997).

⁶⁹ Conforming Regulations Regarding Removal of Section 507 of the Federal Food, Drug, and Cosmetic Act, 64 Fed. Reg. 396, 396 (Jan. 5, 1999).

⁷⁰ *Id.*

⁷¹ 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).

⁷² Beverages: Bottled Water, 61 Fed. Reg. 13,258 (Mar. 26, 1996).

burden.”⁷³ Then Congress passed the Safe Drinking Water Act Amendments of 1996,⁷⁴ which required FDA to issue bottled water monitoring requirements within two years.⁷⁵

Unsurprisingly, the rulemaking did not go well. FDA received significant adverse comments on the direct final rule and was forced to withdraw it. Moreover, the agency didn’t 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.⁷⁶ The second rule in this category implemented another part of the FDAMA, which called on FDA to modify its approval process for food additives.⁷⁷ Although this rule was confirmed without significant comment,⁷⁸ 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.⁷⁹ However, this might instead be read as an example of a rule that followed the Administrative Conference’s suggestion that DFR be used for rules that are the product of negotiated rulemaking.

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,⁸⁰ revising the labeling requirements for over-the-counter skin protectant drug

⁷³ Beverages: Bottled Water, 63 Fed. Reg. 25,764, 25,764 (May 11, 1998).

⁷⁴ Pub. L. No. 104-182, 110 Stat. 1613 (1996).

⁷⁵ See Beverages: Bottled Water, 63 Fed. Reg. at 25,765.

⁷⁶ Bottled Water: Monitoring Requirements, 63 Fed. Reg. 41,199, 42,199 (Aug. 6, 1998).

⁷⁷ National Environmental Policy Act; Food Contact Substance Notification System, 65 Fed. Reg. 30,352 (May 11, 2000).

⁷⁸ National Environmental Policy Act; Food Contact Substance Notification System; Confirmation of Effective Date, 65 Fed. Reg. 60,359 (Oct. 11, 2000).

⁷⁹ See National Environmental Policy Act; Food Contact Substance Notification System, 65 Fed. Reg. at 30,353.

⁸⁰ Presiding Officers at Regulatory Hearings, 67 Fed. Reg. 53,305 (Aug. 15, 2002).

products,⁸¹ and limiting the amount of information the agency would release in response to Freedom of Information Act⁸² (FOIA) requests.⁸³ 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.⁸⁴ The public information regulation did generate significant adverse comment, but FDA ultimately published a final rule identical to the initial direct final rule.⁸⁵ This was not a surprising outcome, given that the restrictions on information were consistent with FOIA – 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.⁸⁶ Although 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 FDA incorporates into its regulations new standards promulgated by other groups such as the EPA or the American National Standards Institute. These would seem to be quite rightly labeled uncontroversial and, indeed, among this

⁸¹ 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).

⁸² 5 U.S.C. § 552 (2000).

⁸³ Public Information Regulations, 69 Fed. Reg. 53,615 (Sept. 2, 2004).

⁸⁴ 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).

⁸⁵ Public Information Regulations, 70 Fed. Reg. 41,956 (July 21, 2005).

⁸⁶ *Id.* at 41,956.

group FDA has a much better than average track record, withdrawing only one of the five. The withdrawn regulation was to have incorporated by reference more recent editions of two reference books into the FDA rule on declaring botanical ingredients in dietary supplements.⁸⁷ The rule was withdrawn in December 2005,⁸⁸ 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.⁸⁹ 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 to 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, “This rule is effective February 8, 1999,”⁹⁰ 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.⁹¹ Clearly the practice of publishing confirmations is a useful means of alerting the public that direct final rules – which are final in name alone⁹² – truly become effective.

⁸⁷ Food Labeling: Ingredient Labeling of Dietary Supplements that Contain Botanicals, 68 Fed. Reg. 51,693 (Aug. 28, 2003).

⁸⁸ Food Labeling: Ingredient Labeling of Dietary Supplements that Contain Botanicals; Withdrawal, 70 Fed. Reg. 76,684 (Dec. 28, 2005).

⁸⁹ Amendment to Examination and Investigation Sample Requirements, 63 Fed. Reg. 51,297 (Sept. 25, 1998).

⁹⁰ *Id.* at 51,297.

⁹¹ Compare *id.* at 51,299 with 21 C.F.R. § 2.10(b)(2) (2008).

⁹² See Levin, *Direct Final Rulemaking*, *supra* note 6, 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

Because efficiency is direct final rulemaking's main selling point and inadequate notice a potential drawback, it will be useful to provide some data about the timing of rulemaking. Of the fourteen withdrawn DFRs, five have never been issued as revised final rules. Two of the fourteen, 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 1997.⁹³ Because the two revised final rules were published after the effective date of the direct final rules,⁹⁴ this means that for some period of time a rule was in effect that FDA intended to withdraw – one for only a month, the other for more than a year. And in both these cases, FDA later determined the rule should be modified in response to the comments. 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 despite FDA not yet responding to the comments.

⁹³ Medical Devices; 30-Day Notices and 135-Day PMA Supplement Review, 63 Fed. Reg. 20,530 (Apr. 27, 1998); Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting, 63 Fed. Reg. 26,069 (May 12, 1998).

⁹⁴ 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. 4112 (Jan. 26, 2000).

Putting aside the five withdrawals that did not lead to a revised final rule and the two revised final rules without prior withdrawals leaves seven direct final rules that were both withdrawn and subsequently reissued as a revised final rule. For these seven, the average time between withdrawal of direct final rule and issuance of the revised final rule was 365 days. The longest took 1,672 days; the shortest 52 days.

III. 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. Some of this can be attributed to random variation, but 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 FDA is misusing the process. This experience suggests 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's not obvious that any efficiency gains are being made. There is some reason to think FDA may be an outlier among agencies that have adopted direct final rulemaking. Still, this paper suggests further study of direct final rulemaking at other agencies could be informative.

The Introduction provided evidence that as a numbers matter a surprising percentage of FDA DFRs are withdrawn, both in the abstract and in comparison to other agencies. Now that we have surveyed the thirty-eight FDA DFRs we can say that a substantial part of rules are withdrawn because they were unsuitable for direct final rulemaking. This is a phenomenon common to both the Clinton and Bush administrations. The discussion in Part II 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 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 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.⁹⁵ These would seem to be obvious indicators that a rule will be controversial, and yet several times FDA has sought to promulgate DFRs under these circumstances. Second, agencies should avoid promulgating discretionary substantive changes to rules. FDA said it limits itself to “minor,” substantive changes,⁹⁶ 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

⁹⁵ On May 14, 1999, 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). 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 FDA would have thought the proposal would be noncontroversial with little likelihood of further comment. *See id.* at 26,282. 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).

⁹⁶ Guidance for FDA and Industry: Direct Final Rule Procedures, 62 Fed. Reg. 62,466, 62,469 (Nov. 21, 1997).

impact of the rule,⁹⁷ 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 this latter category – that I label presumptively controversial – in the thirty-eight DFRs FDA published over the last decade suggests misuse of the 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.⁹⁸ 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.⁹⁹ Depending on the rule, other interagency review may also be necessary.¹⁰⁰ 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.¹⁰¹ 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

⁹⁷ See, e.g., Exec. Order No. 12,866, § 3(f), 58 Fed. Reg. 51,735, 51,735 (Sept. 30, 1993).

⁹⁸ Levin, *Direct Final Rulemaking*, *supra* note 6, at 2.

⁹⁹ See Exec. Order No. 12,866, § 3(f), 58 Fed. Reg. at 51,735.

¹⁰⁰ See THOMAS O. MCGARITY, *REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY* 17-25 (1991).

¹⁰¹ Levin, *More on Direct Final Rulemaking*, *supra* note 6, at 767.

publish a confirmation, the rulemaking work is finished once the comment period ends with no comments. For agencies like 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 DPR — 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 FDA shows that neither assumption holds: 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. If 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 FDA.

The FDA experience also severely undermines much of the theoretical legal basis for direct final rulemaking. 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.¹⁰² 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

¹⁰² See Jordan, *supra* note 21, at 129-35.

labeled as substantive regulations. The question then becomes whether direct final rulemaking actually complies with the substance of section 553. This remains a close legal question. I tend to believe it does comply with section 553, but technical compliance in this context is largely irrelevant. When direct final rulemaking is used for patently controversial rulemaking such as the bottled water regulation in the Clinton Administration,¹⁰³ a midnight regulation in the waning days of the Clinton Administration,¹⁰⁴ and the public information rule in the aftermath of the September 11 terrorist attacks,¹⁰⁵ it is rightly read as an attempt to undermine notice-and-comment rulemaking, not 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.¹⁰⁶ 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. However, this conclusion relies on a faulty premise. As this study and others have shown,¹⁰⁷ 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

¹⁰³ Beverages: Bottled Water, 63 Fed. Reg. 25,764 (May 11, 1998).

¹⁰⁴ Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records, 66 Fed. Reg. 1257 (Jan. 8, 2001); *see supra* note 56.

¹⁰⁵ Public Information Regulations, 69 Fed. Reg. 53,615 (Sept. 2, 2004).

¹⁰⁶ David J. Barron & Elena Kagan, *Chevron’s Nondelegation Doctrine*, 2001 S. CT. REV. 201, 231-32.

¹⁰⁷ *See, e.g.,* Cuellar, *supra* note 57.

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. 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 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 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 FDA so pervasively regulates its industries and because all parties to FDA regulation are repeat players, relationships between FDA and industry may be a more powerful force than the “law” as it can be enforced in court.¹⁰⁸ Regulated parties, more concerned about maintaining those relationships, may thus avoid litigation with FDA, particularly over a matter such as direct final rulemaking, easily characterized as a technicality. FDA, in turn, might be more willing to stretch the definition of “noncontroversial,” knowing regulated parties are unlikely to sue over this issue. 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.¹⁰⁹

¹⁰⁸ Todd Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 169-70 (2000).

¹⁰⁹ Professor Owen Fiss has noted a similar dynamic at play in the much-discussed decline of trials in America: settlements may be coerced and “justice may not be done.” Owen Fiss, *Against Settlement*, 93 YALE L.J. 1073, 1075 (1984).

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. 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.¹¹⁰

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 the FDA practice proves that direct final rulemaking is illegal, studying the experience at this one agency demonstrates real problem with the practice that would otherwise remain obscure.

¹¹⁰ Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007).

Appendix

Summary of FDA Direct Final Rulemakings

Date DFR Published	Subject	Nature	Outcome
4/17/98	Devices: Humanitarian Use	Codification of statutory change	W
4/20/98	Biologics	Regulatory simplification	P
4/27/98	Devices: PMA procedure modification	Codification of statutory change	W
5/11/98	Food: Bottled water standards	Forced substantive change	P
5/12/98	Devices: Adverse Event Reporting	Codification of statutory change	W
5/12/98	Drugs: Certification of Antibiotics	Codification of statutory change	C
5/13/98	Drugs: Insulin	Codification of statutory change	C
6/16/98	Procedure: Scientific Review	Codification of statutory change	W
8/7/98	Devices: Removing Reporting Requirements	Codification of statutory change	C
9/25/98	Procedure: Sample Collection	Inflation adjustment	C
9/29/98	Devices: Registration requirements	Codification of statutory change	C
12/14/98	Drugs: IND procedure	Codification of statutory change	C
1/5/99	Drugs: Certification of Antibiotics	Codification of statutory change	C
5/14/99	Biologics	Regulatory simplification	P
6/17/99	Devices: Mammography	Codification of statutory change	C
8/19/99	Biologics	Regulatory simplification	P
11/3/99	Devices: Hearing Aids	Standards adjustment	C
12/10/99	Animal Drugs: Listed Journals	Regulatory simplification	C
1/24/00	Devices	Standards adjustment	C
5/11/00	Food: Environmental Impact	Forced substantive change	C
12/12/00	Biologics	Regulatory simplification	C
1/8/01	Procedure: Advisory Committees	Regulatory simplification	W
3/28/01	Food: Bottled water standards	Standards adjustment	C
8/15/02	Procedure: ALJs	Unforced substantive change	C
3/3/03	Food: Bottled water standards	Standards adjustment	C
6/13/03	Drugs: Labeling of OTC Skin Protectants	Unforced substantive change	C
8/28/03	Food: Dietary Supplements	Standards adjustment	W
12/30/03	Biologics	Regulatory simplification	C
9/2/04	Procedure: Public Information	Unforced substantive change	W
2/28/05	Devices: Adverse Event Reporting	Regulatory simplification	C
12/2/05	Biologics: Strep organism	Regulatory simplification	C
1/17/06	Drugs: GMP for IND	Regulatory simplification	W
5/12/06	Biologics: Organ transplants`	Regulatory simplification	W
9/25/06	Devices: Single-use devices	Codification of statutory change	W
12/7/06	Devices: Ozone depleting	Regulatory simplification	C
8/16/07	Biologics	Regulatory simplification	C
10/18/07	Biologics: Live vaccine	Regulatory simplification	C
12/4/07	Drugs: GMP	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