

ANOTHER REASON TO REFORM THE FEDERAL REGULATORY SYSTEM: AGENCIES' TREATING NONLEGISLATIVE RULES AS BINDING LAW

Abstract: *This Note analyzes the nonlegislative rule exception to the rulemaking requirements of the Administrative Procedure Act ("APA"). To lend greater accountability to federal agencies, the APA places an obligation on agencies to incorporate public input when creating new rules. Agencies, however, can avoid considering public commentary through a vague exception: section 553(b)(A) of the APA. After analyzing section 553(b)(A), this Note evaluates how one agency, the Food and Drug Administration, has responded to the confusion surrounding the exception. Finally, this Note considers how the Senate has overlooked problems associated with section 553(b)(A) in the Senate's most recent bill to revise administrative procedures.*

INTRODUCTION

Congress creates administrative agencies to execute many of the statutes it enacts. When establishing an agency, Congress grants it several powers, such as the authority to perform investigations, to conduct adjudications and, most pertinent to this Note, to adopt rules. Generally, agencies create two types of rules: legislative rules and nonlegislative rules. Legislative rules, better known as "regulations," have the force of law. The government and the public must conform to the dictates of legislative rules, as if they were statutes. Conversely, nonlegislative rules lack the force of law. Rather, they represent recommendations and advice. Nonlegislative rules have innumerable synonyms, such as interpretative rules, statements of policy, rules of agency organization and guidelines.

Congress briefly addresses legislative and nonlegislative rules in the Administrative Procedure Act ("APA").¹ In 1946, Congress passed the APA to foster clarity, uniformity and public participation in the

¹See Administrative Procedure Act, 5 U.S.C. § 553 (1994).

administrative state. To further those worthy goals, the APA prescribes procedures that agencies must follow when exercising their powers.

For instance, the APA explains how agencies develop legislative rules. According to the APA, to produce legislative rules, agencies must follow a procedure incorporating public input. On the other hand, to create nonlegislative rules, agencies need not follow any prescribed procedure and need not regard public commentary. Thus, a dichotomy exists: created after a process incorporating public input, legislative rules possess the full force of the law; created without any formal process, nonlegislative rules lack the force of law.

Distinguishing between legislative and nonlegislative rules, however, is not always clear. Courts have described the difference between legislative and nonlegislative rules as "tenuous," "enshrouded in considerable smog" and "fuzzy."² The difference between legislative and nonlegislative rules becomes confused when agencies treat nonlegislative rules as if they bear the force of law—as if they were legislative rules. When an agency views a nonlegislative rule as binding law, several unwanted situations can occur.

For example, an agency creates a prudent safety standard by adopting a nonlegislative rule. Although the standard protects public health, a private party may ignore the standard. If the agency commences legal action against that party for violating the nonlegislative rule, a court may dismiss the action because the rule lacks the force of law. Thus, by employing the improper type of rule—nonlegislative rather than legislative—the agency fails to protect public health. Alternately, private parties may defer to the agency's nonlegislative rule because they do not realize that nonlegislative rules lack the force of law or because they wish to avoid provoking the agency into investigating them. Thus, while some companies follow the safety standard, others may ignore it without suffering penalties. Also, a misguided court may concur with the agency and uphold the enforcement action. In any event, by treating the nonlegislative rule as binding law, the agency creates inconsistency, unfairness and confusion.

Additionally, an agency will constrain its own discretion by treating a nonlegislative rule as binding law. A private company may closely follow the agency's safety standard. Other parties, however, fear that the standard is too lenient and that the company is endan-

²See *Community Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting *Chisholm v. FCC*, 538 F.2d 349, 393 (D.C. Cir. 1976); *Noel v. Chapman*, 508 F.2d 1023, 1030 (2d Cir. 1975); *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 37 (D.C. Cir. 1974)).

gering public health, so they petition the agency to take action against the company. The agency probably would be reluctant to take any action. Even if the agency chose to act, a court may hold that the agency is estopped from initiating enforcement proceedings because the company conformed to the rule. Here, public health suffers because an agency treated a nonlegislative rule as law. Moreover, the above examples illustrate situations in which the public and the government follow rules created without public involvement, thereby negating the democratic nature of the APA.

This Note argues that by treating nonlegislative rules as binding law, agencies undermine the APA's propitious objectives of clarity, uniformity and public participation.³ Part I of this Note provides background relating to the APA, rulemaking procedures, legislative rules and nonlegislative rules.⁴ Part II focuses on the different legal effects of legislative versus nonlegislative rules.⁵ Part III addresses one agency's current attempt to revise the role of nonlegislative rules and a bill presently in Congress aimed at regulatory reform.⁶ Specifically, Part III evaluates the Food and Drug Administration's Good Guidance Practices and the Senate's proposed Regulatory Improvement Act of 1999.⁷ Finally, this Note argues that Congress and administrative agencies should clarify the confusion surrounding nonlegislative rules and should ensure that agencies do not treat nonlegislative rules as binding law.⁸

I. THE ADMINISTRATIVE PROCEDURE ACT

In 1789, the first Congress of the United States enacted statutes creating the nation's original administrative agencies, such as the Post Office and the Treasury.⁹ Subsequently, Congress has created innumerable agencies and granted them several powers, including the

³See, e.g., 5 U.S.C. § 553; *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993); UNITED STATES DEP'T OF JUSTICE, ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 9 (1947, Wm. W. Gaunt & Sons, Inc., unabridged republication 1979).

⁴See *infra* notes 9-112 and accompanying text.

⁵See *infra* notes 113-63 and accompanying text.

⁶See *infra* notes 164-293 and accompanying text.

⁷See *infra* notes 164-293 and accompanying text.

⁸See *infra* notes 164-293 and accompanying text.

⁹See, e.g., 1 KENNETH CULP DAVIS & RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE 7 (3d ed. 1994); JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM 4 (4th ed. 1998); J. SANDERS, EVOLUTION OF EXECUTIVE DEPARTMENTS OF THE CONTINENTAL CONGRESS 1774-89, at 187-92 (1935).

authority to make law.¹⁰ Congress creates federal agencies through legislative acts, commonly known as "organic" or "enabling" statutes.¹¹ Through an organic statute, Congress grants an agency several powers, such as the authority to conduct adjudications, to investigate private entities, to initiate enforcement actions and to create legislative rules.¹² Each organic statute is unique, and over a century and a half, the heterogeneity between the various agencies led to inconsistency and confusion.¹³ Furthermore, many members of the public lamented that it was undemocratic for administrative agencies to function without regard for public opinion.¹⁴

In 1946, Congress passed the Administrative Procedure Act ("APA") to promote uniformity, fairness and public participation in how agencies operate.¹⁵ For all intents and purposes, the APA is the bible of administrative law.¹⁶ An agency must abide by both its organic statute and the APA.¹⁷ When a court reviews an agency's actions, the

¹⁰See *United States v. Grimaud*, 220 U.S. 506, 517 (1910) (noting that Congress may delegate rulemaking authority to agencies); *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 678 (D.C. Cir. 1973) (upholding FTC's authority to create legislative-type rules); *DAVIS & PIERCE*, *supra* note 9, at 6 (size and scope of agency activity has increased during every period of U.S. history); *MASHAW ET AL.*, *supra* note 9, at 4-6, 15 (noting that Congress has created many agencies and delegated to them rulemaking authority and other powers).

¹¹See *MASHAW ET AL.*, *supra* note 9, at 56 (stating: "[v]irtually all agency action begins with a statute"); *RICHARD J. PIERCE, JR. ET AL., ADMINISTRATIVE LAW AND PROCESS* 35, 220 (1985) (noting that enabling statutes, also referred to as "organic," convey powers to agencies); Stephen F. Williams, *The Era of "Risk-Risk" and the Problem of Keeping the APA up to Date*, 63 U. CHI. L. REV. 1375, 1384 (1996). Statutes, however, are not the only means by which an agency comes into being. See *MASHAW ET AL.*, *supra* note 9, at 12. Presidential executive orders have created many federal agencies, such as the Environmental Protection Agency and the Army Corps of Engineers. See *id.*

¹²See Administrative Procedure Act, 5 U.S.C. §§ 551, 553-557 (1994); *MASHAW ET AL.*, *supra* note 9, at 13-15.

¹³See JAMES WILLARD HURST, *LAW AND SOCIAL ORDER IN THE UNITED STATES* 150-51 (1977) (noting the growth of administrative state fostered fragmentation of policy making).

¹⁴See *id.*; *MASHAW ET AL.*, *supra* note 9, at 9.

¹⁵See 5 U.S.C. §§ 553-557 (codifying method for rulemaking and for judicial review of agency action); *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993) (noting that the APA invests unrepresentative agencies with public participation and fairness); *MASHAW ET AL.*, *supra* note 9, at 148 (noting that the APA systematized agency procedures); U.S. DEP'T OF JUSTICE, *supra* note 3, at 9 (noting that the purposes of APA are to provide for public participation, public awareness, uniformity and judicial review of agency actions). For a history of the APA, see generally Peter L. Strauss, *Changing Times: the APA at Fifty*, 63 U. CHI. L. REV. 1389 (1996).

¹⁶See 5 U.S.C. §§ 551, 553-596, 701-706; *MASHAW ET AL.*, *supra* note 9, at 148; U.S. DEP'T OF JUSTICE, *supra* note 3, at 9-10.

¹⁷See *MASHAW ET AL.*, *supra* note 9, at 148; U.S. DEP'T OF JUSTICE, *supra* note 3, at 9-10.

court looks first to the agency's organic statute and second to the APA as the default statute.¹⁸ When Congress drafts organic statutes, it often instructs agencies to follow certain provisions of the APA.¹⁹ For instance, many organic statutes defer to the APA's standardized rules for rulemaking.²⁰

The APA describes the procedure by which agencies may create legislative rules.²¹ According to the APA, to produce a legislative rule, an agency must follow a procedure incorporating public input.²² Because they require agencies to consider public commentary, rulemaking procedures impose burdens on administrative agencies.²³ To allow flexibility, the APA provides exceptions that release agencies from following any rulemaking procedure.²⁴ One exception, the focal point of this Note, is for nonlegislative rules under § 553(b) (A) of the APA.²⁵

¹⁸See MASHAW ET AL., *supra* note 9, at 459; PIERCE ET AL., *supra* note 11, at 37; U.S. DEP'T OF JUSTICE, *supra* note 3, at 9-10.

¹⁹See MASHAW ET AL., *supra* note 9, at 459.

²⁰See *id.*

²¹See 5 U.S.C. § 553. Courts tend to treat interpretative rules, policy statements, guidelines and their ilk as virtually the same. See *Community Nutrition Inst. v. Young*, 818 F.2d 943, 945 (D.C. Cir. 1987) [hereinafter "CNI"]; see also *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 93-94 (D.C. Cir. 1997) (stating that "[f]urther confusing the matter is the tendency of courts and litigants to lump interpretative rules and policy statements together in contrast to substantive rules, a tendency to which we have ourselves succumbed on occasion."). In the last few years, the District of Columbia Circuit Court of Appeals has stressed the differences between interpretative rules and policy statements. See *Hudson v. Federal Aviation Admin.*, 192 F.3d 1031, 1036 (D.C. Cir. 1999); *Syncor*, 127 F.3d at 94. Some legal scholars have analyzed all nonlegislative rules as being similar, while others have found interpretative rules and policy statements to be quite distinct. Compare Robert A. Anthony, *Interpretative Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1323-27 (1992) [hereinafter *Interpretative Rules*] (analyzing interpretative rules and policy statements as completely different legal instruments), with Ronald M. Levin, *Nonlegislative Rules and the Administrative Open Mind*, 41 DUKE L.J. 1497, 1499 (1992) (stating: "the proper distinction to be drawn here is between legislative rules . . . and nonlegislative rules . . ."). This Note will not explore extensively all of the nuances between the two types of nonlegislative rules.

²²See, e.g., 5 U.S.C. §§ 553, 556-557; *White*, 7 F.3d at 303.

²³See Anthony, *Interpretative Rules*, *supra* note 21, at 1319; Richard M. Thomas, *Prosecutorial Discretion and Agency Self-Regulation: CNI v. Young and the Aflatoxin Dance*, 44 ADMIN. L. REV. 131, 134 (1992).

²⁴See 5 U.S.C. § 553(a), (b) (A), (b) (B).

²⁵This Note will refer to the statutory provision as "5 U.S.C. § 553(b) (A)." Because the statute's format is ambiguous, however, many courts and scholars refer to the exception as "5 U.S.C. § 553(b) (3) (A)." See, e.g., *CNI*, 818 F.2d at 945; Elizabeth Williams, *What Constitutes "Interpretative Rule" of Agency so as to Exempt Such Action From Notice Requirement of Administrative Procedure Act (5 U.S.C.A. § 553(B)(3)(A))*, 126 A.L.R. FED. 347, 347 (1995). Most authorities, however, refer to the exception as falling within 5 U.S.C. § 553(b) (A). See, e.g., *Thomas v. New York*, 802 F.2d 1443, 1447 (D.C. Cir. 1986); Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 381 n.5 (1985); Daniel A. Kracov &

The following sections explain in more detail the procedures for rulemaking, and how agencies may avoid those procedures through the § 553(b)(A) exception.

A. The Rulemaking Process

Congress has three choices when establishing how agencies produce legislative rules:²⁶ (1) to employ the "informal rulemaking" process of § 553 of the APA; (2) to use the "formal rulemaking" process of sections 553, 556 and 557 of the APA; or (3) to employ unique rulemaking procedures described in the organic statute itself.²⁷ The majority of the time, Congress instructs the agency to employ the informal rulemaking process.²⁸

The key elements of informal rulemaking—also known as "notice-and-comment"—are that before issuing a legislative rule, an agency must notify the public of the proposed rule, accept commentary on the proposal and respond to that commentary.²⁹ Because of

Robert P. Brady, *Food and Drug Administration Advisory Opinions and Guidance Documents After Community Nutrition Institute v. Young*, 48 FOOD & DRUG L.J. 47, 47 n.1 (1993).

Other rules exempted from § 553 rulemaking requirements include rules relating to the military, foreign affairs, agency management, agency personnel, public property, or when there is good cause for an agency to avoid rulemaking procedures. See 5 U.S.C. § 553(a), (b)(B). This Note will not discuss these other exceptions.

²⁶ See 5 U.S.C. §§ 553, 556-557; MASHAW ET AL., *supra* note 9, at 459.

²⁷ See 5 U.S.C. §§ 553, 556-557; MASHAW ET AL., *supra* note 9, at 459.

²⁸ See 5 U.S.C. §§ 553, 556-557; DAVIS & PIERCE, *supra* note 9, at 288; MASHAW ET AL., *supra* note 9, at 459; Andrew F. Popper, *Administrative Law in the 21st Century*, 49 ADMIN. L. REV. 187, 191 (1997).

²⁹ See 5 U.S.C. § 553. See generally DAVIS & PIERCE, *supra* note 9, at 287-375; Richard J. Pierce, Jr., *Rulemaking and the Administrative Procedure Act*, 32 TULSA L.J. 185, 185-201 (1996). To execute informal rulemaking, an agency must undergo numerous actions. See 5 U.S.C. § 553; PIERCE ET AL., *supra* note 11, at 321. First, the agency must publish a notice of proposed rulemaking in the government's official publication, the *Federal Register*. See 5 U.S.C. § 553(b); Federal Register Act, 44 U.S.C. §§ 1501-1511 (1994); DeBraun v. Meissner, 958 F. Supp. 227, 228 (E.D. Pa. 1997); OFFICE OF THE FEDERAL REGISTER, NATIONAL ARCHIVES AND RECORDS ADMINISTRATION, *THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT* 3-4 (Jim Wickliffe & Ernie Sowada eds., rev. 1992). The notice of proposed rulemaking includes the actual terms or the substance of the proposed rule and the legal authority behind it. See 5 U.S.C. § 553(b); DAVIS & PIERCE, *supra* note 9, at 298-99. Private parties may submit commentary to the agency. See 5 U.S.C. § 553(c); DAVIS & PIERCE, *supra* note 9, at 299-300. The agency considers the commentary then publishes a final rule in the *Federal Register*. See Freedom of Information Act of 1966, 5 U.S.C. § 552(a)(1)(D) (1994); 5 U.S.C. § 553(c); OFFICE OF THE FEDERAL REGISTER, *supra*, at 4; PIERCE ET AL., *supra* note 11, at 321; see also *Wagner Electric Corp. v. Volpe*, 466 F.2d 1013, 1016, 1019-20 (3d Cir. 1972) (noting that the final rule must resemble the proposed rule enough so that public had opportunity for meaningful comment). When the agency publishes the final rule, the agency must address the significant commentary in a "concise general statement"

the provisions for public participation, informal rulemaking generally is time-consuming and arduous for agencies.³⁰

Even more extensive and elaborate than informal rulemaking is formal rulemaking which, resembling a trial, includes live testimony and cross-examination.³¹ Unique rulemaking procedures vary, but tend to be less formal than formal rulemakings and more formal than informal rulemakings.³² If Congress adopts a statute creating an agency but does not specify whether the agency has the authority to create rules, the presumption is that the agency has the authority to promulgate rules and that it may do so through the informal § 553 process.³³ If an organic statute empowers an agency to promulgate rules, but does not clearly describe through which process, the default presumption is to employ the § 553 informal process.³⁴ Whether an organic statute prescribes informal, formal or unique rulemaking procedures, the APA provides for an exception from such procedures.³⁵

B. *The Section 553(b)(A) Exception*

Section 553(b)(A) of the APA carves out an important exception to the rulemaking procedures.³⁶ An agency need not follow the prescribed rulemaking process to create "interpretative rules, general statements of policy, or rules of agency organization, procedure, or

of the rule's basis and purpose. See 5 U.S.C. § 553(c); *Reyblatt v. United States Nuclear Regulatory Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997); *South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 886 (4th Cir. 1983); *PPG Indus., Inc. v. Costle*, 630 F.2d 462, 466 (6th Cir. 1980); see generally DAVIS & PIERCE, *supra* note 9, at 309-20. The duration between publishing a notice of proposed rulemaking and issuing the final rule ranges, but can last a year or more. See OFFICE OF THE FEDERAL REGISTER, *supra*, at 7. This procedure exists to ensure the public has an opportunity to participate in agency action. See, e.g., *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979); *Tindal*, 717 F.2d at 885; *American Bus. Ass'n v. United States*, 627 F.2d 525, 528 (D.C. Cir. 1980); PIERCE ET AL., *supra* note 11, at 321; U.S. DEP'T OF JUSTICE, *supra* note 3, at 9.

³⁰See 5 U.S.C. § 553; Anthony, *Interpretative Rules*, *supra* note 21, at 1319; Thomas, *supra* note 23, at 134.

³¹See 5 U.S.C. §§ 553, 556-557; MASHAW ET AL., *supra* note 9, at 459-60.

³²See MASHAW ET AL., *supra* note 9, at 459; PIERCE ET AL., *supra* note 11, at 330-31.

³³See, e.g., *National Petroleum*, 482 F.2d at 673-98 (presuming agencies have rulemaking authority); MASHAW ET AL., *supra* note 9, at 459.

³⁴See *Automotive Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 337 (noting that when the organic statute is ambiguous, it is appropriate to presume the agency may employ § 553 informal rulemaking rather than §§ 553, 556-557 formal process); MASHAW ET AL., *supra* note 9, at 459.

³⁵See 5 U.S.C. § 553(b)(A).

³⁶See *id.*

practice."³⁷ The APA fails to define these terms, and the courts have had difficulty interpreting the exception.³⁸ In general, courts have held that interpretative rules elucidate statutory law, general statements of policy announce potential agency actions and rules of agency organization pertain to the internal operations of an agency.³⁹ These definitions, however, are vague, and courts often struggle with how to apply these definitions to the rules that agencies create. This lack of clarity has caused considerable confusion over what agency rules fall within the § 553(b)(A) exception, and the consequent legal effects of those rules.⁴⁰

Attempting to discern the meaning of the § 553(b)(A) exception, the United States Supreme Court has relied on the explanations found in the 1947 Attorney General's Manual (the "Manual").⁴¹ The Court gives considerable weight to the Manual because the Justice Department was heavily involved in creating the APA.⁴² The Manual provides that interpretative rules explain statutes and that general statements of policy pronounce future agency actions.⁴³ The Attorney General contrasted interpretative rules and general statements of pol-

³⁷*Id.*

³⁸*See, e.g.*, 5 U.S.C. §§ 551, 553; *Chrysler*, 441 U.S. at 302 n.31; *Federal Labor Relations Auth. v. United States Dep't of Navy*, 966 F.2d 747, 762 n.14 (3d Cir. 1992) [hereinafter "FLRA"]; *CNI*, 818 F.3d at 946; *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 37-38 (D.C. Cir. 1974).

³⁹*See, e.g.*, 5 U.S.C. § 553(b)(A); *Thomas*, 802 F.2d at 1446; *Batterton v. Marshall*, 648 F.2d 694, 702 n.34 (D.C. Cir. 1980); *Guardian Fed. Sav. & Loan Ass'n v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 658, 666 (D.C. Cir. 1978); U.S. DEP'T OF JUSTICE, *supra* note 3, at 30 n.3.

⁴⁰*See, e.g.*, 5 U.S.C. §§ 551, 553; *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993); *FLRA*, 966 F.2d at 762 n.14; *CNI*, 818 F.3d at 946; *Kracov & Brady*, *supra* note 25, at 49-50; Marianna E. Beem, *Good Guidance Improves Regulations: a Case Study with the FDA*, 15 No. 4 ALA News 23, 23-24 (1996).

⁴¹*See, e.g.*, *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995); *Chrysler*, 441 U.S. at 302 n.31.

⁴²*See, e.g.*, *Chrysler*, 441 U.S. at 302 n.31; *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council Inc.*, 435 U.S. 519, 546 (1978); *DAVIS & PIERCE*, *supra* note 9, at 13-14; *MASHAW ET AL.*, *supra* note 9, at 9.

⁴³*See* U.S. DEP'T OF JUSTICE, *supra* note 3, at 30 n.3. According to the Attorney General's Manual, interpretative rules are "rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers" and general statements of policy are "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Id.* The Manual, however, provides almost no information regarding rules of agency organization. *See id.*

icy with "substantive rules," another term for legislative rules.⁴⁴ Legislative rules may be substantive, meaning they may have binding, significant and immediate effects on the rights and obligations of the public.⁴⁵ Legislative rules bear the full force of law, and therefore, the public and the government must abide by them as if they were statutes.⁴⁶ Nonlegislative rules, on the other hand, lack the binding effect of law and may not create obligations, convey rights or cause significant effects.⁴⁷ Agencies must perform notice-and-comment procedure prior to issuing a legislative rule, but producing a nonlegislative rule requires no such process.⁴⁸ Congress created this exception to provide agencies with some degree of flexibility.⁴⁹

⁴⁴See *id.* at 22–23, 30 n.3; see also Anthony, *Interpretative Rules*, *supra* note 21, at 1321 n.37 (lamenting how courts and agencies use the term "substantive rules" in place of "legislative rules").

⁴⁵See *Chrysler*, 441 U.S. at 301–02; *Perales v. Sullivan*, 948 F.2d 1348, 1354 (2d Cir. 1991); *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 537 (D.C. Cir. 1986); *Marshall*, 648 F.2d at 701–02; *Pacific Gas*, 506 F.2d at 38.

⁴⁶See *Chrysler*, 441 U.S. at 301–02; *Cathedral Bluffs*, 796 F.2d at 537; see also *Pierce*, *supra* note 29, at 186 (stating: "legislative rules . . . have effects that are functionally indistinguishable from those of statutes").

⁴⁷See, e.g., *Chrysler*, 441 U.S. at 301–02, 315–16; *Batterton v. Francis*, 432 U.S. 416, 425 n.9 (1977); *Perales*, 948 F.2d at 1354; *Cathedral Bluffs*, 796 F.2d at 536–38; *Marshall*, 648 F.2d at 701–02; *Guardian Federal*, 589 F.2d at 666; *Pacific Gas*, 506 F.2d at 38.

⁴⁸See 5 U.S.C. § 553.

⁴⁹See, e.g., *Chrysler*, 441 U.S. at 316. One caveat: the requirements for notice-and-comment and the nonlegislative rule exception only applies to rules. See, e.g., *Lincoln v. Vigil*, 508 U.S. 182, 198 (1993); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414 (1971). According to the APA, a "rule" is "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure or practice requirements of an agency . . ." 5 U.S.C. § 551(4). Other agency activities, such as expenditures of funds or investigations, are not rules, so agencies need not perform any procedure before implementing them. See, e.g., *Overton Park*, 401 U.S. at 414; *Environmental Defense Fund, Inc. v. Costle*, 636 F.2d 1229, 1254–56 (D.C. Cir. 1980). For example, in 1993, in *Lincoln v. Vigil*, the Supreme Court held that the Indian Health Service could discontinue a benefits program without following notice-and-comment procedure. See 508 U.S. at 195–99. The court explained that whether or not the decision to cease the allocation of funds to Native Americans was a rule was irrelevant to the holding. See *id.* at 196–97. The court reasoned that the agency action could have been a funding decision within agency discretion and not subject to rulemaking procedures. See *id.* at 197–98. Likewise, the decision could have been a rule of agency organization or a general statement of policy falling within agency discretion, so even if it had been a "rule," informal rulemaking process was unnecessary. See *id.* at 195–99; *Overton Park*, 401 U.S. at 414.

C. *Purposes Behind the Administrative Procedure Act and the Section 553(b)(A) Exception*

Congress created the rulemaking procedures of § 553 to strike a compromise between administrative efficiency and public participation.⁵⁰ The central restraint of the APA's rulemaking procedures is to ensure that agencies hear public opinion before acting.⁵¹ Thus, the APA makes agencies more accountable to the public and discourages arbitrary agency action.⁵²

Several Supreme Court and Circuit Court of Appeals opinions have expounded upon the purposes behind the APA, the rulemaking procedures and the nonlegislative rule exception.⁵³ The Supreme Court stated in 1974 in *Morton v. Ruiz*, that by forcing agencies to be well-informed and to incorporate public opinion, Congress strove to prevent agencies from acting arbitrarily or unfairly when it passed the APA.⁵⁴ In the 1978 case, *Guardian Federal Savings and Loan Association v. Federal Savings and Loan Insurance Corporation*, the United States Court of Appeals for the District of Columbia Circuit expanded upon the APA's requirements of public participation.⁵⁵ Requiring public participation, the court asserted, assures that when an agency creates a legislative rule the agency will have before it the facts and information relevant to a particular problem, as well as suggestions for alternative solutions.⁵⁶ The court concluded that public rulemaking procedures increase the likelihood of administrative responsiveness to the needs and concerns of those affected by agency rules.⁵⁷ In addition, the court reasoned that because Congress has provided a procedure for public participation, the public tends to acquiesce to the final agency action even when objections to substance remain.⁵⁸ Simply by knowing that there are procedures providing people with a fair

⁵⁰ See *Chrysler*, 441 U.S. at 316; *Guardian Federal*, 589 F.2d at 662; U.S. DEP'T OF JUSTICE, *supra* note 3, at 9.

⁵¹ See 5 U.S.C. §§ 553, 556-557; U.S. DEP'T OF JUSTICE, *supra* note 3, at 26.

⁵² See, e.g., *Chrysler*, 441 U.S. at 316; *New Jersey Dep't of Env'tl. Protection v. United States Env'tl. Protection Agency*, 626 F.2d 1038, 1045 (D.C. Cir. 1980) [hereinafter "NJDEP"]; U.S. DEP'T OF JUSTICE, *supra* note 3, at 26.

⁵³ See, e.g., *Chrysler*, 441 U.S. at 316; *Guardian Federal*, 589 F.2d at 663.

⁵⁴ See *Morton v. Ruiz*, 415 U.S. 199, 232 (1974).

⁵⁵ See *Guardian Federal*, 589 F.2d at 662.

⁵⁶ See *id.*

⁵⁷ See *id.*

⁵⁸ See *id.*

chance to participate in administrative decision making, the public will be more likely to accept the final outcome without dispute.⁵⁹

Notice-and-comment requirements serve beneficial purposes, but courts have recognized that it is very useful when agencies avoid notice-and-comment by properly employing the § 553(b)(A) exception.⁶⁰ Nonlegislative rules are useful because, without burdening agencies with notice-and-comment process, they allow agencies to act more efficiently.⁶¹ For instance, agencies are able to quickly produce rules of agency organization to better manage and streamline their operations.⁶² In addition, the nonlegislative rule exception encourages agencies to disseminate information to the public.⁶³ By publishing information, agencies aid the long-range planning of regulated private entities' and promote uniformity in areas of national concern.⁶⁴ When an agency makes suggestions, private parties have an incentive to follow the agency's advice because the agencies tend to be well-informed in their fields of expertise.⁶⁵ Moreover, by issuing nonlegislative rules, an agency notifies the public that the agency eventually may develop that nonlegislative rule into an actual legislative rule.⁶⁶

⁵⁹See *id.* In 1979, in *Chrysler Corp. v. Brown*, the Supreme Court wrote that "[i]n enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment." 441 U.S. at 316.

⁶⁰See, e.g., *Marshall*, 648 F.2d at 702 n.34; *Pacific Gas*, 506 F.2d at 38; see also Asimow, *supra* note 25, at 385-88 (defending utility of interpretative rules and policy statements); Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating it Too*, 47 CATH. U. L. REV. 113, 122-25 (1997) (noting that nonlegislative rules benefit public and agency by providing consistency); Beem, *supra* note 40, at 23 (asserting pharmaceutical industry depends on nonlegislative rules); Joel E. Hoffinan, *Public Participation and Binding Effect in the Promulgation of Nonlegislative Rules: Current Developments at FDA, ADMIN. & REG. L. NEWS*, Spring 1997, at 1 (stating that the practical importance of nonlegislative rules is "undeniable").

⁶¹See *Marshall*, 648 F.2d at 702 n.34; *Pacific Gas*, 506 F.2d at 38.

⁶²See *Chrysler*, 441 U.S. at 310 n.41; *Marshall*, 648 F.2d at 702 n.34.

⁶³See *Pacific Gas*, 506 F.2d at 38.

⁶⁴See *id.*

⁶⁵See *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 33 (1990) (noting that agencies develop expertise in their fields); *Bowen v. Massachusetts*, 487 U.S. 879, 908 (1988) (noting that agencies deserve discretionary power because of their technical expertise).

⁶⁶See *Pacific Gas*, 506 F.2d at 38 (stating that nonlegislative rules assist long-term planning of regulated parties); Beem, *supra* note 40, at 23 (noting that industries rely on nonlegislative rules to plan ahead); Hoffinan, *supra* note 60, at 1 (same).

The problem with the nonlegislative rule exception is that agencies may sometimes take advantage of the confusion surrounding it.⁶⁷ To avoid the rulemaking process, agencies sometimes create rules and label them as nonlegislative rules.⁶⁸ Agencies then treat those rules as if they were legislative rules with binding legal force.⁶⁹ In essence, agencies attempt to create legislative rules disguised as nonlegislative rules.⁷⁰ Recognizing a misapplication of the exception can be difficult; the courts have found that nonlegislative and legislative rules are not easily distinguishable.⁷¹

D. Distinguishing Between Nonlegislative and Legislative Rules

Agencies often issue rules without following the § 553 process, yet treat those rules as if they bore the full force of the law.⁷² Courts frequently examine disputed rules and determine whether they are nonlegislative, as the agencies claim, or whether they are legislative and,

⁶⁷ See, e.g., *CNI*, 818 F.2d at 945-47 (finding that the agency tried to mislabel substantive rule as interpretative); *American Bus.*, 627 F.2d at 531-32 (same); *Bellarmino Int'l Ltd. v. FDA*, 678 F. Supp. 410, 415-16 (E.D.N.Y. 1988) (same); Robert A. Anthony, "Well, You Want the Permit, Don't You?" *Agency Efforts to Make Nonlegislative Documents Bind the Public*, 44 ADMIN. L. REV. 31, 31 (1992) [hereinafter *Well, You Want the Permit*] (arguing that agencies misuse § 553(b) (A) exception to create rules to bind the public).

⁶⁸ See Anthony, *Interpretative Rules*, *supra* note 21, at 1320. The term "nonlegislative rules" is used in this Note as an inclusive term meaning not only "interpretative rules, general statements of policy, and rules of agency organization, procedure, or practice," but also "advisory opinions," "guidance documents," "opinion letters, policy statements, program policy letters, Dear Colleague letters, regulatory guidance letters, . . . guidelines, staff instructions, manuals, questions-and-answers, bulletins, advisory circulars, models, enforcement policies, action levels, press releases" and other terms employed by federal agencies for those rules created without rulemaking procedures. See, e.g., *Advisory Opinions*, 21 C.F.R. § 10.85 (1998) (employing the term "advisory opinions" for the FDA); *Good Guidance Practices*, 62 Fed. Reg. 8961, 8967 (1997) (employing the term "guidance documents" for the FDA); Anthony, *Interpretative Rules*, *supra* note 21, at 1320 (mentioning other designations). The Court of Appeals for the District of Columbia Circuit states it has "lump[ed]" together the various statements for the purposes of legal analysis. See *Syncon*, 127 F.3d at 93-94.

⁶⁹ See, e.g., *CNI*, 818 F.2d at 945; Anthony, *Well, You Want the Permit*, *supra* note 67, at 31-33.

⁷⁰ See, e.g., *CNI*, 818 F.2d at 946-47; Anthony, *Well, You Want the Permit*, *supra* note 67, at 31-33. In defense of federal agencies, they often provide for public participation when unnecessary. See Asimow, *supra* note 25, at 381 n.5.

⁷¹ See, e.g., *CNI*, 818 F.2d at 946. The distinction between legislative rules and nonlegislative rules has been described as "tenuous," "enshrouded in considerable smog" and "fuzzy." *Id.* (quoting *Chisholm v. FCC*, 538 F.2d 349, 393 (D.C. Cir. 1976); *Noel v. Chapman*, 508 F.2d 1023, 1030 (2d Cir. 1975); *Pacific Gas*, 506 F.2d at 37).

⁷² See, e.g., *Chrysler*, 441 U.S. at 315; *CNI*, 818 F.2d at 945, 948-49; *American Bus.*, 627 F.2d at 526, 531-32.

therefore, subject to the informal rulemaking process.⁷³ If a court finds that an agency created a rule that is substantive in nature without following the rulemaking process, the court will strike it down as invalid.⁷⁴ The courts have ruled that § 553's exceptions must be narrowly construed and should not be used as "escape clauses" for agencies trying to avoid notice-and-comment procedures.⁷⁵ The line between nonlegislative and legislative rules, however, is often unclear.⁷⁶

1. Factors Distinguishing Nonlegislative from Legislative Rules

To distinguish whether a rule is nonlegislative or legislative, courts consider whether the rule is "substantive" in nature.⁷⁷ If a rule has substantive effects, it should have been promulgated as a legislative rule, and therefore, the agency should have performed notice-and-comment to create it.⁷⁸ The courts have examined the following factors:

- Nonlegislative rules do not create law, while legislative rules may impose or remove legal rights and obligations or produce other significant effects on private parties.⁷⁹
- If evidence shows an agency intended for a rule to have substantive effects or to legally bind the public, then it is probably a legislative rule.⁸⁰

⁷³See, e.g., *Chrysler*, 441 U.S. at 315; *CNI*, 818 F.2d at 945, 948-49; *American Bus.*, 627 F.2d at 526, 531-32; *Cooper v. Glickman*, 50 F. Supp. 2d 489, 502-03 (M.D.N.C. 1999).

⁷⁴See, e.g., *CNI*, 818 F.2d at 946-49 (invalidating Food and Drug Administration's "action levels" because produced without notice-and-comment yet applied as law); *American Bus.*, 627 F.2d at 531-34 (invalidating Interstate Commerce Commission "pronouncement" because produced without notice-and-comment yet applied as law); *Texaco v. Federal Power Comm'n*, 412 F.2d 740, 744 (10th Cir. 1969) (invalidating Federal Power Commission "order" because produced without notice-and-comment yet applied as law).

⁷⁵See *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984) (quoting *American Fed'n of Gov't Employees v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981)); *NJDEP*, 626 F.2d at 1045-46.

⁷⁶See, e.g., *Syncor*, 127 F.3d at 93; *CNI*, 818 F.2d at 946.

⁷⁷See, e.g., *Chrysler*, 441 U.S. at 301-02.

⁷⁸See, e.g., *id.*

⁷⁹See *id.* at 315-16; *Perales*, 948 F.2d at 1354; *Linoz v. Heckler*, 800 F.2d 871, 877 (9th Cir. 1986); *Alcaraz*, 746 F.2d at 613; *Marshall*, 648 F.2d at 701-02.

⁸⁰See *Hudson*, 192 F.3d at 1034-35; *Fertilizer Inst. v. United States Envtl. Protection Agency*, 935 F.2d 1303, 1307-08 (D.C. Cir. 1991); *Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n*, 874 F.2d 205, 208 (4th Cir. 1989); *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984); *Levesque v. Block*, 723 F.2d 175, 182-83 (1st Cir. 1983).

- Nonlegislative rules leave agency decisionmakers free to exercise discretion, while legislative rules constrain agency discretion.⁸¹
- Nonlegislative rules employ tentative language, such as "may," while legislative rules use mandatory language, such as "will."⁸²
- Agencies should publish legislative rules in the *Federal Register*, whereas agencies need not publish nonlegislative rules.⁸³
- An agency's contention that a rule is nonlegislative shall carry some weight, but will not be dispositive in a court's determination whether or not the rule should have been subjected to notice-and-comment rulemaking.⁸⁴

⁸¹See, e.g., *CNI*, 818 F.2d at 946; *American Bus.*, 627 F.2d at 529; *Guardian Federal*, 589 F.2d at 666.

⁸²See, e.g., *Cathedral Bluffs*, 796 F.2d at 536-38 (citing *Guardian Federal*, 589 F.2d at 666); *American Bus.*, 627 F.2d at 530; cf. *Synco*, 127 F.3d at 95 (rule stating radiopharmaceuticals "should" be regulated found to be substantive).

⁸³See 5 U.S.C. § 552(a)(1)(D). In 1935, Congress passed the Federal Register Act, which established the *Federal Register* as the government's official publication in which offices of the government may disseminate information. See 44 U.S.C. §§ 1501-1511; OFFICE OF THE FEDERAL REGISTER, *supra* note 29, at 1. Publication in the *Federal Register* provides official notice of a document's existence and its contents, establishes the text as a true copy of the original document and authenticates evidence for trial. See OFFICE OF THE FEDERAL REGISTER, *supra* note 29, at 1. Each federal working day, the Office of the Federal Register publishes the *Federal Register*, providing a uniform system for federal agencies and the President to notify the public. See *id.* at 28. Since 1935, Congress has passed other statutes imposing additional obligations on agencies to publish certain statements in the *Federal Register*. See *id.* at 113-15. According to the Freedom of Information Act, federal agencies must publish in the *Federal Register*:

rules of procedure, . . . substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency. . . . Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the *Federal Register* and not so published.

5 U.S.C. § 552(a).

For a rule to be legislative and have substantive effects, it should be published in the *Federal Register*. See, e.g., *id.*; *Cathedral Bluffs*, 796 F.2d at 538-39. The converse, however, is not true; if an agency publishes a rule in the *Federal Register*, that does not necessarily make the rule legislative. See 5 U.S.C. § 552(a); *Cathedral Bluffs*, 796 F.2d at 538-39. Agencies publish many, but not all, nonlegislative rules in the *Federal Register*. See, e.g., 5 U.S.C. § 552(a); *Cathedral Bluffs*, 796 F.2d at 538-39. Often, agencies publish certain information only in internal agency materials. See, e.g., *Ruiz*, 415 U.S. at 204-05. Courts have held that such information should not have general applicability and usually relates to internal policies. See, e.g., *id.* at 235 (noting that the Bureau of Indian Affairs conceded "real legislative rule[s]" should be published in *Federal Register*); *Cathedral Bluffs*, 796 F.2d at 538-39 (noting that failure to publish in *Federal Register* indicates rule was not meant to bind).

⁸⁴See, e.g., *Mejia-Ruiz v. INS*, 51 F.3d 358, 365 (2d Cir. 1995); *Phillips Petroleum Co. v. Johnson*, 22 F.3d 616, 619 (5th Cir. 1994); *CNI*, 818 F.2d at 946; *Cathedral Bluffs*, 796 F.2d at 537-38; *General Motors*, 742 F.2d at 1565.

- Interpretative rules interpret law while legislative rules create law.⁸⁵
- General statements of policy operate prospectively and speak to future contingencies, but legislative rules have immediate impacts.⁸⁶
- Rules of agency organization apply only to internal agency machinations.⁸⁷

The United States Court of Appeals for the District of Columbia Circuit considered several of these factors in 1987, in *Community Nutrition Institute v. Young*, where the court held that certain rules which the FDA had labeled as nonlegislative were actually substantive, and thus should have been adopted as legislative rules.⁸⁸ The court found the rules to be substantive because they imposed immediate legal obligations on food producers, they constrained agency discretion and the FDA had referred to them as having the force of law.⁸⁹ The Community Nutrition Institute ("CNI"), a public interest group, and other public interest organizations, brought action against the Commissioner of the FDA for granting "action levels" the force and effect of law, even though the FDA produced them without conducting notice-and-comment process.⁹⁰ The FDA had been initiating enforcement proceedings against food producers if their goods exhibited levels of aflatoxins—unavoidable contaminants found in foods such as corn—

⁸⁵See, e.g., *Chrysler*, 441 U.S. at 302 n.31, 315–16 (noting that interpretative rules inform the public how an agency interprets a statute or how it administers its substantive rules and that interpretative rules do not create binding law); *Alcaraz*, 746 F.2d at 613 (noting that interpretative rules are essentially hortatory and instructional and they are used more for discretionary fine-tuning than for general law making); *Pickus v. United States Bd. of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974) (noting that interpretative rules interpret statutes while substantive rules create procedures expected to be followed by agency personnel and the public).

⁸⁶Compare, e.g., *American Bus.*, 627 F.2d at 531–32 (finding agency pronouncement immediately altered restrictions for trade between United States and Canada), and *Bellarno*, 678 F. Supp. at 411, 416 (holding interpretative rule invalid because it provided for automatic detention of merchandise), with *Pacific Gas*, 506 F.2d at 41–43 (holding rule assigning who receives allotments of natural gas during possible national shortages to be valid interpretative rule because tentative and prospective).

⁸⁷See *Chrysler*, 441 U.S. at 310 n.41; *Marshall*, 648 F.2d at 702 n.34.

⁸⁸See *CNI*, 818 F.2d at 945–49. The Court of Appeals for the District of Columbia Circuit hears the majority of cases involving federal agencies, so the court is regarded as having developed a level of expertise for administrative law. See *Stone v. INS*, 514 U.S. 386, 404 (1995); *Vermont Yankee*, 435 U.S. at 535 n.14.

⁸⁹See *CNI*, 818 F.2d at 945–49.

⁹⁰See *id.* at 945.

greater than the action levels.⁹¹ Concerned that the action levels were too low and failed to adequately protect public health, the CNI contended that the action levels should have been adopted only after following notice-and-comment procedures.⁹² The FDA argued the action levels fell within the nonlegislative rule exception of § 553(b)(A).⁹³

The court reasoned that the rule establishing the action levels used mandatory language and created immediate and binding effects.⁹⁴ Specifically, the rules declared that if a food product met an action level, the food "will be deemed" to be contaminated.⁹⁵ Also, the court found it compelling that the FDA had occasionally intimated that action levels established binding norms.⁹⁶ The FDA would not initiate enforcement proceedings against food producers that had amounts of contamination less than the action levels.⁹⁷ Thus, the court held that the action levels constrained agency discretion.⁹⁸ Also, the court found that the rules were substantive because the FDA required food producers to seek exemptions to the action levels.⁹⁹ The court found that if private parties must obtain exemptions to circumvent an agency's rules, then the agency intends for those rules to be substantive.¹⁰⁰ Therefore, the court held that the action levels were substantive and should have been produced only after notice-and-comment, and thus were invalid.¹⁰¹

⁹¹See *id.*

⁹²See *id.* at 945, 949.

⁹³See *id.* at 945.

⁹⁴See CNI, 818 F.2d at 947.

⁹⁵See *id.*

⁹⁶See *id.* at 947-48.

⁹⁷See *id.* at 948; Ashutosh Bhagwat, *Three-Branch Monte*, 72 NOTRE DAME L. REV. 157, 165-66 (1996).

⁹⁸See CNI, 818 F.2d at 948.

⁹⁹See *id.* at 947-49.

¹⁰⁰See *id.*

¹⁰¹See *id.* at 945-49. As a contrasting example, in 1974, in *Pacific Gas & Electric Co. v. Federal Power Commission*, the United States Court of Appeals for the District of Columbia Circuit upheld a general statement of policy as a valid nonlegislative rule because it prospectively addressed possible situations, lacked significant effects and created no binding law. See 506 F.2d at 35, 42-43, 45. In *Pacific Gas*, the Federal Power Commission issued a statement describing how it would allocate natural gas in case of a national shortage. See *id.* at 35-36. Several consumers of natural gas, particularly electric generating companies, challenged the statement by arguing it was substantive and should have been generated through § 553 process. See *id.* at 36. The court explained that although legislative rules establish standards of conduct with the force of law, general statements of policy merely announce what the agency seeks to establish as policy. See *id.* at 38. The court concluded that the policy statement was merely an announcement of the agency's future plans, so it did not require notice-and-comment process. See *id.* at 41, 45. The court noted that the

2. Some Courts Still Use "Substantial Impact" as a Factor

Some courts—including the Fourth and Fifth Circuits—use "substantial impact" as a factor to determine whether a rule should have been promulgated following notice-and-comment procedure.¹⁰² If a rule has a substantial impact on private parties, then it is a legislative rule.¹⁰³ The courts do not provide extensive explanation as to what qualifies as "substantial impact," but the case law suggests that if a rule imposes upon private parties dramatic economic changes, the rule has a substantial impact.¹⁰⁴ Since the Supreme Court's decision in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council* in 1978, however, the test has fallen into disfavor and most courts ignore it.¹⁰⁵

3. The "Public Good" Should Not Be a Factor

Litigants have argued that public policy should enter into courts' decision-making, but courts generally rule only on process and do not

critical distinction between general statements of policy and legislative rules is that policy statements have no binding effect on future administrative proceedings while legislative rules create new law which courts must follow. *See id.* at 38. Because the statement of policy was prospective and created no law, the court held it was a nonlegislative rule and, therefore, valid. *See id.* at 42-43, 45.

¹⁰²*See, e.g., Phillips Petroleum*, 22 F.3d at 620-21; *Alexandria v. Helms*, 728 F.2d 643, 647-48 (4th Cir. 1984); *Pickus*, 507 F.2d at 1112-13.

¹⁰³*See, e.g., Alexandria*, 728 F.2d at 647-48; *Pickus*, 507 F.2d at 1112.

¹⁰⁴*See, e.g., Phillips Petroleum*, 22 F.3d at 620-21. For example, in 1994, in *Phillips Petroleum Co. v. Johnson*, the United States Court of Appeals for the Fifth Circuit held that the Department of Interior ("DOI") should have subjected a disputed "procedure paper" to notice and comment process because it had a substantial impact on the natural gas industry. *See* 22 F.3d at 621. The procedure paper established new criteria for valuing natural gas liquid products. *See id.* at 618. The DOI argued the procedure paper was merely the agency's interpretation of a legislative rule. *See id.* at 619-20. Because the new rule instructed the DOI to change its valuation method from considering the range of various types of natural gas prices to considering only "spot" market prices, the court reasoned that the rule "dramatically" affected the royalty values of all oil and gas leases. *See id.* at 620-21. Despite how the agency labeled the rule, the court struck it down because it was created without process and it substantially impacted private parties. *See id.* at 619, 621.

¹⁰⁵*See, e.g., Alcaraz*, 746 F.2d at 613; *Levesque*, 723 F.2d at 182; Elizabeth Williams, *supra* note 25, § 8 (1995). In *Vermont Yankee*, the Court did not explicitly undo the substantial impact test, but the Court undermined the test to such a degree that it is no longer dispositive. *See Vermont Yankee*, 435 U.S. at 524, 543-45. The Supreme Court held that courts cannot order agencies to conduct more process than already prescribed by statute or substantive rule. *See id.* at 543-44. The Court found unpersuasive plaintiffs' argument that because the subject matter of the case—construction of a nuclear power plant—was an "[i]ssue[] of Great Public Import," the court should order the agency to conduct additional procedure before issuing a rule. *See id.* at 543-45.

incorporate the "public good" into their analyses.¹⁰⁶ Most courts rule that they have only the authority to review whether agencies followed prescribed procedures and whether agencies violated the law, but not whether agencies have formulated flawed opinions.¹⁰⁷ An agency is, ideally, composed of experts in the particular field over which it regulates, and a judge is, ideally, an expert in the field of law.¹⁰⁸ In principle, judges do not substitute agency thinking with their own opinions.¹⁰⁹ Instead, courts generally review agency process, not agency judgment.¹¹⁰ Hence, courts tend to analyze the agency's procedure rather than the real world policy effects of agency judgment.¹¹¹ As a result, the duty to provide for the public good remains with Congress and the agencies.¹¹²

II. THE LEGAL EFFECTS OF RULES

Depending on whether a rule is adopted with or without notice-and-comment process, the rule will have different legal effects.¹¹³ Legislative rules produced after notice-and-comment procedures constitute substantive law and legally bind both agencies and private parties in future legal and administrative proceedings.¹¹⁴ Conversely, non-legislative rules generally may not have binding legal effects.¹¹⁵ Non-legislative rules, however, sometimes have practical legal effects.¹¹⁶

¹⁰⁶ See *id.* at 549; *Alcaraz*, 746 F.2d at 610.

¹⁰⁷ See *Chevron, United States, Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 865-66 (1984); *Vermont Yankee*, 435 U.S. at 524, 543-50.

¹⁰⁸ See *Chevron*, 467 U.S. at 865-66.

¹⁰⁹ See *id.*

¹¹⁰ See *id.*; *Vermont Yankee*, 435 U.S. at 549; *Alcaraz*, 746 F.2d at 610.

¹¹¹ See *Chevron*, 467 U.S. at 865-66; *Vermont Yankee*, 435 U.S. at 549; *Alcaraz*, 746 F.2d at 610.

¹¹² See *Chevron*, 467 U.S. at 864-65; *Vermont Yankee*, 435 U.S. at 549; *Alcaraz*, 746 F.2d at 610.

¹¹³ See *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995); *Chrysler Corp. v. Brown*, 441 U.S. 281, 295, 315-16 (1979).

¹¹⁴ See *Bureau of Alcohol, Tobacco & Firearms v. Federal Labor Relations Auth.*, 464 U.S. 89, 98 n.8 (1983); *Chrysler*, 441 U.S. at 295; *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 537 (D.C. Cir. 1986); *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974).

¹¹⁵ See, e.g., *Guernsey*, 514 U.S. at 99; *Chrysler*, 441 U.S. at 315-16; *Linoz v. Heckler*, 800 F.2d 871, 877 (9th Cir. 1986).

¹¹⁶ See Anthony, *Interpretative Rules*, *supra* note 21, at 1328-29.

A. Nonlegislative Rules Generally Cannot Have Binding Legal Effects

Rules created without process—interpretative rules, general statements of policy, rules of agency organization and other nonlegislative rules—generally cannot have legally binding effects.¹¹⁷ In administrative and judicial proceedings, nonlegislative rules are not treated as law, but as influential agency thought that may factor into a proceeding's outcome.¹¹⁸

According to the courts, nonlegislative rules cannot be the decisive factor in a court proceeding or enforcement action.¹¹⁹ For example, in 1986, in *Thomas v. New York*, the Court of Appeals for the District of Columbia Circuit held that a letter written by the Administrator of the Environmental Protection Agency could not have binding legal effects because it had not been subjected to notice-and-comment process.¹²⁰ Several eastern states—including New York, national environmental groups, American citizens owning property in Canada and a Congressman brought suit against Lee Thomas, Administrator of the EPA under President Reagan in the early 1980s, for not revising certain air pollution standards.¹²¹ Prior to Thomas taking the helm of the EPA, Douglas Costle had been the EPA's Administrator under President Carter.¹²² Days before Reagan took office, Costle wrote a letter to then Secretary of State Edmund Muskie indicating that based on the findings of an official joint American-Canadian commission, he believed pollution emitted by the United States was responsible for causing acid rain in Canada.¹²³ According to the 1977 amendments to the Clean Air Act, if the Administrator of the EPA determines that American air pollution is causing significant harm in Canada, the EPA must order the states causing the acid rain to reduce

¹¹⁷See, e.g., *Hudson v. Federal Aviation Admin.*, 192 F.3d 1031, 1034-35 (D.C. Cir. 1999); *Guernsey*, 514 U.S. at 99; *Chrysler*, 441 U.S. at 315-16.

¹¹⁸See, e.g., *Smith v. Midland Brake, Inc.*, 180 F.3d 1154, 1165-67 (10th Cir. 1999).

¹¹⁹See, e.g., *Guernsey*, 514 U.S. at 99; *Chrysler*, 441 U.S. at 315-16.

¹²⁰See *Thomas v. New York*, 802 F.2d 1443, 1445-47 (D.C. Cir. 1986).

¹²¹See *id.* at 1445-46.

¹²²See *id.* at 1444-45. For a brief description of *Thomas*, see Robert L. Brubaker & Judith L. French-Berry, *Is a Rule by Any Other Name Still a Rule?: Case Answers Under the Clean Air Act*, 18 N. KY. L. REV. 271, 273-76 (1991). For a more thorough history and analysis, see Carol Garland, *Acid Rain over the United States and Canada: The D.C. Circuit Fails to Provide Shelter under Section 115 of the Clean Air Act While State Action Provides a Temporary Umbrella*, 16 B.C. ENV'TL. AFF. L. REV. 1, 18-29 (1988).

¹²³See *Thomas*, 802 F.2d at 1445; Jeffrey L. Roelofs, *United States-Canada Air Quality Agreement: A Framework for Addressing Transboundary Air Pollution Problems*, 26 CORNELL INT'L L.J. 421, 436-37 (1993).

air pollution.¹²⁴ Then, those states would be obligated to intensify the regulation of the private parties contributing to air pollution within the states' jurisdictions.¹²⁵ The new Administrator, Thomas, chose to ignore the letter.¹²⁶ Intent on reducing acid rain in Canada, the plaintiffs brought suit, arguing that the letter obliged the EPA to force the generating states to revise their air pollution controls.¹²⁷

The court found that the letter constituted a rule within the meaning of the APA and that it had not been created as a result of any rulemaking process.¹²⁸ The court reasoned that the rule did not fall within any of the § 553(b)(A) exceptions because it affected individual rights and obligations by causing the states to heighten their regulations, which would result in the termination or restriction of numerous utilities and manufacturers.¹²⁹ Because the EPA had not followed the notice-and-comment process to create the rule, the EPA was not required to constrain its discretion by abiding by the letter.¹³⁰ The holding in *Thomas* evidences the principle that nonlegislative rules cannot have binding legal effects.¹³¹ Reality, however, may differ from this principle.¹³²

B. Agencies May Try to Apply Nonlegislative Rules as Law Against Private Parties

When agencies treat a nonlegislative rule as law, those rules will have the *practical effect* of binding law because people tend to acquiesce to that which the government informs them constitutes the law.¹³³ Most members of the public assume all agency rules constitute legitimate law, so they simply conform to all rules.¹³⁴ By treating non-

¹²⁴See *Thomas*, 802 F.2d at 1446.

¹²⁵See *id.* at 1445.

¹²⁶See *id.*

¹²⁷See *id.* at 1445-46; Shawn M. Rosso, *Acid Rain: The Use of Diplomacy, Policy and the Courts to Solve a Transboundary Pollution Problem*, 8 J. NAT. RESOURCES & ENVTL. L. 421, 431-32 (1992-1993).

¹²⁸See *Thomas*, 802 F.2d at 1446-47; Steve Russell, Comment, *Potential Fallout From the National Acid Precipitation Assessment Program*, 6 BYU J. PUB. L. 423, 430 (1992). For the definition of a rule, see 5 U.S.C. § 551(4).

¹²⁹See *Thomas*, 802 F.2d at 1447.

¹³⁰See *id.* at 1447-48.

¹³¹See, e.g., *Chrysler*, 441 U.S. at 301-03, 315-16; *Batterton v. Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980); *Pacific Gas*, 506 F.2d at 38-39.

¹³²See Anthony, *Interpretative Rules*, *supra* note 21, at 1328-30.

¹³³See *id.*

¹³⁴See Asimow, *supra* note 25, at 384.

legislative rules as law, agencies can convince the public into following nonlegislative rules.¹³⁵

Occasionally, agencies rely upon nonlegislative rules for enforcement actions.¹³⁶ For example, in 1989 in *United States v. Picciotto*, the Court of Appeals for the District of Columbia reversed a conviction based upon a nonlegislative rule because, by virtue of prescribing unlawful conduct, the rule imposed binding obligations on the public.¹³⁷ In 1981, Concepcion Picciotto began a six year, twenty-four-hour-per-day protest against nuclear war across the street from the White House in LaFayette Park.¹³⁸ In 1988 the Park Service issued an "additional condition" without performing any notice-and-comment procedures.¹³⁹ The additional condition prohibited the storage of property in LaFayette Park beyond that which is reasonably necessary to stage a twenty-four hour protest.¹⁴⁰ A Park Service police officer arrested Picciotto for violating the additional condition.¹⁴¹ The United States District Court for the District of Columbia found her guilty and gave her a ten-day suspended prison sentence and six months unsupervised probation.¹⁴² The Court of Appeals reversed the conviction, holding that the additional condition was substantive because it imposed obligations enforceable by criminal penalty, even though the Park Service had created it without notice-and-comment.¹⁴³ Although Picciotto won her appeal, this case demonstrates how agencies may create rules without notice-and-comment and treat them as binding law.¹⁴⁴ Besides initiating or threatening enforcement actions based on nonlegislative rules, agencies often rely on them to grant or deny applications and permits.¹⁴⁵ Similarly, fed-

¹³⁵ See Anthony, *Interpretative Rules*, *supra* note 21, at 1328-31.

¹³⁶ See *United States v. Picciotto*, 875 F.2d 345, 346 (D.C. Cir. 1989); *Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n*, 874 F.2d 205, 206-07 (4th Cir. 1989); Anthony, *Interpretative Rules*, *supra* note 21, at 1333.

¹³⁷ See 875 F.2d at 348-49.

¹³⁸ See *id.* at 346.

¹³⁹ See *id.*

¹⁴⁰ See *id.*

¹⁴¹ See *id.*

¹⁴² See *Picciotto*, 875 F.2d at 346.

¹⁴³ See *id.* at 346-49.

¹⁴⁴ See *id.*

¹⁴⁵ See, e.g., *United States v. Apex Oil Co.*, 132 F.3d 1287, 1288-89, 1291 (9th Cir. 1997) (upholding dismissal of oil tanker captains indicted by the Coast Guard for causing oil pollution according to the terms of a nonlegislative rule); *American Bus. Ass'n v. United States*, 627 F.2d 525, 527, 531-34 (D.C. Cir. 1980) (holding nonlegislative rules regarding applications to transport goods to Canada to be substantive and therefore invalid); Anthony, *Interpretative Rules*, *supra* note 21, at 1333, 1340.

eral agencies can utilize nonlegislative rules to influence programs administered by the states.¹⁴⁶

As the trial court did in *Picciotto*, courts sometimes agree with the agencies and treat nonlegislative rules as binding law.¹⁴⁷ For instance, in 1993, in *United States v. American National Red Cross*, the District Court for the District of Columbia issued an injunction against the Red Cross, as part of a settlement, ordering the Red Cross to conform with all of the FDA's nonlegislative rules regarding blood.¹⁴⁸ Concerned with the integrity of the blood supply, the FDA passed numerous legislative and nonlegislative rules regarding how blood was to be handled.¹⁴⁹ Finding that the Red Cross had failed to meet the standards imposed by the FDA, the court specifically differentiated between the FDA's legislative rules and nonlegislative rules, and ordered the Red Cross to abide by both.¹⁵⁰ Therefore, rules created without notice-and-comment became binding law for the Red Cross.¹⁵¹

¹⁴⁶See, e.g., *Levesque v. Block*, 723 F.2d 175, 177-78 (1st Cir. 1983) (involving "interim rules," issued by the Secretary of Agriculture, which reduced expenditures to New Hampshire Food Stamp program); *Marshall*, 648 F.2d at 696-99 (involving "Balance of State procedure," issued by the Department of Labor, which reduced expenditures to Maryland unemployment program). See also Anthony, *Interpretative Rules*, *supra* note 21, at 1353.

¹⁴⁷See, e.g., *Picciotto*, 875 F.2d at 349 (reversing trial court's conviction based on nonlegislative rule); *United States v. American Nat'l Red Cross*, 1993 WL 186094, at *1-2 (D.D.C. 1993) (issuing injunction ordering company to abide by numerous nonlegislative rules).

¹⁴⁸See 1993 WL 186094, *1-2; see generally Dept. of Justice, *Injunction Gives FDA Broad Power over Red Cross*, DEP'T OF JUSTICE ALERT, May 1993, at 13-15 [hereinafter *Injunction*]. Created by an act of Congress, the Red Cross is a private corporation that supplies blood to health care facilities. See *Red Cross*, 1993 WL 186094, at *1.

¹⁴⁹See, e.g., 21 C.F.R. §§ 210-11, 600-80 (1998); *Red Cross*, 1993 WL 186094, at *1-2. Both the FDA and the Red Cross have been targets in lawsuits by families of those who contracted AIDS from blood transfusions. See, e.g., *Doe v. American Nat'l Red Cross*, 112 F.3d 1048, 1048-50 (9th Cir. 1997).

¹⁵⁰See *Red Cross*, 1993 WL 186094, at *2. The opinion states:

Within the time frames specified in this Decree, [the Red Cross] shall take steps necessary to ensure compliance with: (a) the provisions set forth in this Decree; (b) the [Food, Drug and Cosmetics Act], the [Public Health Service Act], and all applicable regulations (hereafter, collectively, "the law"); and (c) [the Red Cross] standard operating procedures, including, but not limited to, Blood Services Directives ("BSDs"), Blood Service Letters ("BSLs"), regional and local standard operating procedures, and any other instruments (hereafter, collectively, "SOPs").

Id. (emphasis added).

Throughout the injunction, the court ordered the Red Cross to follow the SOPs. See *id.* at *1-*14; see also *Injunction*, *supra* note 148, at 13 (noting injunction's provisions "detailed," "broad" and "numerous").

¹⁵¹See *Red Cross*, 1993 WL 186094, at *2.

C. Analysis of the Legal Effects of Nonlegislative Rules

The situation in *Red Cross* must be avoided because it robs the public of the opportunity to offer input on nonlegislative rules.¹⁵² Because the Red Cross, the FDA and the court agreed to this settlement, the FDA's nonlegislative rules regarding blood bind the Red Cross, even though the rules create new law, impose legal obligations, have immediate effects, are not necessarily published in the *Federal Register* and may have significant effects on the public.¹⁵³ Moreover, the public lost the opportunity to participate in the creation of laws that will affect many people, including patients in need of blood transfusions.¹⁵⁴

When courts allow nonlegislative rules to have substantive effects on the public, they undermine the foundation underlying the APA and the notice-and-comment procedures therein.¹⁵⁵ Nonlegislative rules should not impose obligations or immediate effects on the public, and courts and agencies should strive to avoid using them in such a manner. Too often, nonlegislative rules have a practical binding legal effect because people do not realize those rules are not binding. The parties affected by the rules choose to acquiesce to the rules rather than attract agency attention, they lack the resources to challenge the rules, or they have already fought the rule in court and have given up on the appeals process.¹⁵⁶

Agency personnel and the public should be able to use nonlegislative rules for guidance, but not as binding law.¹⁵⁷ This would allow agency personnel to deviate freely from nonlegislative rules, therefore producing the downside of diminished uniformity between agency actions.¹⁵⁸ Accordingly, for matters on which an agency wishes to act

¹⁵²See *id.* at *1-*2.

¹⁵³See *id.*; see also, e.g., *Morton v. Ruiz*, 415 U.S. 199, 235 (1974) (noting that rules with binding effects should be published); *Marshall*, 648 F.2d at 701-02 (noting that nonlegislative rules do not impose obligations); *Alcaraz v. Block*, 746 F.2d 593, 613 (9th Cir. 1984) (interpretative rules do not create new law); *American Bus.*, 627 F.2d at 531-32 (noting that interpretative rules may not have immediate effects).

¹⁵⁴See *Red Cross*, 1993 WL 186094, at *1-*2.

¹⁵⁵See, e.g., 5 U.S.C. § 553; *Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, 1027-28 (D.C. Cir. 1978) (stating that the APA infuses the administrative process with "openness, explanation and participatory democracy"); *Red Cross*, 1993 WL 186094, at *1-*2.

¹⁵⁶See Anthony, *Interpretative Rules*, *supra* note 21, at 1327-32; Asimow, *supra* note 25, at 384.

¹⁵⁷See, e.g., *Alcaraz*, 746 F.2d at 613 (noting that interpretative rules are essentially hortatory and instructional and they are used more for discretionary fine-tuning than for general law making).

¹⁵⁸Cf. Noah, *supra* note 60, at 120-27 (suggesting that nonlegislative rules should bind because that would foster agency consistency).

consistently, it would not be able to rely on nonlegislative rules. Rather, the agency should follow the APA procedures for creating binding, uniform rules: legislative rules created after notice-and-comment process.¹⁵⁹

Either Congress, the courts or the agencies themselves should create law clarifying that nonlegislative rules cannot have binding effects.¹⁶⁰ For example, the FDA recently promulgated a set of rules to better exercise the § 553(b)(A) exception.¹⁶¹ On their surface, the FDA's new rules attempt to elucidate how the agency will create nonlegislative rules and to pronounce that nonlegislative rules lack binding legal effect.¹⁶² The next Part analyzes the FDA's new rules, as well as an act proposed by the Senate to reform agency regulation in general.¹⁶³

III. THE FUTURE OF NONLEGISLATIVE RULES

Many members of Congress have argued that federal agencies create too many regulations and cost the American public and the United States government too much money.¹⁶⁴ Many have clamored for a reform of agencies that would dramatically restrain agency authority to create legislative rules.¹⁶⁵ Possibly as a response to Congress's plans for broad reforms and the confusion surrounding nonlegislative rules, the FDA has taken steps to clarify how it creates and applies its nonlegislative rules.¹⁶⁶

¹⁵⁹See 5 U.S.C. § 553.

¹⁶⁰See, e.g., *Guardian Fed. Sav. & Loan Ass'n v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 658, 666 (D.C. Cir. 1978).

¹⁶¹See Good Guidance Practices, 62 Fed. Reg. 8961, 8967-71 (1997) (to be codified at 21 C.F.R. pt. 10).

¹⁶²See *id.*

¹⁶³See *infra*, notes 164-293 and accompanying text.

¹⁶⁴See, e.g., COMMITTEE ON GOVERNMENTAL AFFAIRS, THE REGULATORY IMPROVEMENT ACT OF 1999, S. REP. NO. 106-110, at 5-6 (1999) (language identical to COMMITTEE ON GOVERNMENTAL AFFAIRS, THE REGULATORY IMPROVEMENT ACT OF 1998, S. REP. NO. 105-188, at 5-6 (1998)).

¹⁶⁵See, e.g., S. REP. NO. 106-110, at 1-4 (language identical to S. REP. NO. 105-188, at 1-4).

¹⁶⁶See *id.*; see also Hoffman, *supra* note 60, at 10-11 (noting that the FDA created Good Guidance Practices because the agency had become potential target for Congress to enact administrative reform).

A. The Food and Drug Administration's Good Guidance Policies

In February of 1997, the FDA published a set of guidelines entitled *Good Guidance Practices* ("GGPs") in the *Federal Register*.¹⁶⁷ The GGPs set forth the Agency's policies and procedures for the development, issuance and use of "guidance documents"—the FDA's term for nonlegislative rules.¹⁶⁸ The FDA has asserted that the purposes of guidance documents are to clarify statutes or substantive rules and to implement the Agency's congressional mandate in an "effective, fair, and consistent manner."¹⁶⁹

Among the revisions listed in the GGPs, the FDA provided for clearer nomenclature and greater public input.¹⁷⁰ The GGPs revised the appropriate terminology for guidance documents by requiring all of them to include the label "guidance."¹⁷¹ The term "guidance documents" includes and excludes numerous categories of documents.¹⁷² As well, guidance documents must identify to whom they apply.¹⁷³ According to the GGPs, the FDA will publish a list of all of its guidance documents in the *Federal Register*.¹⁷⁴ Furthermore, the FDA

¹⁶⁷See *Good Guidance Practices*, 62 Fed. Reg. at 8967-71.

¹⁶⁸See *id.* The FDA previously requested suggestions on how best to improve its procedures addressing interpretative rules. See *Request for Comments Regarding the FDA's Development and Use of Guidance Documents*, 61 Fed. Reg. 9181, 9181 (1996).

¹⁶⁹See *Good Guidance Practices*, 62 Fed. Reg. at 8967.

¹⁷⁰See *id.* at 8967-71.

¹⁷¹See *id.* at 8969.

¹⁷²See *id.* at 8967. "Guidance documents" include:

documents prepared for FDA staff, applicants/sponsors, and the public that: (1) Relate to the processing, content, and evaluation/approval of submissions; (2) relate to the design, production, manufacturing, and testing of regulated products; (3) describe the agency's policy and regulatory approach to an issue; or (4) establish inspection and enforcement policies and procedures. "Guidance documents" do not include documents relating to internal FDA procedures, agency reports, general information documents provided to consumers, speeches, journal articles and editorials, media interviews, press materials, warning letters, or other communications directed to individual persons or firms.

Id.

¹⁷³See *id.* at 8969.

¹⁷⁴See *Good Guidance Practices*, 62 Fed. Reg. at 8969. For example, the FDA published lists of guidance documents in the *Federal Register* at: Update of Guidance Documents at the Food and Drug Administration, 64 Fed. Reg. 42,382, 42,382-91 (1999); Annual Comprehensive List of Guidance Documents at the Food and Drug Administration, 64 Fed. Reg. 31,228, 31,228-80 (1999); Quarterly List of Guidance Documents at the Food and Drug Administration, 64 Fed. Reg. 888, 888-903 (1999); Quarterly List of Guidance Documents at the Food and Drug Administration, 63 Fed. Reg. 36,413, 36,413-24 (1998);

will update existing guidance documents to include these standards as the Agency revises them.¹⁷⁵

In addition, the GGP's establish a mechanism to include public participation in the development of guidance documents.¹⁷⁶ The GGP's rank guidance documents into two levels—level 1 and level 2—and establish procedures for public input for both.¹⁷⁷ Prior to promulgating level 1 guidance documents, the FDA will solicit public input by posting a draft of the document on the FDA's World Wide Web home page.¹⁷⁸ Then, the FDA will review all comments before promulgating the final guidance document.¹⁷⁹ For level 2 guidance documents, the FDA will provide an opportunity for the public to comment after the FDA issues and implements them.¹⁸⁰

Furthermore, the GGP's stipulate that guidance documents are not binding on the public or the FDA.¹⁸¹ The proposed GGP's instruct FDA personnel that "[b]ecause guidance documents are not binding, mandatory words such as 'shall,' 'must,' 'require' and 'requirement' are inappropriate"¹⁸² Correspondingly, the GGP's declare that

Comprehensive List of Current Guidance Documents at the Food and Drug Administration, 63 Fed. Reg. 9795, 9795-9843 (1998).

¹⁷⁵See Good Guidance Practices, 62 Fed. Reg. at 8969.

¹⁷⁶See *id.* at 8968-69.

¹⁷⁷See *id.* at 8968. For an example of a level 1 guidance, see the guidance for industry entitled *Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products* (visited Oct. 1, 1999) <<http://www.fda.gov/cder/guidance/2836dft.htm>> (notice of availability published at 64 Fed. Reg. 29,657, 29,657 (1999)). For an example of a level 2 guidance, see the compliance guide entitled *Evaluation and Processing Post Donation Information Reports* (visited Oct. 1, 1999) <http://www.fda.gov/ora/compliance_ref/cpg/cpgbio/cpg230-140.htm> (notice of availability published at 64 Fed. Reg. 44,740, 44,740-41 (1999)). Note that the FDA also publishes guidances without classifying them as either level 1 or 2. See International Conference on Harmonisation; Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products, 64 Fed. Reg. 44,928, 44,929 (1999).

¹⁷⁸See Good Guidance Practices, 62 Fed. Reg. at 8968 (mentioning FDA WWW home page, at <<http://www.fda.gov>>).

¹⁷⁹See *id.* The GGP's provide three exceptions, allowing the FDA to issue level 1 guidance without prior public input if:

- (1) there are public health reasons for immediate implementation; (2) there is a new statutory requirement, executive order, or court order that requires immediate implementation and guidance is needed to help effect such implementation; or (3) the guidance is presenting a less burdensome policy that is consistent with public health.

Id.

¹⁸⁰See *id.*

¹⁸¹See *id.* at 8967, 8969.

¹⁸²See Good Guidance Practices, 62 Fed. Reg. at 8969. The entire provision states:

"[g]uidance documents do not themselves establish legally enforceable rights or responsibilities and are not legally binding on the public or the agency."¹⁸³ FDA guidance documents will state:

This guidance document represents the agency's current thinking on * * *. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both.¹⁸⁴

Another part of the GGPs reads, in pertinent part: "decisionmakers will take steps to ensure that their staff do not deviate from the guidance document without appropriate justification and appropriate supervisory concurrence."¹⁸⁵

B. Analysis of the Good Guidance Policies

The FDA's proposed GGPs represent a worthy first step because they attempt to abrogate some of the confusion surrounding nonlegislative rules.¹⁸⁶ The GGPs ultimately fail, however, because they include contradictory notions and they do not address all nonlegislative rules.¹⁸⁷ Nevertheless, some of the GGPs' provisions serve prudent public policy.¹⁸⁸

Absence of Mandatory Language. Because guidance documents are not binding, mandatory words such as "shall," "must," "require" and "requirement" are inappropriate unless they are being used to describe or discuss a statutory or regulatory requirement. Before a new guidance is issued, it should be reviewed to ensure that mandatory language has not been used.

Id.

¹⁸³*Id.* at 8967. When the FDA published the GGPs in the *Federal Register*, the agency stated that the GGPs were, ironically enough, still nonbinding guidance documents, pending the amendment of FDA's regulations. *See id.* at 8961. The FDA intimated that it planned to update its current legislative rules, which state that an FDA interpretative rule "obligates the agency to follow it." *See* Advisory Opinions, 21 C.F.R. § 10.85 (1998); Good Guidance Practices, 62 Fed. Reg. at 8961. In its commentary on the GGPs, the FDA asserted that it would begin adhering to the GGPs although it has not yet fully implemented them. *See* Good Guidance Practices, 62 Fed. Reg. at 8961.

¹⁸⁴*Id.* at 8969.

¹⁸⁵*Id.* at 8967.

¹⁸⁶*See id.* at 8961-71; Hoffman, *supra* note 60, at 11 (noting that commentators applauded FDA's effort, but highly criticized GGPs).

¹⁸⁷*See* Good Guidance Practices, 62 Fed. Reg. at 8961-71; *infra* notes 196-236 and accompanying text.

¹⁸⁸*See* Good Guidance Practices, 62 Fed. Reg. at 8969.

1. The Benefits of the Good Guidance Practices

The GGP's provide some improvements to how the FDA approaches nonlegislative rules. For example, requiring all guidelines to specify to whom they apply can only enhance understanding among the public and the Agency.¹⁸⁹ Additionally, printing a list of all nonlegislative rules in the *Federal Register* contributes to better awareness of the FDA's rules.¹⁹⁰

The provisions providing for public participation in the creation of guidance documents serve the purposes behind the APA.¹⁹¹ The process for creating level 1 guidance documents resembles informal rulemaking because the FDA will accept commentary and respond to it.¹⁹² This procedure seems beneficial because it fosters public participation, which makes the Agency better aware and the public better represented.¹⁹³ This arrangement raises the question, however, if the agency is going to accept commentary prior to implementing a rule, why not simply employ informal notice-and-comment rulemaking as defined in the APA?¹⁹⁴ Perhaps the FDA wishes to have more information when it promulgates guidelines lacking the binding force of law, thereby reserving agency discretion.¹⁹⁵ Regardless, the two-tier system is not completely successful. Like the rest of the GGP's, it presents potential problems.

2. Problems with the Good Guidance Practices

The two-tier system may contribute to the fog already engulfing nonlegislative rules.¹⁹⁶ Now, rather than legislative rules versus nonlegislative rules, people must contend with legislative rules, level 1 guidance and level 2 guidance. Also, the provision for level 2 guidance offers no improvement to the status quo. Because the agency will not consider public comment prior to issuing a level 2 guidance, level 2 guidance is the same as a nonlegislative rule. Essentially, level 2

¹⁸⁹ See *id.*

¹⁹⁰ See *id.*

¹⁹¹ See *id.* at 8968-69.

¹⁹² See *id.* at 8968; Nancy K. Plant, *Prescription Drug Promotion on the Internet: Tool for the Inquisitive or Trap for the Unwary?*, 42 ST. LOUIS U. L.J. 89, 93 n.26 (1998).

¹⁹³ See Good Guidance Practices, 62 Fed. Reg. at 8968.

¹⁹⁴ See *id.*

¹⁹⁵ See *id.*; see also, e.g., *Community Nutrition Inst. v. Young*, 818 F.2d 943, 948 (D.C. Cir. 1987) (noting that nonlegislative rules cannot restrain agency discretion).

¹⁹⁶ See Good Guidance Practices, 62 Fed. Reg. at 8968.

guidance documents are everyday nonlegislative rules, while level 1 documents purport to be pseudo-legislative rules.¹⁹⁷

One problem that could arise from this arrangement is that the FDA could publish notice of a proposed level 1 guidance document, accept commentary and publish the rule.¹⁹⁸ Later, the FDA may treat the document as if it were binding law by arguing the Agency conducted notice-and-comment while creating the document, so it has met the requirements of § 553.¹⁹⁹ The FDA should not take this path, because a private party potentially could overlook or disregard a proposed level 1 guidance document, while that same party would have taken more seriously a proposal for an actual legislative rule.²⁰⁰ Still, by encouraging public participation, the procedure for creating level 1 guidances will probably accomplish more good than ill.²⁰¹

Furthermore, the two-level system could confuse the process by which the FDA repeals rules. To repeal a legislative rule, an agency must create a second legislative rule.²⁰² To repeal a nonlegislative rule, an agency need only issue another nonlegislative rule.²⁰³ Because both level 1 and level 2 guidance documents are nonlegislative rules, the FDA could use either level to amend or repeal a guidance within another level. For example, the FDA could create a level 1 guidance document after the public has an opportunity to participate, then later amend or repeal that document with a level 2 guidance document without engaging in notice-and-comment.²⁰⁴ Such a situation would mislead the public and negate the accountability inherent in the process to create level 1 guidance. The FDA should not have bothered to introduce the two-tier system because it adds to the complexity of nonlegislative rules.

The main problem with the GGP's, however, is that they create contradictory presumptions.²⁰⁵ The GGP's state that the FDA must

¹⁹⁷ See *id.*; Plant, *supra* note 192, at 93 n.26.

¹⁹⁸ See Good Guidance Practices, 62 Fed. Reg. at 8968.

¹⁹⁹ See *id.*

²⁰⁰ See *id.*

²⁰¹ See *id.*; see, e.g., *Guardian Fed. Sav. & Loan Ass'n v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 658, 662 (D.C. Cir. 1978) (noting that public participation improves agency rulemaking).

²⁰² See *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109-10 (D.C. Cir. 1993).

²⁰³ See *Chevron, United States, Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 865-66 (1984); see also *Hudson v. Federal Aviation Admin.*, 192 F.3d 1031, 1035 (D.C. Cir. 1999) (upholding policy statement that negated prior policy statement).

²⁰⁴ See Good Guidance Practices, 62 Fed. Reg. at 8968.

²⁰⁵ See *id.*

avoid including words such as "shall" and "must" in guidance documents and that the FDA's guidelines will not "operate to bind FDA or the public."²⁰⁶ Elsewhere, the GGPs contradict these provisions by declaring that FDA personnel must follow guidance documents unless there is "appropriate justification and appropriate supervisory concurrence."²⁰⁷ The no-mandatory-language and do-not-operate-to-bind provisions establish a presumption that FDA personnel *are not* bound by guidance documents, but the appropriate-justification-and-concurrence provision establishes a presumption that agency personnel *are* bound by guidance documents.²⁰⁸ This inconsistency will only prove to exacerbate the schizophrenia already surrounding the § 553(b) (A) exception. Agency personnel will be unsure how to act and private entities will be uncertain whether nonlegislative rules may bind agency personnel and whether the rules may have indirect obligatory effects on them.²⁰⁹

Aimed at improving administrative consistency, the appropriate-justification-and-concurrence provision initially may appear prudent.²¹⁰ The provision puts the public on notice that the FDA *usually* will do as it says. The appropriate-justification-and-concurrence provision establishes a presumption that the FDA must follow its guidelines. It also provides two vague exceptions, allowing staff members to deviate from them if they have "appropriate justification" or "appropriate supervisory concurrence."²¹¹ The GGPs, however, fail to define either exception.²¹²

The meaning of "appropriate justification" is completely unclear.²¹³ The other half of the exception, that employees can only deviate from guidelines with "appropriate supervisory concurrence," is also vague, but probably more useful.²¹⁴ While the phrase "appropriate supervisory concurrence" is horribly imprecise, it seems to create a procedural step.²¹⁵ The GGPs suggest that before an FDA employee may abridge a guidance document, the employee must obtain permission from a superior. The GGPs, unfortunately, do not explain further

²⁰⁶ See *id.* at 8967, 8969.

²⁰⁷ See *id.* at 8967.

²⁰⁸ See *id.* at 8967, 8969.

²⁰⁹ See Good Guidance Practices, 62 Fed. Reg. at 8967, 8969.

²¹⁰ See *id.* at 8967.

²¹¹ See *id.*

²¹² See *id.*

²¹³ See *id.*

²¹⁴ See Good Guidance Practices, 62 Fed. Reg. at 8967.

²¹⁵ See *id.*

the exception.²¹⁶ Should a low-level FDA employee simply ask his supervisor for permission? Should an employee write a formal petition to the Administrator? Should supervisors obtain permission from higher-ranking managers before authorizing subordinates to deviate from guidance documents? The language creates the possibility for an FDA employee with subordinates to circumvent the spirit of the GGP's. For example, if a supervisor orders a subordinate to deviate from guidance documents and simultaneously grants that subordinate the authority to perform the action—which could arguably amount to “supervisory concurrence”—the supervisor can ignore nonlegislative rules.²¹⁷

The no-mandatory-language and do-not-operate-to-bind provisions, however, help resolve the complexity surrounding nonlegislative rules.²¹⁸ As numerous courts have held, nonlegislative rules should not include compulsory language and may not create legally binding standards.²¹⁹ By emphasizing this point for agency personnel, the FDA is wisely serving itself and the public. If both agency employees and members of the public understand that nonlegislative rules use tentative language and are not legally binding, less confusion will exist. All parties concerned will understand that nonlegislative rules are only tentative guidelines, and that only legislative rules carry the force of law.

To remedy the contradiction in the GGPs, the FDA should excise the appropriate-justification-and-concurrence provision and maintain both the no-mandatory-language and do-not-operate-to-bind provisions.²²⁰ Including the appropriate-justification-and-concurrence pro-

²¹⁶See *id.*

²¹⁷See *id.*; Hoffman, *supra* note 60, at 11 (pointing out that commentators have noted the GGPs pay insufficient attention to ensuring FDA personnel will follow them).

²¹⁸See Good Guidance Practices, 62 Fed. Reg. at 8967, 8969.

²¹⁹See, e.g., *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 536–38 (D.C. Cir. 1986); Good Guidance Practices, 62 Fed. Reg. at 8967, 8969.

²²⁰See Good Guidance Practices, 62 Fed. Reg. at 8967, 8969. In a comment written in 1996, the Community Nutrition Institute (“CNI”) recommended the FDA specify that its guidelines have no legal effect in judicial proceedings and that the FDA should not expect courts to defer to those guidance documents. See David Wirth, Comments of the Community Nutrition Institute on FDA’s Notice Concerning Development and Use of Guidance Documents 4–8 (1996) (on file with author). Following that logic, the CNI also suggested the FDA should specify in all of its guidance documents that the guidelines do not limit agency discretion. See *id.* at 4–8. As the CNI suggested, the FDA would do better to establish the presumption that the agency may not always follow guidance documents because they are never legally binding. See *id.* at 4–8. The CNI also recommended that the GGPs should specify guidance documents are final agency actions and should explain standards for judicial review of guidance documents. See *id.*

vision will only cause more confusion. The purpose behind the provision seems to be to assure the public that agency personnel will follow guidance documents.²²¹ Because the appropriate-justification-and-concurrence provision is so ambiguous, however, FDA personnel could easily sidestep agency guidelines.²²² Moreover, informing the public that there is a presumption that agency personnel follow guidance documents would mislead the public, because courts of law will hold otherwise.²²³

The FDA should retain the do-not-operate-to-bind provision, but it should expand on it.²²⁴ The FDA should provide further information and explain the ramifications of the provisions. The GGP's should specify that FDA personnel may not rely on nonlegislative rules to establish obligations on private parties, initiate enforcement actions or affect applications.²²⁵ Nonlegislative rules are a confusing subject matter, and the FDA would do well to thoroughly describe to its personnel and constituents how to approach them.

One other potential problem is that the GGP's state that guidance documents include only certain types of agency statements.²²⁶ The GGP's never actually mention interpretative rules, general statements of policy, nonlegislative rules or § 553(b)(A).²²⁷ The language of the GGP's suggests that interpretative rules and policy statements would fall under the definition of guidance documents, but that is not explicitly stated.²²⁸ Therefore, it is possible that the FDA could create a rule without notice-and-comment process and label it as an "interpretative rule," even though that rule creates rights and obligations and is actually a legislative rule in disguise.²²⁹ If a private party challenges the validity of the rule and tries to classify it as a guidance document, which by the FDA's own GGP's cannot operate to bind the public, the FDA could argue that the rule is an interpretative rule and not a guidance document. Thus, the GGP's should state that "guidance documents" also include all agency statements promulgated under

²²¹ See Good Guidance Practices, 62 Fed. Reg. at 8967.

²²² See *id.*

²²³ See, e.g., *Cathedral Bluffs*, 796 F.2d at 536-38.

²²⁴ See Good Guidance Practices, 62 Fed. Reg. at 8967, 8969.

²²⁵ See *id.*; Anthony, *Interpretative Rules*, *supra* note 21, at 1332-55.

²²⁶ See Good Guidance Practices, 62 Fed. Reg. at 8967.

²²⁷ See *id.*

²²⁸ See *id.* at 8967-69.

²²⁹ See *id.* at 8967.

§ 553(b) (A) of the APA.²³⁰ That would help reduce the confusion surrounding the exception and guidance documents.²³¹

Finally, the GGPs fail because by describing the numerous types of agency statements that do not fall within the term "guidance documents"—such as internal FDA procedures, agency reports, journal articles, press releases and speeches—the FDA suggests that such statements *could* operate to bind the Agency and the public.²³² The GGPs state that guidance documents may not operate to bind and may not include mandatory language, so by excluding these other categories of statements, the GGPs imply that FDA personnel may treat them as legally binding.²³³ The FDA could circumvent the purposes of the APA by issuing an "agency report"—a document specifically excluded from the definition of guidance documents—without taking into account public input, and then treat that report as binding law.²³⁴ Again, the FDA has an opportunity to issue a rule in nonlegislative trappings that could have significant effects on the public.²³⁵

Thus, the GGPs fail to curtail the abuses and misunderstandings surrounding the § 553(b) (A) exception.²³⁶ The GGPs, however, succeed in introducing some worthwhile measures that may help assuage the nonlegislative rule dilemma. Specifically, explaining that guidance documents do not operate to bind, specifying to whom guidance documents apply, requiring the FDA to publish all of its guidance documents, and providing for more public input in the creation of level 1 guidance are pragmatic provisions. The GGPs, however, apply to only one agency. To establish greater efficiency and consistency in the use of nonlegislative rules throughout the federal government, Congress ought to revise nonlegislative rules for all agencies.

C. *The Proposed Regulatory Improvement Act*

Senator Carl Levin (D-MI), with Fred Thompson (R-TN) and numerous other co-sponsors, introduced the Regulatory Improve-

²³⁰ See 5 U.S.C. § 553(b) (A); Good Guidance Practices, 62 Fed. Reg. at 8967.

²³¹ See 5 U.S.C. § 553(b) (A); Good Guidance Practices, 62 Fed. Reg. at 8967.

²³² See Good Guidance Practices, 62 Fed. Reg. at 8967.

²³³ See *id.* at 8967, 8969.

²³⁴ See *id.*

²³⁵ See *id.*

²³⁶ See 5 U.S.C. § 553(b) (A); Good Guidance Practices, 62 Fed. Reg. at 8967-71.

ment Act of 1999 ("Act") to the Senate.²³⁷ In July 1999, the Senate Committee on Governmental Affairs ("Committee") published a Report on the proposed Act.²³⁸ In the Report, the Committee noted that the annual cost of agency regulations is nearly \$300 billion and that there are about sixty federal agencies issuing regulations at a rate of approximately 4000 per year.²³⁹ The Committee contended that federal agencies overly regulate and interfere with individuals, businesses and local governments.²⁴⁰ The proposed Act provides that federal agencies should follow complex procedural requirements before adopting "major" legislative rules—those that would impose costs of more than \$100 million.²⁴¹ According to the Act, when agencies attempt to adopt major legislative rules they would have to conduct thorough cost-benefit analyses at both the proposed and final rule-making stages.²⁴² If an agency attempts to create rules affecting health, safety or the environment, the agency also would have to conduct a thorough risk assessment.²⁴³ Moreover, the Act provides the

²³⁷ See The Regulatory Improvement Act of 1999, S. 746, 106th Cong. §§ 601–12, 621–29, 631–32, 641–44 (1999). In 1997, Senator Levin first introduced the Regulatory Improvement Act during the 105th Congress. See S. 981, 105th Cong. (1997). Senator Thompson was one of the bill's first co-sponsors, and people often refer to the bill as the Levin-Thompson Regulatory Improvement Act. See John F. Cooney, *Regulatory Reform: The Long and Winding Road*, 23 ADMIN. & REG. L. NEWS, Fall 1998, at 1. During 1998, the bill's title changed to the Regulatory Improvement Act of 1998. See S. 981, 105th Cong. (1998). For the 106th Congress, Senator Levin reintroduced the bill, virtually unchanged, in 1999 as S. 746, the Regulatory Improvement Act of 1999.

²³⁸ See COMMITTEE ON GOVERNMENTAL AFFAIRS, THE REGULATORY IMPROVEMENT ACT OF 1999, S. REP. NO. 106–110. In 1998, the Senate Committee on Governmental Affairs published a report describing the proposed act, then bill S. 981. See COMMITTEE ON GOVERNMENTAL AFFAIRS, THE REGULATORY IMPROVEMENT ACT OF 1998, S. REP. NO. 105–188. In 1999, the Senate Committee on Governmental Affairs issued another report—almost identical to the 1998 report—to accompany the proposed statute. See S. REP. NO. 106–110.

²³⁹ See S. REP. NO. 106–110, at 5–6 (language identical to S. REP. NO. 105–188, at 5–6).

²⁴⁰ See *id.*

²⁴¹ See S. 746. A "major rule" is a rule that:

- (A) the agency proposing the rule or the Director [of the Office of Management and Budget] reasonably determines is likely to have an annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs; or
- (B) is otherwise designated a major rule by the Director on the ground that the rule is likely to adversely affect, in a material way, the economy, a sector of the economy, including small business, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, or communities

S. 746 § 621(7). For a brief overview of the proposed statute, see generally Cooney, *supra* note 237, at 1.

²⁴² See S. 746 § 623(b), (c).

²⁴³ See *id.* § 624.

Office of Management and Budget ("OMB")—an agency mandated to improve the efficiency of other administrative agencies—with the authority to conduct oversight review of major rules.²⁴⁴

The Regulatory Improvement Act states that it does not apply to rules falling within § 553's exceptions.²⁴⁵ The Senate Report, however, states that if a nonlegislative rule "alters or creates rights or obligations of persons outside the agency," then it must be considered a legislative rule within the meaning of the proposed Act.²⁴⁶ Furthermore, the Report reads:

the Committee cautions the agencies that any statement of general applicability that actually alters or creates rights or obligations of persons outside the agency is included in this definition. While informal agency guidance is encouraged, agencies should not attempt to evade the requirements of this legislation through mischaracterizations of such materials.²⁴⁷

Although the proposed statute itself does not address interpretative rules, the accompanying Senate Report addresses the potential misuse of the § 553(b) (A) exception.²⁴⁸

D. Analysis of the Proposed Regulatory Improvement Act

The proposed Regulatory Improvement Act says little about nonlegislative rules and the Act's potential effect on them is unclear.²⁴⁹ The language of the Senate Report attempts to restrain agencies that may misuse nonlegislative rules by requiring burdensome and time-consuming cost-benefit analyses and risk assessments for substantive rules dressed in the trappings of nonlegislative rules.²⁵⁰ It appears that

²⁴⁴See Office of the Management and Budget Act, 31 U.S.C. §§ 501–22 (1994); S. 746 § 642.

²⁴⁵See S. 746 § 621(10) (A).

²⁴⁶S. REP. NO. 106–110, at 27 (language identical to S. REP. NO. 105–188, at 23).

²⁴⁷See *id.*

²⁴⁸See *id.*; Daniel Cohen, S. 981, *The Regulatory Improvement Act of 1998: The Most Recent Attempt to Develop a Solution in Search of a Problem*, 50 ADMIN. L. REV. 699, 705–06 (1998).

²⁴⁹See S. 746 § 621(10); S. REP. NO. 106–110, at 26–27 (language identical to S. REP. NO. 105–188, at 22–23). For a criticism of the proposed Act, see generally Cohen, *supra* note 248; Esther Boykin, *Poor Proposal on Federal Regulatory Changes*, THE TIMES-PICAYUNE, July 19, 1999, at B4. For an argument in support of the bill, see C. Boyden Gray, *Regulatory Reform: Past and Future*, NAT. RESOURCES & ENV'T, Winter 1998, at 158–59; Jeff Stier, *Better Ways to Regulate*, J. OF COM., July 8, 1998, at 7A.

²⁵⁰See S. REP. NO. 106–110, at 27 (language identical to S. REP. NO. 105–188, at 23).

some members of Congress are well aware that agencies sometimes use the nonlegislative rule exception to avoid proper rulemaking procedures.²⁵¹ The Senate Committee's command to agencies that they should properly label their rules may discourage agencies from mislabeling their legislative rules as nonlegislative.²⁵²

If Congress passes the Act, however, it is just as likely that agencies may attempt to abuse the nonlegislative rule exception more often than before.²⁵³ If all major legislative rules must follow more process than the already burdensome § 553 procedure, agencies may attempt to avoid the procedures more often by disguising legislative rules as nonlegislative.²⁵⁴ An agency could issue a rule creating costs of more than \$100 million, yet identify it as an interpretative rule or a general statement of policy.²⁵⁵ Considerable time could pass before the OMB or an aggrieved private party challenges the rule and demands the agency conduct a cost-benefit analysis.²⁵⁶ The agency would be taking a risk by mislabeling its rules, in effect daring the OMB or the public to act.²⁵⁷ That risk, however, may be worthwhile for agencies.²⁵⁸ The proposed Act imposes such huge burdens on agencies that they will adopt fewer legislative rules than they do now.²⁵⁹ Accordingly, to continue meeting the demands of their congressional mandates, agencies may have no choice but to rely more heavily on the nonlegislative rule exception.²⁶⁰

The Act specifically states that nonlegislative rules are excluded from the cost-benefit analysis requirements, but does not specifically address those major substantive rules mislabeled as nonlegislative.²⁶¹

²⁵¹ See *id.*

²⁵² See *id.*

²⁵³ See *id.*; see also Anthony, *Interpretative Rules*, *supra* note 21, at 1318 (discussing how agencies inclined to use § 553(b) (A) exception to avoid rulemaking procedures).

²⁵⁴ See S. 746 §§ 621 (7), 623-24.

²⁵⁵ See *id.* § 621 (7); see, e.g., *Phillips Petroleum Co. v. Johnson*, 22 F.3d 616, 618, 621 (5th Cir. 1994) (noting that the agency placed nonlegislative label on substantive rule "dramatically" affecting oil and gas royalty values).

²⁵⁶ See S. 746 §§ 623, 642.

²⁵⁷ See *id.* § 642; S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23).

²⁵⁸ See S. 746 § 642; S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23).

²⁵⁹ See S. 746 §§ 623-24; S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23); Anthony, *Interpretative Rules*, *supra* note 21, at 1319 (noting that some agencies already view rulemaking procedure as burdensome).

²⁶⁰ See S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23).

²⁶¹ See S. 746 § 621; S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23).

Rather, only in the Report does the Senate assert that nonlegislative rules with major effects must be subjected to cost-benefit analysis.²⁶² Were this issue ever to come up in litigation, the court would probably consider the Senate Report, but it would not be dispositive.²⁶³ A court could hold that the language of the proposed Act is sacrosanct and that nonlegislative rules simply cannot be major rules.²⁶⁴ Of course, if a rule costs more than \$100 million, it probably also has significant effects or creates legal obligations, and a judge would probably hold that it must be a legislative rule.²⁶⁵ One way or the other, the small discrepancy can only contribute to the confusion surrounding § 553(b) (A).²⁶⁶ The Committee would be wise to rewrite § 621(10) (A) of the Act to reflect that substantive rules disguised as nonlegislative must go through the cost-benefit analysis.²⁶⁷ Such a revision of the Act would be more consistent with the original intentions behind the APA.

The purpose of the APA is to bolster clarity, consistency and public participation in federal agencies.²⁶⁸ If Congress adopts the Act as is, it would undermine these beneficial aims to the extent that it fails to ameliorate the confusion surrounding nonlegislative rules.²⁶⁹ Congress should not adopt the Regulatory Improvement Act in its current form.²⁷⁰ If Congress seeks to implement meaningful regulatory reform, Congress ought to revise § 553(b) (A) of the APA now.²⁷¹

²⁶² See S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23).

²⁶³ See *id.*

²⁶⁴ See S. 746 § 621(10) (A); S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23).

²⁶⁵ See S. 746 § 621(7); see, e.g., *Thomas v. New York*, 802 F.2d 1443, 1447 (D.C. Cir. 1986) (implying letter was substantive because its enforcement would cause considerable economic impact).

²⁶⁶ See 5 U.S.C. § 553(b) (A); S. 746 § 621(10) (A); S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23).

²⁶⁷ See S. 746 § 621(10) (A); S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23).

²⁶⁸ See 5 U.S.C. §§ 553, 556-57; *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993).

²⁶⁹ See S. 746 § 621; S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23).

²⁷⁰ See S. 746 § 621. Much debate still encircles the proposed Act, and members of Congress currently are considering amending the bill. See William A. Niskanen, *Legislative Implications of Reasserting Congressional Authority over Regulations*, 20 CARDOZO L. REV. 939, 943-44 (1999).

²⁷¹ See 5 U.S.C. § 553; S. 746 § 642; S. REP. NO. 106-110, at 27 (language identical to S. REP. NO. 105-188, at 23). Differing from this Note's argument, the American Bar Association has voiced its support for the proposed Act because it would increase uniformity between federal agencies and provide for systemic review of agency rules. See Warren Belmar, *Chair's Message*, ADMIN. & REG. L. NEWS, Spring 1998, at 2. Nevertheless, the proposed Act

E. Congress or the Agencies Should Revise Nonlegislative Rules

Nonlegislative rules continue to confuse the government and public alike, and agencies still are able to misuse them to bind the public.²⁷² Whether Congress or agencies attempt to remedy the nonlegislative rule problem, they should affect law that would require federal agencies to: (1) correctly and uniformly label nonlegislative rules; (2) publish a list of all of their nonlegislative rules in the *Federal Register*; (3) avoid using mandatory language in nonlegislative rules; (4) specify that nonlegislative rules do not legally bind either agencies or individuals; (5) specify that neither the public nor the government should rely on nonlegislative rules; and (6) remember to use the full informal § 553 process when creating rules with substantive effects.²⁷³

The best solution would be for Congress to amend the APA to better explain the § 553(b)(A) exception.²⁷⁴ Courts repeatedly have lamented that Congress has never defined or revised nonlegislative rules.²⁷⁵ According to the Senate Committee on Governmental Affairs, Congress is aware that there is the potential for abuse of § 553(b)(A).²⁷⁶ The confusion over nonlegislative rules has existed for more than half a century and calls for a legislative response.²⁷⁷ Because Congress is currently considering reforming how administrative

has failed to garner widespread support. See Marc Landy & Kyle D. Dell, *The Failure of Risk Reform Legislation in the 104th Congress*, 9 DUKE ENVTL. L. & POL'Y F. 113, 131 n.83 (1998). But see OFFICE OF THE GENERAL COUNSEL, SEC., RECENT LEGISLATIVE DEVELOPMENTS AFFECTING THE WORK OF THE SECURITIES AND EXCHANGE COMMISSION 536-37 (1998) (suggesting the bill has considerable support because only two witnesses voiced opposition to it during a hearing before the Senate Governmental Affairs Committee).

²⁷²See Anthony, *Interpretative Rules*, *supra* note 21, at 1316, 1327-55.

²⁷³See, e.g., *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99-100 (1995) (noting that nonlegislative rules lack the force and effect of law); *CNI*, 818 F.2d at 948 (noting that nonlegislative rules cannot restrain agency discretion); *Cathedral Bluffs*, 796 F.2d at 536-38 (noting that nonlegislative rules should only use tentative language); Good Guidance Practices, 62 Fed. Reg. at 8967-71 (recommending uniform nomenclature, listing all nonlegislative rules, eschewing mandatory language and that nonlegislative rules may not bind public or agency).

²⁷⁴See U.S.C. § 553(b)(A).

²⁷⁵See, e.g., 5 U.S.C. § 551, 553; *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979); *CNI*, 818 F.2d at 946; *Noel v. Chapman*, 508 F.2d 1023, 1029-30 (2d Cir. 1975).

²⁷⁶See S. REP. NO. NO. 105-188, at 23.

²⁷⁷See 5 U.S.C. §§ 551, 553; *MASHAW ET AL.*, *supra* note 9, at 148. Congress, however, has made few substantial changes to the APA over its 53-year history. See *MASHAW ET AL.*, *supra* note 9, at 149; *Strauss*, *supra* note 15, at 1391-92.

agencies regulate in general, now is the ideal time to address non-legislative rules.²⁷⁸

Congress should create a "Nonlegislative Rule Act," which would amend and clarify the law surrounding the § 553(b) (A) exception.²⁷⁹ The courts have held that nonlegislative rules should not employ mandatory language and that they cannot have binding effects.²⁸⁰ Agencies, however, are able to manipulate the § 553(b) (A) exception to impose substantive effects on the public.²⁸¹ The best solution to halt this potential for abuse is for Congress to legislate that all rules created without notice-and-comment cannot have binding legal effects on agencies or the public, unless they fall under another of § 553's categorical exceptions.²⁸² Learning from the FDA's GGP's, Congress should require agencies to publish lists of their nonlegislative rules in the *Federal Register* and to refer to those rules with a uniform nomenclature.²⁸³ Furthermore, the hypothetical Nonlegislative Rule Act should require agencies to avoid using compulsory language in their nonlegislative rules, to specify that nonlegislative rules do not legally bind either agencies or individuals and to assert that neither the public nor the government should rely on nonlegislative rules.²⁸⁴ In addition, Congress statutorily should compel agencies to use full notice-and-comment process when creating rules with substantive effects.²⁸⁵ The courts have ruled that only legislative rules may create rights or obligations, so agencies should rely only on notice-and-comment to create binding and consistent rules of law.²⁸⁶

²⁷⁸See Cindy Skrzycki, *The Regulators: The Costs and Benefits of Cost-Benefit Analysis*, THE WASH. POST, Aug. 6, 1999, at E1 (stating that the Senate Governmental Affairs Committee is currently pushing Regulatory Improvement Act toward Senate floor).

²⁷⁹See 5 U.S.C. § 553.

²⁸⁰See, e.g., *Chrysler*, 441 U.S. at 315; *Cathedral Bluffs*, 796 F.2d at 537-38; *American Bus. Ass'n v. United States*, 627 F.2d 525, 529-30 (D.C. Cir. 1980).

²⁸¹See, e.g., *United States v. American Nat'l Red Cross*, 1993 WL 186094, *1-*2 (D.D.C. 1993); Anthony, *Interpretative Rules*, *supra* note 21, at 1315-16.

²⁸²See, e.g., 5 U.S.C. § 553(a), (b)(B); *Morton v. Ruiz*, 415 U.S. 199, 230-38 (1974) (holding that rule relating to benefits program, and created without notice-and-comment, was binding because it was exempted under § 553(a)(2)). The other exceptions—rules relating to the military, foreign affairs, agency management, public property, public contracts or for emergencies—are more clear than the vague terms "interpretative rules" and "general statements of policy," so they generate less litigation and controversy. See 5 U.S.C. §§ 553(a)(1), (a)(2), (b)(B).

²⁸³See Good Guidance Practices, 62 Fed. Reg. at 8969.

²⁸⁴See *id.* at 8967, 8969.

²⁸⁵See *Chrysler*, 441 U.S. at 301-02; *American Bus.*, 627 F.2d at 528.

²⁸⁶See *Perales v. Sullivan*, 948 F.2d 1348, 1354 (2d Cir. 1991); *Linoz v. Heckler*, 800 F.2d 871, 877 (9th Cir. 1986).

If Congress fails to take this opportunity to amend the Regulatory Improvement Act's bill, then the agencies should revise how they create and apply nonlegislative rules. Although each agency may treat nonlegislative rules differently, as long as the agencies strive to improve their use of nonlegislative rules, it will benefit the public. Like the FDA, other agencies should develop their own versions of the GGPs.²⁸⁷ The FDA's GGPs are not the best model, however, and other agencies should attempt to formulate better policies regarding nonlegislative rules.²⁸⁸ Other agencies would be wise to borrow from the GGPs the provisions requiring the FDA to publish a list of all of its guidance documents and to refer to nonlegislative rules with a standardized nomenclature.²⁸⁹ The public is always better served when the government keeps it informed in a lucid and comprehensive manner.²⁹⁰ As argued in Section B of this Part, a better set of GGPs would not feature contradictory principles, would clarify that nonlegislative rules do not operate to bind and would not further complicate the issue by devising a two-tier system.²⁹¹ Moreover, agencies should include in their definitions of nonlegislative rules all rules falling within the § 553(b)(A) exception.²⁹² Other agencies should learn from the GGPs' mistakes and develop their own more clear and more efficient policies for nonlegislative rules.²⁹³

CONCLUSION

The federal government is cognizant that agencies sometimes misuse the § 553(b)(A) exception because of its inherent complexity. The Food and Drug Administration deserves recognition for attempting to ameliorate the problem by developing the Good Guidance Practices. The GGPs, however, fail because they contradict themselves and leave open avenues for potential agency abuse. While one administrative agency is confronting the issue, Congress is ignoring it. The Regulatory Improvement Act of 1999 only briefly touches on the role of nonlegislative rules. The proposed statute fails to engage the complications surrounding the § 553(b)(A) exception. Moreover, because

²⁸⁷ See Good Guidance Practices, 62 Fed. Reg. at 8967-71.

²⁸⁸ See *id.*

²⁸⁹ See *id.* at 8969.

²⁹⁰ See *id.*; Asimow, *supra* note 25, at 386 (stating that "[b]ecause the public must live with agency interpretations, it should have the fullest possible access to them.").

²⁹¹ See *supra* notes 196-236 and accompanying text.

²⁹² See Good Guidance Practices, 62 Fed. Reg. at 8967.

²⁹³ See *id.* at 8967-71.

of the burdens the Act would impose on administrative agencies, it could encourage agencies to promulgate nonlegislative rules.

If Congress truly wishes to overhaul the administrative system with this legislation, Congress should take the opportunity now to clarify the creation and use of nonlegislative rules. Likewise, the FDA should act soon to revise its GGP's before the agency becomes too entrenched with the GGP's' inadequate standards.²⁹⁴ Specifically, Congress and the agencies should adopt statutes or legislative rules, respectively, ensuring that agencies: correctly label nonlegislative rules; publish a list of all rules in the *Federal Register*; avoid using compulsory language in nonlegislative rules; explain that nonlegislative rules do not legally bind either agency employees or individuals; specify that agencies, courts and the public should not rely on nonlegislative rules; and remember to use full informal rulemaking process when creating rules affecting individual rights or obligations. By formally establishing these principles, Congress and federal agencies will accomplish more successfully the APA's auspicious objectives of uniformity, fairness and public participation.

JAMES HUNNICUTT

²⁹⁴When it published the GGP's in 1997, the FDA stated it would review them three years after their implementation. See Good Guidance Practices, 62 Fed. Reg. at 8969.