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M. ELIZABETH MAGILL*

I. INTRODUCTION

Contemporary observers of the administrative state chronicle a number of developments that have altered the landscape of administrative law. One prominent change is the effort by Congress to assert control—either temporal or substantive—over the regulation writing process. Another development is the growing difficulty agencies encounter in attempting to make use of traditional informal rulemaking, a change Professor E. Donald Elliot dubbed the "ossification" of the rulemaking process. Both developments are evident in the innovative form of legislative control of agency rulemaking that is the focus of this article.

On November 8, 1990, President Bush signed into law the Nutrition

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Labeling and Education Act of 1990 (NLEA). The law embodied an aggressive agenda, dictating a comprehensive overhaul of food labels. The law clarified and enhanced the Food and Drug Administration’s (FDA’s) authority to require nutrition labels on foods, and established circumstances under which health claims could be made about the nutritional composition or value of foods. Culminating two years of activity on Capitol Hill, the consideration and passage of the bill coincided with a major initiative at the FDA to overhaul food labeling requirements.

The provision of the NLEA that is the focus of this article received little attention during the deliberations on the bill, and in fact might be called a procedural curiosity. The provision—known as the “hammer”—was an innovative instrument used to put teeth into the NLEA’s statutory deadlines. Despite its low profile, the hammer had a significant impact on the character of the rule writing process at the FDA. One plausibly could claim, a claim this article will test, that the relative speed—given the enormous nature of the task—with which the NLEA regulations were promulgated was in part attributable to the unique pressures created by the hammer.

Two of the key provisions of the NLEA, section 2, which established standards for the new mandatory nutrition labels, and section 3, which governed a variety of health messages contained on food labels, included hammer provisions that dictated the pace of the FDA’s rulemaking. The agency was required to issue proposed regulations under these sections within twelve months of the date of enactment. Then, if final regulations had not been promulgated within twenty-four months of the date of enactment, the proposed regulations “[shall] be considered as the final regulations upon the expiration of the 24 months.”


7. “Hammer” has been used to describe a wide variety of statutory devices—most prominently utilized in a number of environmental statutes—that require an automatic action if the agency subject to the hammer does not act within a specified timeframe. There is no prototypical hammer. As the name implies, the purpose of such hammers is to push the agency to act within the statutory timeframe. See infra notes 18-23 and accompanying text for a more detailed discussion of varieties of hammer provisions.

8. Pub. L. No. 101-535, §§ 2(b), 3(b), 104 Stat at. 2356, 2361-62. Should this occur, the agency was required to publish notification of the status of the proposed regulations promptly in the Federal Register. Id. The preemption section of the law, section 6, also included a hammer provision.
The hammer was attached to a law of intense interest to many parties. Decisions about what information should be contained in food labels have enormous stakes. Decades of research demonstrated a substantial connection between dietary habits and chronic diseases. Based on this research, it was clear that substantial public health benefits could be achieved if consumers could be convinced to change their dietary habits.

The FDA’s effort to revise food labels in the late 1980s, and the NLEA, fastened on the informational content of food labels as a key vehicle to effect the public health goals of educating consumers about the nutritional content of foods and encouraging them to alter their dietary patterns. The NLEA adopted a two-tiered strategy to accomplish these aims: mandatory disclosure of specific information that was relevant to contemporary understandings of diet and health, and control of what and how certain health-related messages could be included on the label. The choice of these two strategies had important implications.

First, obvious economic consequences flowed from these requirements. Mandatory disclosure of information meant that nutrition labeling would be required on many more food products than had been required previously. In addition, some information that had to be disclosed about foods—such as cholesterol content—would be costly to discover. The assumption of the new regime was that food producers should expend significant resources to convert to the new system of labeling.

Second, the strategies adopted in the NLEA and resulting regulations had important competitive implications. If dietary patterns were changed, there would be economic winners and losers. A nutrition labeling regime that encouraged consumption of fiber and discouraged consumption of fat, for instance, might boost fruit and vegetable sales at the expense of meat and poultry product sales. Finally, mandatory disclosure of certain information and limitations on the form and content of health messages on food labels would significantly influence the marketing of food products for years into the future.

Because of the public health, economic, and competitive implications, any debate over food labels is one that naturally would draw the interest of many parties. The balance struck in the law and the regulations would have critical implications for the public health goals of altering dietary patterns; and, in an important way, the rules established for the new food

Id. § 6(b)(3), 104 Stat. at 2364.

The NLEA contained a number of other statutory deadlines. For instance, section 2(a)(4), governing nutrition information for agricultural commodities and seafood, included the following deadlines: 12 months to issue voluntary nutrition guidelines (after opportunity for comment) for food retailers; 12 months to issue final regulations defining “substantial compliance” with these voluntary nutrition guidelines; 30 months to issue a report on voluntary compliance actions taken by food retailers. On finding that there had not been substantial compliance with the voluntary guidelines, the Secretary was required to issue mandatory regulations. Final regulations were required to be issued within six months of the proposed regulations, and to become effective six months after the date of promulgation.
labels would dictate the marketing and advertising practices of most sectors of the food industry. Thus, with or without a hammer, the NLEA and the resulting regulations would have attracted the attention and interest of many parties.

This article examines the origin and impact of the hammer, an innovative tool of congressional control. First, the hammer will be placed in the context of a growing congressional tendency to exert influence over the regulation writing process of executive agencies. Statutory timetables are an important manifestation of this penchant for control over the regulatory process. The choice of the hammer also can be located in the traditions of agency-congressional interaction in food and drug law. Then, the article briefly examines the actual operation of the hammer provisions in the case of the NLEA and the relatively novel legal implications of the hammer. Finally, and most importantly, the article examines the way the hammer influenced the NLEA rulemaking process. This aspect of the article could not be captured in cases or commentary. It is based, therefore, on interviews with participants in the legislative and rulemaking stages of the NLEA. The aim of this study is to illustrate the way the hammer influenced the NLEA rulemaking and to draw broader lessons for other uses of such legislative pace-controlling mechanisms.

This study of the effect of the hammer provision on the regulation writing process reveals that this procedural device had an important impact on the character of the rulemaking. The hammer helped to create a pressured environment in which the regulations were crafted. This environment operated to push the agency toward closure on key issues, and considerably strengthened the hand of an agency—with respect to those who ultimately would be subject to the rules and to those in the executive branch—that wanted to overhaul food labeling rules.

II. INCREASING ASSERTION OF LEGISLATIVE CONTROL OVER THE REGULATION WRITING PROCESS

The NLEA’s hammer should be seen as one part of a broader picture of legislative efforts to exert influence over agency rulemaking. A prominent theme of the last twenty years in the relationship between Congress

9. Until 1990, this type of hammer had never been used in food and drug law. In 1990 Congress utilized it both in the NLEA and in the Safe Medical Devices Act of 1990 (SMDA), Pub. L. No. 101-629, 104 Stat. 4511. Section 3(c)(2) of the SMDA provided that if final regulations were not issued within 18 months of enactment (proposed regulations had to be issued within nine months of enactment) “the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comments because the implementation of [these sections] are [sic] essential to protect the health of patients who use such devices.”

See infra notes 18-22 and accompanying text for a discussion of hammer provisions in other areas of law.

10. The author spoke to a number of people about the development, operation, and impact of the hammer. Some insisted on anonymity. Transcripts or notes of all of these interviews are on file with the author.
and the executive branch is the effort Congress has made to increase its influence over that aspect of lawmaking that occurs after the President attaches his signature to a statute.\footnote{11}

**A. Congressional Tools to Influence the Regulation Writing Process**

Congress wields a number of statutory mechanisms in its effort to exercise influence over agency rulemaking.\footnote{12} Some tools of control aim to exercise substantive influence over the content of rulemaking, others purport to dictate only the pace of agency rulemaking, and some attempt to control both the substance and the pace of rulemaking. As this examination will demonstrate, in an era of prescriptive statutes there is not a clear boundary between tools aimed at substance and those aimed at the pace of rulemaking.

1. **Tools of Congressional Control: Statutory Specificity, Deadlines, and Hammers**

   Broadly speaking, prescriptive statutes are one way Congress attempts to be certain that elements of a substantive agenda, or a timeframe for action, will be reflected in the final rules of an agency. Commentators have described this trend, and it is evident in a number of areas of public law, including environmental law\footnote{13} and food and drug law.\footnote{14} Statutory specificity can manifest itself in a variety of ways.\footnote{15} Statutory directives can include detailed requirements that either must be incorporated into

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\footnote{11}{See supra note 1.}

\footnote{13}{ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE & POLICY 664-73 (1992).}

\footnote{14}{For instance, the 1976 Medical Device Amendments were 45 pages long, and took 87 pages to explain in the House Report accompanying the bill. In contrast, the original Federal Food, Drug, and Cosmetic Act of 1938 was 19 pages long. Peter Barton Hutt & Richard A. Merrill, *Food and Drug Law: Cases & Materials* 744 (2d ed. 1991). A number of people interviewed for this article contended that the NLEA is reflective of this trend toward prescriptive statutes. Interviews with Fred Shank, Director, CFSAN, FDA, Washington, D.C. (Feb. 28, 1994); Robert Lake, Senior Assoc. Director for Policy, Planning, and Strategic Initiatives, CFSAN, FDA, Washington, D.C. (Feb. 28, 1994); Philip Derfler, Office of Gen. Counsel, FDA, Washington, D.C. (Feb. 28, 1994). See also infra note 20.}

\footnote{15}{Two observers divide the congressional inclination increasingly to control administrative agencies into three categories: the coercive model, where the agency is required to act although the agency has control over the substantive content of the regulations; the prescriptive model, where the agency has the discretion to act, but if it chooses to act, it must adhere to substantive criteria; and the ministerial model, combining a requirement to act and substantive requirements for that action. Shapiro & Glicksman, supra note 1, at 824-40.}
regulations or that take effect regardless of the promulgation of regulations.\textsuperscript{16}

Statutory deadlines are another manifestation of the congressional taste for prescription. Most deadlines simply place a time limit on agency action for the promulgation of certain regulations.\textsuperscript{17} Some statutory deadlines, however, are accompanied by a device that has come to be called a “hammer.”\textsuperscript{18} The most frequently used form of the hammer—used in a number of environmental statutes—provides a certain amount of time for the agency to regulate; if the agency fails to promulgate regulations within that timeframe, substantive standards that are set forth in the statute go into effect.\textsuperscript{19}

\textsuperscript{16} The 1984 Hazardous Solid Waste Amendments (HSWA), Pub. L. No. 98-616, 98 Stat. 3221, which amended the Resource Conservation and Recovery Act of 1976 (RCRA), Pub. L. No. 94-580, 90 Stat. 2795, provides an excellent illustration of the variety of statutory directives Congress may enact, many of which are accompanied by statutory deadlines. See 42 U.S.C. § 6924(c)(1) (1988) (effective six months after November 8, 1984, bulk or noncontainerized liquid hazardous waste or free liquids contained in hazardous wastes prohibited from landfills); id. § 6924(c)(2) (“Not later than 15 months after November 8, 1984,” Administrator must promulgate final regulations to “minimize disposal of containerized liquid hazardous wastes in landfills” and the presence of free liquids to be disposed of in landfills, and the regulations shall prohibit disposal in landfills of liquids that have been absorbed in materials that biodegrade or that release liquids when compressed); id. § 6924(c)(3) (nonhazardous liquid for which a permit is required cannot be placed in a landfill unless owner demonstrates or Administrator determines that there is no reasonable alternative and no risk of contamination to groundwater); id. § 6924(l) (prohibits the use of waste or used oil which is mixed with dioxin or any other hazardous waste for dust suppression or road treatment). See also Congressional Limits, supra note 1.

One form of this type of device leaves the question of whether to regulate to the agency, but if the agency chooses to regulate, it must follow detailed criteria. Shapiro and Glicksman point to section 112 of the Clean Air Act, Pub. L. No. 101-549, 104 Stat. 2399 (1990), as reflective of this model. The law allowed the Environmental Protection Agency (EPA) to determine whether or not emissions from hazardous air pollutants should be limited, but once the decision to limit emissions was made, the EPA had to follow detailed statutory criteria in setting the appropriate limit. Shapiro & Glicksman, supra note 1, at 837 n.85. See also 42 U.S.C. § 6921(e)(2) (Administrator of EPA shall make decision within 15 months after date specified whether or not to “list,” and therefore subject to regulation, a series of specified wastes).

\textsuperscript{17} The United States Code is littered with statutory deadlines requiring a particular agency to act within a time certain. See supra note 1, especially Shapiro & Glicksman at 828-30. For instance, one commentator notes that the HSWA included 76 statutory deadlines for promulgating regulations, issuing reports, and permitting facilities. See Congressional Limits, supra note 1, at 533. Another commentator states that this act contained 60 statutory deadlines. Abbott, supra note 1, at 173. See also description of the statutory deadlines contained in the NLEA, supra note 8.

\textsuperscript{18} Two commentators argue that the hammers have been attached to minimize the problems associated with straightforward statutory deadlines. Shapiro & Glicksman, supra note 1, at 838-39; Congressional Limits, supra note 1, at 533 (“Because experience indicated that simple deadlines could often be stretched and even ignored, Congress also included a series of restrictive default standards, or ‘hammers,’ that would take effect if the EPA failed to issue certain regulations [under the HSWA] by the assigned dates.”).

\textsuperscript{19} The 1984 RCRA Amendments contained a variety of such hammers: 42 U.S.C. § 6924(d)(1) (thirty-two months after November 8, 1984, land disposal of certain hazardous wastes is barred “unless the Administrator determines that the prohibition on one or more methods of land disposal of such waste is not required in order to protect human health and the environment for as long as the waste remains hazardous . . . . ”); id. § 6924(e) (parallel provision to (d)(1) for dioxin-containing hazardous wastes and solvents, except that prohibition on their land disposal goes into effect within 24 months after November 8, 1984, if Administrator does not act); id. § 6924(f)(3) (if Administrator does not promulgate final regulations within 45 months of November 8, 1984, regarding disposal by underground injection into deep wells of certain hazardous wastes, such disposal will be barred).
The NLEA hammer diverges from this model. The NLEA hammer was to transform proposed regulations—not specific statutory provisions-authored by the agency into final regulations, although admittedly these proposed regulations were drafted pursuant to a prescriptive statute. A key difference between the two types of hammers, then, is that the content of the automatic action that might be required under the NLEA hammer was not known at the time the NLEA became law; in contrast, in the environmental law hammers examined here the automatic action that might go into effect was spelled out in the statute. The extent of the threatening nature of the hammer is controlled by the agency in one case and by Congress in the other.

Obviously, the automatic nature of such hammers is intended to ensure that some policy is in place when the specified period elapses. But Congress also has other goals: providing added incentives for the agency to meet the deadline and perhaps inducement for those affected by the rulemaking to be cooperative partners in the rulemaking process. As two commentators stated, "The 'hammer' label is appropriate: Congress adopts these provisions to beat the agency into submission to the legislative will." Both types of hammers identified here have these built-in incentives. When the statute has outlined the contours of the rule that will be in place if the hammer falls, the agency and at least some in the regulated community have tried to keep the hammer from falling. In the case of an

See also Asbestos Hazard Emergency Response Act of 1986, Pub. L. No 99-519, 100 Stat. 2970 (codified at 15 U.S.C. § 2644 (1988)) (If administrator fails to promulgate final regulations within specified time periods under certain provisions, local agency shall be authorized to carry out requirements.).
A sort of reverse hammer has been included in statutes as well. That is, Congress enacts specific standards that take effect until the agency changes them by regulation. See 42 U.S.C. §§ 6924(o)(1)(A); (5)(1)(A)(B) (Administrator shall promulgate regulations or issue guidance documents to implement requirements for technological requirements for landfills; until such documents are issued, statute specifies sufficient liners that must be used at landfills.).
20. Because the NLEA was so prescriptive, it is hardly fair to characterize the hammer as being purely a pace-setting, or "procedural," mechanism. For one example of the prescriptive nature of the statute, consider the nutrition labeling section of the law. The statute almost set forth the exact contours of the new food label; it dictated the specific categories of information that must appear on the food label: serving size, calories, and the number of calories derived from total fat; and the amounts of fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, and dietary fiber. Pub. L. 101-535, § 2(a), 104 Stat. at 2353. The Secretary was not granted general authority to exempt foods from the labeling requirements; instead the exceptions were spelled out in the statute itself. Id. The provisions governing health claims were similarly prescriptive. Id. at § 3, 104 Stat. at 2357-62.

21. Shapiro & Glicksman, supra note 1, at 839 n.96.
22. There theoretically may be situations where the agency or those subject to the potential rule prefer the statutory standard that serves as the hammer to what the agency might propose. In studying particular cases, however, such as the HSWA, it is clear that the agency and the regulated community wanted to avoid the hammer. See Congressional Limits, supra note 1, at 539. See also infra notes 164, 170-78 and accompanying text for discussion of these effects in the case of the NLEA hammer; Shapiro & Glicksman, supra note 1, at 840 n.98 (discussing, because of a desire to avoid the hammer in most instances, the incentive the hammer has on agency and regulated community). It is worth noting that all the HSWA statutory deadlines accompanied by hammers were met, in contrast to many of the other deadlines contained in the law, which were missed. Id. at 539-40.
NLEA-type hammer, the incentive to induce the agency to meet the deadline is also likely to be strong. The basis for that incentive is the prospect of proposed rules (as authored by the agency) being transformed into final rules. Proposed rules often are preliminary or tentative statements of policy that will change in response to comments. The more complex the rules, the more likely they are to change after comment is received. Thus, the goal of preventing such tentative assessments from becoming the final rules is a fairly compelling motivation for the agency to meet deadlines.25 Finally, while the failure to meet a standard statutory deadline might otherwise pass unnoticed, the hammer provisions examined here advertise an agency's failure to meet congressionally-imposed deadlines. This, by itself, might spark a strong agency commitment to meet the deadline.

2. Reasons for Congressional Assertion of Control

Congressional desire to influence agency rulemaking can be explained by a number of factors. First, regulatory delay is a source of great frustration for Congress.24 No matter the source of such regulatory delay,25 the legislative branch is, and subjects of agency rulemaking may be, impatient with the time it takes for an agency to accomplish tasks set forth in statutes. Deadlines or hammers that force the agency to act do address this concern.26 Certainly since the 1980s era of Republican control of the executive branch and Democratic dominance of Congress, and perhaps in the 1970s as well, members of Congress also have displayed distrust of the executive branch's implementation of statutes.27 Members may fear that

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23. In the case of the NLEA, as is explored later in this article, there was a strong desire on the part of the agency, as well as those in the regulated community, to avoid the hammer falling. See infra notes 164, 170-79 and accompanying text.

24. See Edward A. Tomlinson, Report on the Experience of Various Agencies with Statutory Time Limits Applicable to Licensing or Clearance Functions and to Rulemaking, Administrative Conference of the United States: Recommendations & Reports 119, 120 (1978), Shapiro & Glicksman, supra note 1, at 826. See also H.R. Rep. No. 538, supra note 4 ("For the past 11 years FDA has been engaged in a regulatory proceeding to modernize and improve nutrition labeling requirements . . . . [The] FDA has been extremely slow in issuing comprehensive nutrition regulations . . . .").

25. Such delay is in part attributable to the increasing burdens placed on agency rulemaking (some of them by Congress), the sheer number of tasks assigned to agencies in statutes, and the enormous complexity entailed in contemporary rulemaking. Furthermore, current members of Congress are not always attentive to tasks previously assigned to the agency that might impede quick action on their most recent assignment.


the agency will not act at all, or, if it does, that it may distort legislative intent in regulations. Thus, statutory specificity and action-forcing deadlines are viewed as ways to address concerns about delay and feared distortion of legislative will in the rulemaking process.

A related, but slightly different, explanation is rooted in the political and institutional competition between the White House and Congress that was especially acute in the 1980s. At its broadest, this competition was reflected in the fact that each government branch wanted to take credit for accomplishments and place blame for failures on the other. Another related explanation is that Congress has a desire to be seen as acting in response to an important public policy problem. Here the mistrust and competition factors overlap; Congress can capitalize on the mistrust by showcasing its attempts to ensure that its will to act with dispatch or to achieve a particular substantive result is carried out in the regulation writing process.

Finally, it should not be ignored that a prominent form of legislative control, the legislative veto, was declared unconstitutional by the Supreme Court in 1983. Some forms of the veto gave Congress a postenactment look at the handiwork of agencies; the gap left as a result of this decision was filled in part by the mechanisms of congressional influence just examined.

B. Judicial Response to Statutory Deadlines

Courts do entertain suits based on agency delay, but the judicial response has not been decisive enough in forcing agency action for legislators to withdraw their imposition of deadlines on agencies. In brief, courts entertain suits to enforce deadlines but do not demand more than “good faith” from agencies. Suits may be brought under the “unreasonable delay” provision of the Administrative Procedure Act (APA) or under the

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31. In a leading case, Natural Resources Defense Counsel v. Train, 510 F.2d 692 (D.C. Cir. 1975), the court set forth the considerations to be used in statutory deadline suits. First, the court should determine if compliance with the deadline would be impossible (considering resource constraints and technical requirements). Even where meeting the deadline is not impossible, the court may refrain from issuing an order mandating agency action if the court is convinced that the official acted in good faith. Id. The difficulty of this “good faith” standard varies. Some courts express frustration with a loose interpretation of good faith. See Conservation Law Foundation of New England v. Reilly, 755 F. Supp. 475, 477-79 (D. Mass. 1991) (agency must show compliance with deadline is impossible; if not impossible, court can still refrain from forcing action if convinced agency employed “utmost diligence”); Sierra Club v. Thomas, 658 F. Supp. 165 (N.D. Cal. 1987); State v. Gorsuch, 554 F. Supp. 1060 (S.D.N.Y. 1983). But see Environmental Defense Fund v. Thomas, 627 F. Supp. 566 (D.D.C. 1986) (good faith standard).
32. 5 U.S.C. § 706(1) (1988) (“The reviewing court shall . . . compel agency action unlawfully withheld or unreasonably delayed”); 5 U.S.C. § 555(b) requires that “[w]ith due regard for the convenience and necessity of the parties . . . within a reasonable time, each agency shall proceed to conclude a matter presented to it.”
statutory deadline itself. Courts consider a number of factors when examining whether an agency has delayed action unreasonably, including the nature and extent of the interests prejudiced by delay, the agency's justification for the delay, and the context of the statutory scheme.\textsuperscript{33} Even if a court determines that the agency is acting in good faith, the court still may retain jurisdiction over the case to supervise a schedule for rulemaking.\textsuperscript{34}

While complaining litigants may not be satisfied with the result obtained after bringing an action based on agency delay, litigation involving statutory deadlines can prove to be costly and frustrating for the agency. One illustration of the length of such judicial involvement in agency action is the litigants' attempt to force the Occupational Safety and Health Administration (OSHA) to adopt a field sanitation standard governing farmworkers' field working conditions. The effort to force the agency to act, which was predicated on the initiation of an investigation of the matter in 1973, was not resolved until 1987.\textsuperscript{35}

From the perspective of a legislature that imposes statutory deadlines in an effort to prompt quick agency action, reliance on judicial "enforcement" of statutory deadlines is inadequate. The most obvious difficulty is that unreasonable delay or statutory deadline claims will not be resolved until after, perhaps long after, the statutory deadline passes.\textsuperscript{36} Given the reluctance of courts to force agency action, and their willingness to consider the good faith of the agency, a certain length of time must elapse beyond a statutory deadline in order for a court to take seriously the claim of delay. Arriving with a complaint in hand one day after the statutory deadline is not likely to portend a successful challenge to a missed deadline.

\section*{C. Statutory Deadlines in Food and Drug Law}

The trend of legislative exertion of influence over agency rulemaking through statutory mechanisms is evident in food and drug related statutes. Even early amendments to the Federal Food, Drug, and Cosmetic Act (FDCA)\textsuperscript{37} such as the Food Additives Amendment of 1958,\textsuperscript{38} the Color

\textsuperscript{33} Natural Resources, 510 F.2d at 692.
\textsuperscript{34} See Conservation Law Foundation of New England, 755 F. Supp. at 475 (retaining jurisdiction in case where court ordered EPA to comply with deadlines related to assessments of federal hazardous waste facilities); In re Center for Auto Safety, 793 F.2d 1346 (D.C. Cir. 1986) (retaining jurisdiction over case until fuel economy standards for 1989 model year promulgated); Telecommunications Research & Action v. FCC, 750 F.2d 70 (1984) (refusing to grant mandamus because agency moving to handle issue of unlawful overcharges, but retaining jurisdiction over case until final agency disposition).
\textsuperscript{35} For a description of the many steps in the continuing judicial supervision of OSHA, see JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: CASES & MATERIALS 851-54 (3d ed. 1992).
Additive Amendments of 1960,\textsuperscript{39} and the Drug Amendments of 1962,\textsuperscript{40} contained statutory deadlines. Modern statutes—the Medical Device Amendments of 1976,\textsuperscript{41} the Drug Price Competition and Patent Term Restoration Act of 1984,\textsuperscript{42} and the Safe Medical Device Act of 1990\textsuperscript{43}—all include statutory deadlines.\textsuperscript{44} These deadlines are reflections of the congressional goals already discussed—to pressure the agency to act and to overcome reluctance to regulate. The FDA has failed to meet most of these deadlines, and this failure has been a source of both congressional criticism and judicial scrutiny.\textsuperscript{45}

D. Judicial Response to Statutory Deadlines in Food and Drug Law

Courts have entertained unreasonable delay cases in food and drug law, and occasionally have ordered agency action and established a schedule for compliance.\textsuperscript{46} This record of judicial treatment of statutory deadlines and unreasonable delay cases reflects some aggressive supervision of the agency by courts. It falls far short, however, of ensuring agency action within the statutory deadline, however unrealistic those deadlines may have been.

E. Criticism of Statutory Deadlines

Despite the popularity and widespread use of statutory deadlines, they have been the object of criticism by commentators. The Administrative

\begin{footnotesize}
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  \item 39. Pub. L. No. 86-618, 74 Stat. 397 (codified at 21 U.S.C. § 376). The Health Research Group (HRG), calling on some of the deadlines contained in this law, attempted to force the FDA to take all colors off the market that did not have adequate safety data. In one case, the HRG claimed that colors could not be listed provisionally, under the 1960 Amendments, for more than two and one-half years. The claim was rejected. Health Research Group v. Califano, Food Drug Cosm. L. Rep. (CCH) ¶ 38,125 (D.D.C. 1977). A later claim was also rejected in Mcllwain v. Hayes, 690 F.2d 1041 (D.C. Cir. 1982), where the court found that Congress placed no limit on the number of times the Commissioner could postpone the date when safety data would be necessary to allow the additive to stay on the market.
  \item 44. Hutt & Merrill, supra note 14, at 1322.
  \item 46. American Public Health Ass'n, 349 F. Supp. at 1311; Cutler, 818 F.2d at 879. But see Health Research Group, Food Drug Cosm. L. Rep. (CCH) ¶ 38,125; Mcllwain, 690 F.2d at 1041.
\end{itemize}
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Conference of the United States (ACUS) has twice, once in 1978 and again in 1993, recommended that Congress not legislate time limits for agency action. Instead, ACUS recommended that agencies set their own deadlines. Should statutory deadlines be necessary, ACUS argued, additional resources should be provided to the agency to make certain the deadline could be met. The Conference also recommended that statutory “hammers” not be utilized, and asserted that judicial consideration of statutory deadlines is preferable to such hammer provisions.

Critics advance numerous arguments against deadlines. They point out that statutory deadlines rarely accomplish the purposes of getting regulations promulgated by the statutory deadline or of ordering the agency’s work. These critics argue that statutory deadlines are a crude tool to combat the multi-factored reasons for regulatory delay. Regulatory delay, at least in part, is rooted in the increasingly complex tasks assigned to agencies, the variety of ancillary requirements that are now part of the rulemaking process, and resistance from outside the agency. Statutory deadlines do not address these sources of regulatory delay, thus their utility is limited. Furthermore, the sheer number of deadlines dilutes their utility: Congress imposed 600 deadlines in environmental laws between 1970 and 1983. Abbott points to the 1984 amendments to the RCRA, which he says contained 60 legislative-imposed time limits on rulemaking, while understandable, can be unrealistic, resulting in either hastily-imposed rules or missed deadlines that undermine respect for the rulemaking process. Legislative deadlines backed by statutory or regulatory “hammers” (mandating, for example, that the proposed rule or some other policy change automatically take effect upon expiration of the deadline) are particularly undesirable and often counterproductive.

47. See Title Limits on Agency Actions, Recommendation 78-3, in Administrative Conference of the United States: Recommendations & Reports 9 (1978) (“Congress ordinarily should not impose statutory time limits on rulemaking proceedings . . . [M]odern rulemaking proceedings are too complex and varied, and involve too many stages, to permit fixing unyielding time frames for agency decision-making.”) See also Edward Tomlinson, Report on the Experience of Various Agencies with Statutory Time Limits Applicable to Licensing or Clearance Functions and to Rulemaking, Administrative Conference of the United States, in Administrative Conference of the United States, Recommendations and Reports (1978) (report forming the basis of this recommendation) [hereinafter Recommendation 78-3].

48. Improving the Environment for Agency Rulemaking, Recommendation 93-4, Administrative Conference of the United States, Recommendations and Reports (1993) (on file with author) [hereinafter Recommendation 93-4]: [L]egislative-imposed time limits on rulemaking, while understandable, can be unrealistic, resulting in either hastily-imposed rules or missed deadlines that undermine respect for the rulemaking process. Legislative deadlines backed by statutory or regulatory “hammers” (mandating, for example, that the proposed rule or some other policy change automatically take effect upon expiration of the deadline) are particularly undesirable and often counterproductive.


50. Recommendation 93-4, supra note 48, sec. II.B.

51. Id. at 2-3. Recommendation 93-4 (II.B) noted that if Congress does determine that a hammer should be used, it should specify the terms of the default option and should not impose “regulatory hammers” that transform the proposed rule into the final rule automatically. Thus ACUS, although hostile to hammers in general, supra note 48, favors the type of hammer utilized in the 1984 HSWA rather than an NLEA hammer.

52. The main exception to the generally critical tone of commentary on statutory deadlines is a 1985 study conducted by the Environmental and Energy Study Institute and the Environmental Law Institute. See supra note 20. While the study found that statutory deadlines are often ineffective in setting priorities, it concluded that “there are no real alternatives to statutory deadlines.”


54. Abbott, supra note 1, at 171-86; Tomlinson, supra note 47, at 121-23 (effectiveness in reducing delay is limited).

55. One observer claims that Congress imposed 600 deadlines in environmental laws between 1970 and 1983. Abbott points to the 1984 amendments to the RCRA, which he says contained 60
effect, making it difficult, if not impossible, to meet all of them. Unrealistic deadlines are unlikely to be met, and may serve simply to frustrate the agency and the authors of the deadline.

Resource costs associated with statutory deadlines—particularly agency defense of suits challenging failure to comply with the deadline—may be high. Furthermore, some observers charge that the substantive quality of regulations has suffered due to court-imposed deadlines established pursuant to statutory deadline cases.

III. The Nutrition Labeling and Education Act of 1990

A. The Law

The NLEA was the culmination of decades of interest in reforming the information and claims contained on food labels, an issue of longstanding concern to the public health community. The FDA last prescribed major changes in food labels in 1973. Although ambitious at the time, the labels required by the earlier regulations increasingly were recognized as inadequate in the face of mounting evidence linking particular types of nutrients, such as fat, with chronic disease. The limitations of the 1973 regulations were clear by the late 1980s, if not earlier. The labels were not mandatory for all foods—by 1989 only sixty percent of FDA-regulated statutory deadlines. Abbott, supra note 1, at 173. See also supra note 17. Former EPA Administrator Reilly asserted that Congress and the courts imposed 800 deadlines on the EPA through 1989. See Lazarus, supra note 53, at 323 n.51.

56. Alden Abbott studied 11 cases of statutory deadlines, and argued that the studies revealed 8 cases of wasted resource costs (expense of resources without curbing delay), 5 cases of agency resource misallocation costs (inappropriate skewing of regulatory priorities), and 4 examples of regulatory inefficiency costs (hasty action by agency and subsequent promulgation of cost-inefficient regulations) associated with statutory deadlines. In no cases did Abbott find a salutary effect of the deadline (prompting quicker agency action, for instance). Alden F. Abbott, Case Studies on the Costs of Federal Statutory and Judicial Deadlines, 39 ADMIN. L. REV. 467, 487 (1987).

57. Abbott argues, for instance, that the deadline in section 3004 of the RCRA, which included an 18-month deadline to promulgate regulations for the treatment, storage, and disposal of hazardous wastes and to develop standards for disposal facilities, was unrealistically short. The subsequent court-ordered deadline “forced officials to promulgate regulations hastily; in the absence of deadline pressures, the regulations might have been better crafted.” Id. at 471-73. Abbott makes the same claim about sections 3001(a) and (b) of the RCRA, which required EPA to identify and list hazardous wastes within 18 months of enactment. After allowing a number of delays because the agency was proceeding in good faith, a court set a deadline of April 1980. EPA issued the regulations the next month. Abbott drew three conclusions after study of this episode: the original deadline was unrealistic, significant costs were expended defending the agency in the deadline suits, and the ultimate court-imposed deadline forced the agency to “act hastily, to the detriment of the quality of final section 3001 regulations.” Id. at 475-76.


The FDA arguably had been attempting to modernize the food label since the late 1970s, when the FDA, the U.S. Department of Agriculture (USDA), and the Federal Trade Commission held a series of public hearings on food labeling issues. The three agencies announced tentative positions on a variety of issues, 44 Fed. Reg. 75,990 (Dec. 21, 1979), but took no further action.
lated foods bore nutrition labels. The label did not provide easy-to-follow nutritional information for consumers. With its heavy focus on vitamins and minerals, the label also did not reflect information relevant to contemporary understandings of diet and health.

The 1980s increasing interest in the connection between diet and health prompted a change in food marketing practices to attract the growing number of health-conscious consumers. There was a burgeoning number of health claims made for foods (such as claims linking the consumption of fiber with a reduction in cancer risk) and a spiraling number of nutrient content claims, or descriptors (such as "light" and "low-fat"). The FDA had been hostile to health claims that linked food consumption to a reduction in risk for diseases because it viewed such claims as false and misleading. In the mid-1980s, however, the FDA was forced to re-evaluate its hostility to such claims because of growing evidence of linkages between dietary patterns and some chronic diseases. In the late 1980s, the FDA had proposed regulations permitting certain health claims to be made on food products.

1. The FDA's Nutrition Labeling Initiative

Long on the agenda of the public health community, comprehensive revision of nutrition labels moved to center stage in the late 1980s. In August 1989, the FDA announced its intention to implement significant changes in food labeling. The FDA pointed to the many factors that required re-evaluation of food labeling requirements: authoritative information regarding the links between diet and health; consumers' increasing interest in nutrition information; difficulty in understanding existing labels; and the focus of the old labels on vitamins, instead of fat and fiber, that was outdated in light of current understanding of nutritional needs.

The FDA held four public hearings and in July 1990 proposed ambi-

60. The FDA's long-standing hostility to disease-specific health claims on foods slowly began to change in the 1980s, when the agency was confronted with mounting evidence linking diet and certain chronic diseases. See Peter Barton Hutt, Government Regulation of Health Claims in Food Labeling and Advertising, 41 FOOD DRUG COSM. L.J. 2, 3 (1986); HUTT & MERRILL, supra note 14, at 183-85; Richard M. Cooper et al., History of Health Claims Regulation, 45 FOOD DRUG COSM. L.J. 655, 655 (1990).
61. H.R. REP. NO. 538, supra note 4, at 9. For a history of health claims regulation, see Hutt, supra note 61; Richard M. Cooper et al., supra note 60. In the late-1980s, the FDA published proposed regulations permitting disease specific claims that had not met the FDCA's requirements applicable to drugs, 52 Fed. Reg. 28,843 (Aug. 4, 1987), and published a reproposed rule in February 1990, 55 Fed. Reg. 5176 (Feb. 13, 1990). Developing FDA policy was eclipsed by the NLEA.
62. V.E. Irons, Inc. v. United States, 244 F.2d 34 (1st Cir. 1957); see also Hutt, supra note 60; Cooper et al., supra note 60.
63. See supra note 61; Peter Barton Hutt, Speech to Kellogg Institute, quoted in HUTT & MERRILL, supra note 14, at 183-85.
64. See supra note 60.
tious new nutrition labeling regulations. The proposals addressed many of the concerns the agency had identified. The FDA proposed to revise the list of required nutrients; to require the disclosure of the number of calories from fat, saturated fatty acids, cholesterol, and dietary fiber; and to make the listing of certain vitamins—thiamin, riboflavin, and niacin—optional instead of mandatory. To reduce confusion, the FDA’s proposals defined and set forth the proper uses for nutrient descriptors such as “cholesterol-free” and “low cholesterol,” and proposed to standardize serving sizes for 159 food categories.

2. The NLEA

Just months after the FDA proposed its nutrition labeling regulations, Congress passed the NLEA, and President Bush signed the bill into law in November 1990. The NLEA endorsed many of the proposals the FDA had authored. The mandatory nutrition labeling provision required the agency to develop a uniform label format that would emphasize contemporary dietary concerns, like fat and fiber. The health claims provisions also required that rules be established to govern nearly every type of health message that might be made about food, including nutrient content claims (descriptors) and health claims. In addition, the Act preempted certain state regulations and allowed for state enforcement of the law.

The NLEA mandated an immense overhaul of the rules governing food labeling. By the FDA’s own estimate, the final NLEA regulations affected 17,000 food manufacturers and 260,000 labels. The FDA estimated the cost of compliance with the NLEA regulations to be anywhere from $1.4 billion to $2.3 billion.

3. The NLEA’s Hammer Provisions

As previously mentioned, hammers were attached to the nutrition labeling and health claims sections of the law. The nutrition labeling provision mandated that certain nutritional information about foods appear on the new label, such as caloric content, number of calories derived from fat, and amounts of fat, dietary fiber, protein, cholesterol, sodium, sugars, and carbohydrates in the food. The label also would include a standardized...
serving size based on the amount of food customarily consumed.\textsuperscript{74} This provision also contained a series of complicated subprovisions for voluntary labeling of raw agricultural commodities, raw fish, and the exception of certain small businesses from nutrition labeling requirements.\textsuperscript{75}

Under the health claims section of the NLEA, certain health messages were barred unless they were made in accordance with rules prescribed by the FDA. This section, like the nutrition labeling provision, was quite complicated. Claims about the amount of certain nutrients were to be monitored closely to control misleading claims such as “low in saturated fat” on a high cholesterol food or “high in dietary fiber” on a food that was high in total fat.\textsuperscript{76} This section also barred claims characterizing the relationship of a nutrient to a disease or health-related condition, unless the claim was approved by regulations based on a “significant scientific agreement” about the relationship.\textsuperscript{77} Finally, this section required the Secretary to issue uniform definitions of nutrient descriptors.\textsuperscript{78}

Both sections—nutrition labeling and health claims—included hammer provisions that required proposed regulations to be published within twelve months of enactment.\textsuperscript{79} They further provided, “If the Secretary . . . does not promulgate final regulations . . . [under this section] upon the expiration of 24 months after the date of enactment of this Act, the proposed regulations . . . shall be considered as the final regulations upon the expiration of such 24 months.”\textsuperscript{80}

The presence of the hammer can be traced to a number of factors. The provisions reflected a frustration with the FDA’s inability to meet deadlines in general and a perceived delay in modernizing nutrition labeling rules. The hammer was indicative of Congress’ desire for regulations to be in place by a certain date. The hammer, too, was an expression of the importance of the issue to Congress—or at least to the committees that authored and approved the law—and an attempt to force nutrition labeling issues to the top of the agency’s agenda. Finally, the hammer reflected a concern about potential delay in getting the regulations out of the agency, including the delay that might result from review by the Office of Management and Budget (OMB).\textsuperscript{81} At the time, then-Vice-President Quayle’s Council on Competitiveness was involved deeply in the review of regulations, often provoking controversy.\textsuperscript{82}
The Committee report accompanying the bill noted that the deadlines contained in the bill were "consistent with the FDA's current schedule for its nutrition labeling initiative." Furthermore, the report explained that the Committee expected the Secretary to meet the deadlines; if the Secretary failed to do so, the Committee had determined that the nutrition labeling required by the bill was "so important that if the deadline is not met, there will be good cause to issue the proposed regulations as final regulations."

B. NLEA Regulations

1. Proposed Rules

On November 27, 1991, the FDA proposed a series of regulations pursuant to the NLEA. The FDA issued thirty-eight separate documents on that day, proposing rules on the nutrition labeling, health claims, preemption, and state enforcement provisions of the law. The agency later issued a proposed rule that discussed food label formats and re-opened the comment period on a number of the health claims linking diet and certain diseases.

The proposed rules were greeted critically by many who would be subject to them. Some commentators called them the "worst-case" scenario
for the industry.\textsuperscript{89} The FDA's decision to permit only four of ten potential health claims, "restrictive" definitions of nutrient content claims, and intricate size and type requirements for health claims rendered the regulations unpalatable to many in the regulated community.\textsuperscript{90}

In late July 1992, the FDA issued a proposal regarding formats for nutrition labels and presented the results of research conducted on a variety of nutrition label formats.\textsuperscript{91} The document discussed the FDA's then-proposed label format, which presented the nutrient content of the food as a percentage of a hypothetical 2350-calorie daily diet.\textsuperscript{92} Under this proposal, the agency reasoned, the consumer would have some "context" against which to compare the nutritional value of the food. The document also discussed a number of alternative label formats, including one proposed by the U.S. Department of Agriculture (USDA).\textsuperscript{93} The USDA's proposed label formats would not have contained the hypothetical context for the nutrients, but instead would have included general dietary guidance accompanying the label. Under the USDA's proposals, the nutrient levels of the food would not be compared directly to a hypothetical diet.\textsuperscript{94} This issue of label format, and the appropriate context in which to provide nutrition information, would be one of the critical issues that delayed the promulgation of final regulations when a late interagency dispute flared up and could not be resolved.

The rulemaking process was an immense effort.\textsuperscript{95} The issues addressed by the law required resolution of a host of difficult questions. After proposed rules were published, the FDA received and reviewed over 40,000 comments, held three public hearings, and ultimately crafted final rules in over twenty proceedings.\textsuperscript{96}


\textsuperscript{90} \textit{Id.} See also Peter Barton Hutt, \textit{A Brief History of FDA Regulation Relating to the Nutrient Content of Food} (1994) (copies available from the author at the following address: Peter Barton Hutt, Esq., Covington & Burling, 1201 Pennsylvania Ave., NW, P.O. Box 7566, Washington, D.C. 20044).

The four health claims that the FDA proposed to be permitted were: the links between calcium and osteoporosis, \textsuperscript{56 Fed. Reg. at 60,689} lipids and cardiovascular disease, \textit{id.} at 60,727; dietary lipids and cancer, \textit{id.} at 60,764; and sodium and hypertension, \textit{id.} at 60,825. The six rejected health claims involved: dietary fiber and cancer, \textit{id.} at 60,566; dietary fiber and cardiovascular disease, \textit{id.} at 60,582; folic acid and neural tube defects, \textit{id.} at 60,610; antioxidant vitamins and cancer, \textit{id.} at 60,624; zinc and immune function in the elderly, \textit{id.} at 60,652; and omega-3 fatty acids and coronary heart disease, \textit{id.} at 60,663.

\textsuperscript{91} 57 Fed. Reg. at 32,058.

\textsuperscript{92} \textit{Id.} at 32,062, 32,073-74 (app. B); see also 56 Fed. Reg. at 60,366 (nutrition label format).


\textsuperscript{94} 57 Fed. Reg. at 39,346-49.

\textsuperscript{95} Fred Shank noted that the NLEA was the most important legislation regarding food and its labeling since the FDCA, and that it was also "one of the more complex and—in terms of implementation—most resource-intensive laws that the Food and Drug Administration has had the opportunity to deal with." Fred Shank, \textit{The Nutrition Labeling and Education Act of 1990, 47 Food Drug Cosm. L. J. 247} (1992).

\textsuperscript{96} See 58 Fed. Reg. 2066, 2067 (Jan. 6, 1993). On January 6, 1993, the FDA issued 27
2. Interagency Disputes

The agency had resolved countless issues, and reportedly had prepared the final rules for imminent publication in the Federal Register when the inability to reach agreement with the USDA on a number of issues delayed final publication. The USDA's jurisdiction over meat and poultry products meant it had control over an important segment of food labels. The NLEA respected this jurisdictional boundary, but the USDA determined that it would revise meat and poultry nutrition labeling in conjunction with the FDA. This set the stage for disagreement between the two agencies as they struggled to develop consistent approaches to nutrition labeling.

Although there are only sketchy details available about the substantive issues involved in this late dispute between the FDA and the USDA, one key issue involved the appropriate context for the labeling format. The FDA's proposed rule stated that the food's content had to be listed in absolute amounts as well as a percentage of a recommended daily diet; by Fall 1992, the FDA had set the recommended daily diet at 2000 calories per day, the recommended diet for the average woman.\(^97\) The USDA objected to this percentage format, and reportedly charged that the contextual format was weighted against meat and dairy products.\(^98\)


One other dispute centered on the applicability of the NLEA provisions regarding nutrient content and health claims rules to restaurants. The law exempted restaurants from nutrition labeling but was silent on the applicability of other provisions. The FDA proposed to apply nutrient descriptor and health claims rules to restaurants, although the restaurant industry objected. The industry, reportedly with the OMB's support, argued that the testing requirements necessary to comply with the nutrient descriptor rules would be extremely burdensome due to restaurants' frequently changed menus, diverse food preparation procedures, and limited resources.

The White House, reportedly with President Bush's personal involvement, ultimately brokered a resolution of these disputes—substantially agreeing with the FDA's position on the context of the nutrition label, but exempting restaurants from the nutrient content and health claims rules. This negotiation delayed promulgation of the final rules beyond the hammer deadline. After a month of reportedly intense negotiating, a compromise agreement was announced on December 2, 1992, and the regulations embodying those agreements ultimately were issued January 6, 1993.

3. Hammered Final Rules

The negotiations stretched past the November 8, 1992 deadline for the final rules, and the agency announced that the hammer had fallen. On November 27, 1992, the agency placed a notice in the Federal Register disclosing that the proposed regulations were "now considered final regulations" pursuant to the hammer provisions of the NLEA. Without explanation as to the importance of this announcement, the agency stated that the November 27 document was part of a separate rulemaking—apparently simply consisting of the transformation of the proposed rules into the final rules—that was intended by the law in the event final regulations were not published by the deadline. Thus, the agency stated that the rulemakings pursuant to the proposed rules remained ongoing. The agency expressed its intention to issue final regulations that would supersede the hammered final regulations. Those regulations would be

100. Frank et al., supra note 89; Interagency Fight, supra note 97.
101. 58 Fed. Reg. at 644-45; Hutt, supra note 90. See also Bush to Seek to End Feud Over Food Labeling Rules, L.A. Times, Nov. 28, 1992, at 28; Food Label Agreement Reached, supra note 98, at A1; Frank et al., supra note 89. The FDA later reversed its position and proposed to apply nutrient content and health-claim rules to restaurants. 58 Fed. Reg. 33,055 (June 15, 1993).
103. 58 Fed. Reg. at 2066. See supra note 96 for a full listing of regulations.
based on comments already received or, "in its discretion," the agency might propose new rules and seek comment.\textsuperscript{106}

C. \textit{The FDA's Replacement of Hammered Final Regulations}

Once the White House negotiations were over and an agreement had been reached, the FDA faced a problem. The agency had authored proposed rules that were hammered final in November 1992, but the FDA found them undesirable. The agency—like many of those parties interested in the rules—wanted to replace those hammered final rules with new rules agreed upon after interagency negotiation. Rule amendment normally requires compliance with the APA,\textsuperscript{106} which dictates the invitation of comment on proposed action,\textsuperscript{107} and that could take months. If it invited comment, the FDA might have received an avalanche of new material to which it would have been required to respond. Time, however, was of the essence. The new administration would take office within the month and, even if it was committed to the NLEA's goals, that administration would want to review such major regulations. In addition, the short compliance period and the lead time needed to convert all nutrition labels meant that the FDA would have to act quickly to replace the hammered final rules.

The FDA responded to this dilemma one month after the agreement was announced. On January 6, 1993, the agency promulgated 900 Federal Register pages of final regulations.\textsuperscript{108} The agency, without inviting comment, both revoked the November 1992 hammered final rules and replaced them with final rules that were described as the "logical outgrowth" of the original proposed regulations.\textsuperscript{109}

The agency explained its action by emphasizing that the hammer already had achieved its purpose. The hammer existed to make certain that some rules were in place by a particular date, a purpose served by the hammered final rules. The hammer also was intended to prod the agency and all parties involved to act quickly to resolve issues associated with the rulemaking. That purpose, the agency asserted, also was achieved because "[the hammer] has encouraged prompt resolution of outstanding issues and led to agreement on final rules that represent substantial improvement over the proposed rules and that will be in place sufficiently before the date the statute must be applied to allow full industry compliance."\textsuperscript{110}

The FDA argued that Congress had not instructed the agency to ignore

\textsuperscript{105} 57 Fed. Reg. at 56,348.
\textsuperscript{107} 5 U.S.C. § 553(b)-(d).
\textsuperscript{108} 58 Fed. Reg. at 2066-2964. \textit{See supra} note 96 for a full listing of regulations.
\textsuperscript{109} 58 Fed. Reg. at 2066. The agency's invocation of the phrase "logical outgrowth" echoes the requirement that the final rules be the logical outgrowth of the proposed rules. \textit{Shell Oil Co. v. EPA}, 920 F.2d 741 (D.C. Cir. 1991).
\textsuperscript{110} 58 Fed. Reg. at 2066.
comments received on the proposed regulations in the event that the hammer fell. Consideration of public comment could improve the rules considerably, and the new final rules (as opposed to the hammered final rules) would approximate more closely the goals of the NLEA. Thus, the agency argued that its action was consistent with the NLEA.\footnote{Id. at 2066-67.}

The agency also defended its revocation and replacement—without notice and comment—as fully consistent with the APA, citing the good cause exceptions to the notice-and-comment requirements of the APA.\footnote{5 U.S.C. § 553(b)(3)(B) ("[Notice-and-comment is not required] . . . when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."). Here the agency invoked the legislative history cited \textit{supra} notes 83-85 and accompanying text. 58 Fed. Reg. at 2067.} First, the agency asserted that notice-and-comment was impracticable, given the short amount of time between the final rules and the effective date for some of the provisions of the law. The provisions governing health claims were effective May 8, 1993, without the possibility of extension.\footnote{58 Fed. Reg. at 2067.} The FDA did act to extend the effective date for nutrition labeling and nutrient content claims regulations to May 8, 1994, but argued that even a brief notice-and-comment period would delay promulgation of final regulations for months, reducing the amount of time industry would have to comply with the law.\footnote{Id. at 2068.} Second, the agency reasoned that a round of comments on the revocation would be contrary to the public interest because the delay would lead to confusion as to which rules were operative. The public interest would be served best by having final rules (based on public comments) in place quickly.\footnote{Id. at 2068.}

The agency noted that "[p]ublic comment is not an end in itself."\footnote{Id. at 2066.} If the full examination of nutrition labeling issues was considered, extensive opportunity for public comment had occurred. There had been three prior occasions for comment on the FDA-initiated nutrition labeling proposals, in addition to the 40,000 comments on the proposed NLEA regulations.\footnote{Id. at 2067.}

Despite this elaborate defense of its actions, the agency did provide thirty days for technical comments on the final rules,\footnote{Id.} perhaps to protect itself from a challenge to its decision to revoke and replace the hammered final rules without requesting comment.
D. Use of Hammers in Other FDA Proceedings

The justifications for the agency's actions in January 1993 have not been tested because no challenge to this particular action has been brought; a challenge probably could not be raised at this stage. But in the proceedings that will now be examined, the FDA has invoked this, or similar, legal reasoning where hammers have been operative. These proceedings provide a fuller picture of the agency's experience with hammer provisions, an understanding that is necessary to draw broader lessons about the operation of these devices.

1. Dietary Supplement and Nonfunctional Slack-Fill Regulations

In early January 1994, the FDA announced that hammers had fallen to transform proposed rules governing dietary supplements and slack-fill containers into hammered final rules. For dietary supplements, October 1993 proposed regulations (one proposing to authorize a health claim regarding the relationship between folate and the risk of neural tube defects, and the others rejecting a variety of health claims) became final regulations through the operation of the original NLEA hammer, as amended by the Dietary Supplement Act of 1992.

The January 1994 nonfunctional slack-fill action was akin to the FDA's January 1993 NLEA action. Like its January 1993 action, the agency revoked and replaced hammered final rules that had been made final on May 10, 1993, pursuant to a hammer provision contained in the NLEA. When the FDA announced that the proposed rules were to become final rules by operation of the hammer, it repeated the reasoning of its earlier hammered final documents, noting that the hammered final rules "did not conclude the [proposed] rulemaking" but were "part of a separate proceeding that is compelled [by the hammer provision of the law]."
With the hammered final rules in place, the FDA then announced in December 1993 that it proposed to withdraw the hammered final regulation and replace it with new final rules published on the same day.\(^\text{128}\) Unlike its previous revocation and replacement of the majority of the NLEA regulations, the FDA did request comment (allowing just ten days), although only on its decision to withdraw the hammered final regulations. The agency did not request comment on the substance of the final rule that was published that day. No comments were received and on January 5, 1994, the FDA revoked the previously hammered final rule and replaced it with the new final rule promulgated in December 1993.\(^\text{129}\)

2. The Safe Medical Devices Act of 1990

The Safe Medical Devices Act of 1990 (SMDA)\(^\text{130}\) directed the agency to establish a system to require manufacturers to track certain devices from manufacture to patient use. Like the NLEA, the SMDA contained hammer provisions.\(^\text{131}\) In the case of the SMDA, the FDA missed the deadline for a proposed rule on device tracking and issued a proposed rule just two months before the May 1992 deadline for the final rule.\(^\text{132}\) This March 1992 proposal was the focus of intense comment that questioned basic elements of the rule. The comments raised concerns about the effective date, the applicability of the tracking requirements to imported and exported devices, the sanctions for noncompliance with the rule, alternative methods of tracking, reporting requirements, and costs.\(^\text{133}\) In response, in late May 1992, the FDA—within two days—withdrawed the proposed rule, issued a revised proposed rule and, by operation of the hammer, the revised proposed rule was transformed into the final rule on May 28, 1992.\(^\text{134}\) Even as it hammered the rule final, the agency admitted that the statutory deadline did not permit sufficient time to "give full and careful consideration and response to all comments."\(^\text{135}\)

Congress intervened and on June 16, 1992, enacted legislation that transformed the May 28 hammered final regulation into a proposed regulation.\(^\text{136}\) That rule, however, was again transformed into a final rule by

131. See supra note 9 for discussion of the SMDA hammer.
134. 57 Fed. Reg. 22,966 (May 29, 1992). On this date, the agency also published the revised proposed rule, and discussed the reasons for the withdrawal of the original proposed rule. Id. at 22,971. Thus, the agency was in the awkward position of publishing its revised proposed rule, and announcing that the rule had been hammerered final on the same date. See also 58 Fed. Reg. 43,442 (Aug. 16, 1993).
135. 57 Fed. Reg. at 22,971.
operation of the hammer contained in the 1992 amendments. This occurred because the agency believed that the comments received did not require changes to be made to the once hammered final and proposed rules. Even though the hammered final rule would remain the final rule, the FDA "decided" to respond to the most significant comments on the proposal in August 1993, although it implied that its response to comments was a discretionary act.137

IV. LEGAL ISSUES ASSOCIATED WITH THE USE OF HAMMERS

Two agency actions under the NLEA could have provided the basis for constitutional or statutory challenges. First, a direct challenge could have been raised to the NLEA rules that were hammered final without opportunity for comment. Second, a plaintiff might have challenged the agency’s subsequent action of revoking and replacing the hammered final rules, also without comment. If raised today, these challenges likely would be dismissed on timing grounds. This discussion, therefore, is of hypothetical claims.

A. Challenge to the Hammer Provision and Hammered Final Rules

If the hammer operated precisely in accordance with its statutory language and the FDA allowed the hammered final rules to remain unchanged, could these hammered final rules withstand a challenge predicated on either the due process clause or the APA?

It is worth observing that this question could be largely academic. In NLEA rulemaking, the agency had a strong desire to keep the hammer from falling and then to replace the hammered final rules once they were in place, which is a testament to the strength of the incentive effects of this type of hammer. In the one case in which the FDA allowed a hammered final rule to remain final—i.e., the medical device tracking rulemakings discussed previously—the agency substantively defended this rule (as it might any other final rule) by responding to significant comments even as it implied that it was not required to do so.138

The question posed here does remain relevant, however. In each instance where a hammer fell, the agency maintained that it would continue the underlying rulemaking proceeding and promulgate new final rules based on the comments received. A challenge conceivably could be

passed and the May 28 rules again became final in November 1992. The agency announced that they had been hammered final in an August 16, 1993 Federal Register document. 58 Fed. Reg. at 43,443. 137. The FDA stated, “Despite the statutory ‘hammer,’ however, the agency has decided to respond to the most significant comments in order to communicate its views to the industry and to the public.” 58 Fed. Reg. at 43,443 (emphasis added).

138. See supra note 137 and accompanying text. See also interviews with Robert Lake, Fred Shank, supra note 14; Edward Scarborough, Director, Office of Food Labeling, FDA, Washington, D.C. (Jan. 11, 1994) (agency unlikely to allow hammered final rule to remain final rule without response to comments received).
brought, however, to hammered final rules prior to the agency action to revoke and replace them. There is also the possibility that an agency would not be able to revoke and replace the hammered final rules because of inability to reach agreement, a change in administration or important agency personnel, or some other factor.

1. Due Process Challenge

One possible challenge to hammered final rules would be rooted in the Due Process Clause. A party subject to hammered final rules could charge that the FDA constitutionally cannot enforce costly and complex rules against a party that has had no opportunity to comment on the substance of those rules. A due process challenge to hammered final rules, however, likely will fail. The Supreme Court has imposed a variety of constraints on agency action, including requiring hearings in certain cases, under the rubric of due process. That line of cases, however, is limited to individualized, adjudicatory determinations, and has not been applied to cases involving legislative rules, as is the case here. Furthermore, when the NLEA hammer fell—although the agency's tardiness caused the hammer to fall—the statute itself explicitly dictated that notice and comment could be dispensed with. Thus the question would be whether Congress had the authority under the Due Process Clause to impose the hammer. Given the Court's modern jurisprudence of deference to legislative decisions, a due process challenge to the hammer is unlikely to prevail.

Although the NLEA created the possibility that the hammer would fall, it did not prescribe the rules that were hammered final; those rules were authored by the agency. Furthermore, the jurisprudence of deference to non-adjudicatory legislative decisions notwithstanding, the government probably could not point to a case in which rules as complex as those associated with the NLEA have been enforced without notice and com-

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139. U.S. Const. amend. V.
141. Bi-Metallic Investment Co. v. State Bd. of Equalization, 239 U.S. 441 (1915) (taxpayer not entitled to individualized hearing in proceeding revaluing all property within city); Pacific States Box & Basket Co. v. White, 296 U.S. 176 (1935) (rejection of due process challenge to state agency order prescribing type, size, and shape of containers for fruits).
142. See Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Insurance Co., 463 U.S. 29 n.9 (1983) ("We do not view as equivalent the presumption of constitutionality afforded legislation drafted by Congress and the presumption of regularity afforded an agency in fulfilling its statutory mandate.").
ment. In fact, there is a source of some support to a due process challenge, in that agency attempts to invoke the good cause exception to the APA, which allows an agency to dispense with notice and comment if “good cause” is shown, are greeted skeptically by courts. Special scrutiny of agency attempts to avoid notice and comment can be read to reflect concern about the fundamental fairness—perhaps rooted in the constitutional notion of due process—of a rulemaking process that does not allow for notice and comment. These fairness concerns might lend more weight to a due process challenge to hammered final rules.

Ultimately, for the reasons mentioned, a due process challenge to hammered final rules likely would have failed because the question would be formulated as one about legislative power to prescribe procedures for agency rulemaking. Framed this way, an agency defending hammered final rules is likely to prevail.

2. Administrative Procedure Act Challenge

A claim arising under the APA would be a more promising challenge. There, court examination of agency action is much more searching. The notion that final rules might become effective without the opportunity for comment clearly flies in the face of the principles of notice-and-comment rulemaking as embodied and interpreted in section 553 of the APA.

Nonetheless, an APA challenge to hammered final rules would have been difficult. The APA specifically contemplates occasions—the “good cause” exception—in which notice and comment can be dispensed with. In fact, the Committee report on the NLEA explicitly invoked this exception to justify the hammer, stating that if the agency failed to issue rules by the statutory deadline there was “good cause” to transform proposed rules into final rules without comment. The agency simply would be following the prescriptive procedural requirements set forth in the law. Thus, the question would again devolve into one about the authority of Congress to alter the APA requirements or to elaborate on the existing APA exceptions. The authority of Congress likely would be sustained in that case. A court could view the hammer as a legitimate amendment to the “default” option of the APA.

143. See infra note 152.
144. National Tire Dealers & Retreaders Ass’n v. Brinegar, 491 F.2d 21 (D.C. Cir. 1974); Motor Vehicle Manufacturers Ass’n, 463 U.S. at 103 (agency must, but did not, provide “adequate basis and explanation” for revoking passive restraint requirement and thus rescission is “arbitrary and capricious”); United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240 (2d Cir. 1977); Wagner Electric Corp. v. Volpe, 466 F.2d 1013 (3d Cir. 1972); Shurz Communications, Inc. v. FCC, 982 F.2d 1043 (7th Cir. 1992). This more searching review could be seen to be rooted in the Due Process Clause.
146. Section 559 of the APA states that “[s]ubsequent statutes may not be held to supersede or modify this subchapter . . . except to the extent that it does so expressly.” This might be a statutory basis for a court to determine that the hammer did not amend the APA’s informal rulemaking re-
B. Challenge to January 1993 Revocation and Replacement of Hammered Final Rules

The FDA theoretically could have faced a more serious APA challenge to its January 1993 action to revoke the hammered final regulations and replace them with new final regulations. The agency did not invite comment on either action. The agency cited a number of factors in support of its decision, including the good cause exceptions contained in the APA and consistency with the NLEA's goals. The legitimacy of these actions in the context of a statutory hammer would have been a question of first impression.

There are two potential problems with the agency's action. First, revocation of regulations is subject to judicial review and must be supported by an adequate basis and explanation, or it will be deemed arbitrary and capricious. Second, an agency must request comment before issuing final rules, unless it has "good cause" not to do so. In this case, because the hammered final rules already were in place, the new final rules were of questionable status, and the agency arguably should have treated them as a new set of proposed rules. Issuance of proposed rules normally has to be accompanied by an invitation to comment on the substance of the proposals. Rather than inviting comment, the FDA promulgated new final rules as if the hammered final rules never existed.

The agency had stated in the hammered final rules that the docket on the proposed rules remained open, and in its January 6, 1993, rulemaking argued that the new final rules were the logical outgrowth of the proposed rules issued in November 1991. Furthermore, in the preambles to each of the new final rules, the agency explained and justified the differences between the proposed rules and the final rules.

One principal argument supporting the agency's decision is rooted in the statutory scheme of the NLEA. The agency could argue that the NLEA—the hammer and the brief effective date provisions—reflected a commitment to make certain that regulations governing the new nutrition labels were in place without delay. The law was so committed to quick action that it effectively amended the APA's informal rulemaking requirements to allow proposed rules to become final automatically (without notice and comment), should that have been necessary. This statutory

requirements. The argument would be difficult to sustain. A court would have to ignore the very specific dictates of the NLEA in favor of the informal rulemaking requirements of the APA. Courts have treated the APA procedures as a default option, and have interpreted individual statutes as prescribing procedural requirements that are in addition to the APA requirements.

151. In the House report accompanying the bill that eventually became the NLEA, the Committee declared that if the Secretary did not act within the time frames established, there was "good cause" to hammer final the regulations to make certain some rules were in place. The Committee also
scheme should inform judicial review of agency action and the traditional "arbitrary and capricious" standard for judicial review embodied in section 706 of the APA must be applied in light of Congress' commitment to quick action as reflected in the hammer. Given the context of the statutory scheme, the FDA could argue that its action met the good cause requirements.

One problem with this argument is that courts are skeptical of agency invocations of "good cause" and they have erected a high hurdle over which agencies rarely can scramble to invoke the good cause exceptions. While the statutory scheme surely embodies commitment to quick action, the fact was that the law's goal had been met: hammered final rules were in place at the time the FDA failed to request comment on its actions. It does not necessarily follow that the hammer can insulate any future action by the agency after it falls. The agency would have to demonstrate that, even though the professed goal of the law had been fulfilled, the additional delay that would result from a requirement to invite and respond to comment would frustrate the statutory scheme.

If the agency's argument based on the NLEA failed, its actions would be subject to review based on the principles of the APA, a rather searching judicial review. As just noted, the "good cause" exception is notoriously difficult to invoke, but this situation might provide such a case. The new final regulations were based on an exhaustive record, and this surely would influence a court's judgment. It also is important that the only matter on which there was not comment was the decision to revoke and replace the final rules.

A threshold requirement for surviving APA review is that the agency's final rules must adopt proposals that were considered fairly in the rulemaking process. If this hurdle is passed, a court might cite a series of cases that have allowed agencies to change rules based on a previous rulemaking record without opportunity for additional comment. A long passage of time or intervening factors that are relevant to the substance of the rulemaking surely would frustrate the agency's ability to invoke this line of cases.

asserted that the hammer provision allowed more public comment than the APA "good cause" exception required. See supra note 85.


V. INSTITUTIONAL AND POLICY ISSUES OF THE HAMMER

A. Introduction

The task the NLEA assigned the agency may be one of the largest single projects the FDA has ever undertaken. Yet, the agency did not receive any significant additional resources, and the hammer required the FDA to accomplish this ambitious task under a tight time schedule. This combination of factors created an atmosphere that influenced the process, and arguably the substance, of the rulemaking.

The NLEA embodied an ambitious agenda, and the agency devoted substantial resources to the task. The law added new sections to the FDCA that required mandatory nutrition labeling and the development of rules to govern the use of health messages contained on food labels. Each of these tasks involved a multitude of complex and difficult questions. In addition, the law included provisions on federal preemption and permitted state enforcement.

To work on the regulations, the agency diverted resources from other missions of the Center for Food Safety and Applied Nutrition (CFSAN); transferred personnel from research laboratories and field staff; and hired contractors to assist in reading and responding to comments. Dr. Fred Shank, Director of CFSAN, said in January 1992 that “the labeling regulations . . . proposed to date have been shaped under great time constraints. The statutory deadlines of the NLEA were, and remain, a major challenge and . . . the agency has been under considerable strain.” The agency devoted eighty-five full-time equivalents over the two years it was crafting the regulations, translating into $6.4 million in personnel costs alone. The agency estimated that 135 full-time equivalents would be used each year for the next twenty years to perform implementation tasks such as enforcement and petition review. The agency reviewed over

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154. Bill Schultz noted that the time frame Congress attached to the hammer tracked the schedule the FDA laid out in its 1990 regulations. Thus, he argued the time frame was reasonable. Interview with Bill Schultz, supra note 26. It is true that the NLEA’s general contours tracked many of the proposals the FDA had put forward in its 1990 regulations, but the NLEA also set forth different requirements than those envisioned in the 1990 proposed regulations. Furthermore, to say that the law tracked the time frame of the 1990 regulations and was reasonable presupposes that the FDA would have met its own time frame, which, in retrospect, seems doubtful. Finally, those who encountered the rulemaking, both inside and outside the agency, argued that the agenda set forth in the NLEA, and the lack of significant additional resources, translated into an extremely pressured two years. See infra notes 161-63 and accompanying text.

155. For much of the following discussion, the article speaks in rather broad terms, with some exceptions. This reflects the fact that those interviewed for this study of the effects of the hammer also spoke in these terms, especially agency officials, who are understandably reticent to outline any negative effects of this rulemaking on other agency functions.


159. 58 Fed. Reg. at 2929. Discounted at five percent, this meant $127,000,000 in recurring costs. Id.
40,000 comments and conducted rulemakings on over twenty separate topics.\textsuperscript{160} It is difficult to quantify the aggregate amount of time the agency spent on the regulations,\textsuperscript{161} but the anecdotal evidence complements the numbers given here: most of the persons interviewed for this article agreed that the agency absolutely was stretched to the limit for two years, and that the matter continues to occupy significant agency attention.\textsuperscript{162} Many compared the collective task to other major efforts of the agency, and some said that it was the most significant and complex task assigned to the agency in the food area in recent memory.\textsuperscript{163} The hammer meant that the statutory deadlines contained in the NLEA had particular bite. Even if it is assumed that any agency desires to meet its statutory deadlines, most deadlines are not self-executing, and many are missed. The hammer's self-enforcing character provides especially strong incentives for the agency to meet the deadlines. When an agency does not know what the proposed regulations are, the prospect of having a hammer fall must be particularly unpalatable. The automatic transformation of proposed rules into final rules would advertise a failure to accomplish the task assigned—and one that did not let the agency defend its deadline slippage as being in good faith. Furthermore, for bodies schooled in the obligation to respond to public comment as a policymaking tool, the prospect of hammered final rules likely would strike many in the agency as unwise.\textsuperscript{164} Given these predictions about agency behavior, perhaps it is not surprising that many who were interviewed agreed that the hammer played an important role in the commitment of both the agency and of the administration to meet the deadlines set forth in the law. Early on, the hammer played a role in the decision by the agency and the administration to attempt to complete the rules on time.\textsuperscript{165} \\

\textsuperscript{160} See supra note 96.  
\textsuperscript{161} Edward Scarborough stated that the internal tracking system at the FDA for judging the amount of time people spent on the regulations was imperfect, with some recording the time they spent on the regulations and others not doing so. Interview with Edward Scarborough, supra note 138.  
\textsuperscript{162} Interviews with Fred Shank, Robert Lake, supra note 14; Edward Scarborough, supra note 138; and Stuart Pape, Patton Boggs LLP, Washington, D.C. (Feb. 25, 1994).  
\textsuperscript{163} Id.  
\textsuperscript{164} When asked whether they could envision a situation in which a hammered final rule would stay final, interviewees suggested that such a case would be rare, and would not be a good idea in principle. Interviews with Ed Scarborough, supra note 138; Robert Lake, Philip Derfler, supra note 14.  
\textsuperscript{165} In a January 11, 1991 Federal Register document on the status of the FDA's food labeling proposals in light of the NLEA, the agency stated "the [NLEA] mandates extremely tight deadlines for FDA to propose and make final an extraordinarily large number of major food labeling regulations. The agency is committed to meeting all of the deadlines set by Congress." 56 Fed. Reg. 1151, 1152 (Jan. 11, 1991).  
See also interviews with Michael Taylor, then Deputy Comm'r for Policy, FDA, Washington, D.C. (Jan. 10, 1994); and Ed Scarborough, supra note 138. These agency officials spoke of the early commitment to meet the deadlines. This is not to say that the hammer created this commitment by itself. See infra notes 166-67 and accompanying text.
But the hammer did not operate in a vacuum at the agency. Regulatory delay can result from disagreement or lack of commitment within an agency. In this case, FDA leaders already had dedicated the agency to revision of nutrition labeling rules through its 1990 proposals. Those interviewed agreed that the attention and commitment of the top departmental management, from the Secretary to the Commissioner, and among many career employees, played an important role in the commitment of resources to the task of completion, and to resolution of critical matters along the way.166

The hammer thus coincided with a pre-existing agency pledge to reform nutrition labels. Perhaps a hammer provision could not, by itself, overcome internal dissent or resistance to action.167 Nonetheless, in this case, the hammer certainly spurred the agency to act by particular dates on a calendar, dates that would not have held such importance without the hammer.168

Obviously, the factors just discussed are in tension. The NLEA required a major resource commitment, yet the agency did not receive additional resources nor was it formally relieved of any of its other duties. On the other hand, the hammer meant that deadlines for agency action were unusually firm, or at least perceived to be so. These tensions—along with other factors—created an atmosphere in which there was significant time pressure, and this pressure had an important influence on the rulemaking process.

B. Re-Ordering Agency Priorities

The most obvious effect of the hammer was to place the NLEA regulations at or near the top of the agency’s agenda. The project required and received the sustained attention of a large segment of the FDA staff and top management.

This development arguably fulfilled the law’s aspiration to have the project completed by a designated date, and the regulations were promul-
gated within a few months after this date.169 This achievement is substantial. The FDA habitually missed statutory deadlines. In addition, the odds might have been against completion of this task. The NLEA set forth a complex and ambitious task, and there was a distinct possibility of opposition from either those who would be subject to the law or from others in the administration. In this context, substantially meeting the NLEA deadline is an achievement.

The fact that the issue was at the top of the agency's agenda was important internally and externally. Internally, the agency was forced toward closure. Difficult decisions could not be postponed.170 Significant delay was not an option if the agency was to meet the deadlines set forth in the law. Externally, constituents of the agency also knew that the agency was under time pressure and that delay might mean losing a chance to influence a decision.

The hammer's forced ordering of priorities at the agency had some costs, however. While the NLEA clearly intended for this project to be important at the agency, the law did not rank priorities for the agency or relate the project to other ongoing obligations of the agency. Congress did not, for instance, signal that other agency functions could be neglected or that nutrition labeling could take precedence over other ongoing work; nor did it even acknowledge that this would in fact occur.171

The hammer catapulted the NLEA regulations to the top of the agenda for a considerable percentage of the agency devoted to food issues, as well as its top management. A number of implications follow from this development. There clearly was potential for the neglect of other duties. It is nearly impossible to identify what the agency might have accomplished had it not worked almost full time on the NLEA regulations. Nonetheless, many of those interviewed admitted that the agency neglected other ongoing activities—although none would say which ones.172 This full-time occupation with one subject also could have an impact on those outside the agency. Some may not be able to attract the attention of the agency to get

169. Bill Schultz sees the hammer as a success for this reason. Interview with Bill Schultz, supra note 26.
170. Interviews with Margaret Jane Porter, supra note 166; Philip Derfler, supra note 14.
171. Bill Schultz stated that because Congress tied its deadline to those set forth in the 1990 FDA regulations, the time frame was reasonable and fair. Interview with Bill Schultz, supra note 26. But see supra note 154. As noted there, those who participated in the regulation-writing process were nearly unanimous in their assessment that the resource commitment required within that time frame meant that other agency functions suffered.
172. Agency officials are understandably reticent to discuss statutory functions that might have been neglected. Agency officials, when highlighting difficulties with the rules, would speak in only the most general terms. Ed Scarborough, for instance, said that work related to food standards, food fortification, common and usual names for food, and general nutrition issues such as nutrition monitoring and surveys were "placed on the back burner." Interview with Ed Scarborough, supra note 138. Fred Shank admitted that work on food additives suffered, as did the general research program. Interview with Fred Shank, supra note 14.
action on some urgent matter, or there may be a general understanding that the agency’s policing functions are being neglected.

The pressure created in this case influenced the substance of the rulemaking. Broadly speaking, it diminished the amount of time that could be spent on complex issues. This also is true for entities both inside and outside the agency. Examination of certain issues was truncated in the agency, and fewer issues could be disputed and resolved among agency staff.178 Outsiders, too, were forced to order their objections to proposals.174

An important byproduct of the rulemaking environment was significant delegation of decisions to lower-level staff without as much opportunity for supervisory review as might occur in a less pressured environment.176 Little overall policy coordination occurred. Indeed, one agency official recalled that only one person in the whole agency read the entire set of regulations.178 Inconsistencies in the final rules may have been the result of this system of rule development. Some agency staff argued that there was inadequate time to resolve certain scientific issues, some of them associated with health claims,177 or to obtain independent data on particular matters, such as consumers’ perception of food labels.178

Had Congress intended these trade-offs, perhaps the developments just described would be a necessary cost of the hammer. But, the hammer was rooted in general frustration and concern on the part of Congress that the agency would delay or distort implementation of the law,179 rather than the product of a comprehensive comparison of the relative importance of each agency function. If the only valuative test of the hammer is whether the agency came close to meeting the deadline, then the hammer is a success. But this evaluation does not account for the trade-offs or the potential for systematic difficulties associated with this kind of pressure on the agency.

C. Instrument of Congressional Control

Aside from pushing the NLEA to the top of the agency’s agenda, the hammer also operated as a tool of legislative control. Through the ham-

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173. Interviews with Fred Shank, supra note 14; and confidential source.
174. Interview with Juanita Duggan, Senior Vice-President, Gov’t Affairs, National Food Processors Ass’n, Washington, D.C. (Jan. 10, 1994).
175. Interview with Fred Shank, supra note 14.
176. Fred Shank, for instance, pointed to inconsistencies in the laboratory analysis required by the regulations. Shank stated that the rule development and drafting process was arranged so that one person would be responsible for each rule, and that there was much less debate, oversight, and coordination than would normally occur in the course of a major FDA rulemaking. Id.
177. Id. 178. Id.; interview with Ed Scarborough, supra note 138.
179. Bill Schultz noted that at the time the hammer was adopted, it was not possible to know how committed the agency might be to implementing the NLEA, nor what role Commissioner Kessler would play. Interview with Bill Schultz, supra note 26.
mer, Congress extended its influence—at least as to the pace of rulemaking—beyond the date of enactment. The key feature of the hammer is its self-enforcing character, which was no accident. A chief attraction of the hammer is its ability to obviate litigation as the primary mechanism to enforce statutory deadlines. In one step, Congress eliminated the need for—and the ability of—the judiciary to examine the “good faith” of the agency in its compliance with deadlines.

The other purpose of the hammer was to create strong incentives in the agency to meet the statutory deadline. Here, the agency had that exact desire in order to avert the hammer falling.\textsuperscript{180}

The hammer provided incentives for the regulated community as well. The hammer supplied added credibility to agency claims that it intended to act within the deadline. Delay, a possible strategy of those opposed to agency action, was potentially a self-defeating strategy in the context of a hammer. Once the FDA's proposed regulations were the operative threat, the hammer provided the strongest incentives for the regulated community.\textsuperscript{181} Because the parties interested in the regulations wanted to prevent the proposed rules from becoming the final rules, there was strong pressure on the agency to promulgate its final rules, and to push the White House to approve rules that would avoid the hammer falling.\textsuperscript{182}

Generally, the hammer as a tool of Congress creates pressure—within the FDA and between the agency and the regulated community—to reach closure on difficult issues. Legislative wishes, with respect to the pace of rulemaking, are more likely to be realized. Indeed, it is difficult to argue with the results in this case as compared to other statutory deadlines imposed on the FDA.

This manifestation of legislative control should be contrasted with the substantive influence that certain environmental law hammers embody. In some cases,\textsuperscript{183} laws exert influence in order to dictate the content of rules by specifying substantive standards that will go into effect if the agency does not act. Under the NLEA, for those issues left to the FDA to decide, the content of the rules was left to the agency. Any substantive effect of the hammer itself was incidental to the pace-quickening effects of the hammer. It is worth noting that if certain members of Congress do have a substantive agenda that they worry may not be reflected in the rulemaking, the hammer could frustrate even their efforts to influence the content of rules because of the pressure to act quickly. Agency deliberation is

\textsuperscript{180} Interviews with Robert Lake, supra note 14; Ed Scarborough, supra note 138; and Michael Taylor, supra note 165.

\textsuperscript{181} Interviews with Juanita Duggan, supra note 174; Richard Frank, Olsson, Frank & Weeda, P.C., Washington, D.C. (Feb. 25, 1994); Ed Scarborough, supra note 138; and Stuart Pape, supra note 162.

\textsuperscript{182} Interviews with Juanita Duggan, supra note 174; and Stuart Pape, supra note 162.

\textsuperscript{183} See supra note 19 and accompanying text (discussing HSWA hammers).
truncated by the hammer, so the potential to influence the agency might be diminished.

D. Enhancement of the FDA’s Influence

The most interesting effect of the hammer is its role in strengthening the FDA’s hand—ironically, by limiting its power to delay rulemaking—in its effort to overhaul food labeling. Observe that the hammer changes the balance considerably from that present in ordinary rulemaking: the effect of an inability to promulgate final rules is that the proposed rules are transformed into final rules. In short, the default option, rather than no final rules at all, becomes an action from which legal obligations arise. This feature considerably strengthened the influence of an agency that wanted to accomplish the task of revising food labeling.

In a general way, the hammer strengthened the agency by adding legitimacy to the agency’s claims that it intended to act on nutrition labeling. This meant that delaying tactics, such as filing long, complex comments and challenges to the agency’s legal authority to act, would be less useful and potentially self-defeating. Furthermore, the hammer played a role in the devotion of significant internal resources to the effort of complying with the deadlines set by the NLEA. The hammer also played a role in getting other actors in the executive branch to agree to the deadlines contained in the legislation.

Some of this fortification of the FDA’s position occurred because of the unique time pressure associated with the hammer. As discussed, such an environment necessarily means that only a limited number of issues can be subjected to extended debate, and those who object to the agency’s position must rank their objections.

More specifically, the hammer strengthened the agency at each stage of the rulemaking process. At the proposed rule stage, the hammer strengthened the agency’s position in its negotiations with the OMB. The agency was able to point to the rigorous timetable—proposed rules within twelve months and final rules within twenty-four months—that would constrain the OMB’s ability to conduct extended review. The proposed rules were complex and the FDA had a natural advantage in defending proposals it authored. In this context, a tight timeframe surely affected the OMB’s opportunity to ask for major changes in the proposals.

184. Interviews with Michael Taylor, supra note 165; and Juanita Duggan, supra note 174.
185. See supra notes 164-65 and accompanying text.
186. See supra note 165 and accompanying text.
187. Admissions of the existence and/or outcome of negotiations with the White House or other agencies are rare. One acknowledgement that the FDA prevailed in its discussions with the White House about food labeling rules is provided by David McIntosh, a former assistant to Vice-President Quayle and Executive Director of the Council on Competitiveness in the Bush Administration. While reviewing the Bush regulatory record, he noted that “the FDA prevailed over our [Competitiveness Council] objections and has greatly restricted the type of information that can be placed on labels unless it is pre-cleared by the FDA.” David McIntosh, Reflections on the Bush Regulatory Record,
Once published, the proposed rules became the concrete embodiment of the potential final rules, should the agency miss the twenty-four month deadline. The agency’s influence was enhanced here as well. Some argued that the agency’s proposed strict interpretation of the NLEA was a deliberate choice. Others argued that it was not a strategic choice, but simply a fair assessment of the options at that time. Regardless of whether the agency intended its proposals to be considered restrictive, the industry and even the FDA ultimately considered the proposed rules undesirable as final action. Thus, the desire to avoid them was intense.

The desire to avoid the hammer played an important role in the remainder of the rulemaking. First, the agency’s position was enhanced because it was also industry’s goal to avoid the hammered rules. Some speculated that compromises may have been extracted from the industry that would not have occurred had the hammer situation not existed.

Furthermore, the potential for hammered final rules played a role in the charged atmosphere in which the ultimate final rules were resolved, namely the negotiation between the USDA and the FDA that was brokered by the White House. Questions of food and drug law rarely have risen to the White House for resolution. In fact, in certain circumstances, a disagreement between department heads simply might lead to prolonged conflict without resolution. The fact that the last issues associated with the NLEA—the format context issue and the applicability of the law to restaurants—were resolved by the White House reportedly with Presidential involvement is somewhat remarkable.

The hammer played an important role in forcing this final negotiation at the White House. The substance of hammered final rules and the legal uncertainty about the potential difficulty of changing hammered final

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16 REG. 22, 30 (1993).
188. See supra notes 89-90 and accompanying text for discussion of the “strictness” of the proposed rules. Ed Scarborough stated that it was clear to the agency, after the proposals were published and comments received, that significant changes would be necessary. Interview with Ed Scarborough, supra note 138. Some interviewees gave a hammer-related justification for this “propose hard” strategy. One indicated that it was a strategic choice, intended to provide the agency with a club that would serve as a hammer. Another did not offer this reason, but attributed this development to the limited timeframe available prior to promulgation. When time is short, this interviewee stated, proposing more strictly is a natural tendency because generally it is easier to pull back in the final rules rather than make them stricter.
189. Interviews with Philip Derfler, Fred Shank, supra note 14.
190. Juanita Duggan and Stuart Pape stated that some of the most intense pressure to avoid the hammer falling came from industry that wanted to avoid both the hammered final rules as well as the uncertainty that would come with agency-altered hammered-final rules. Interviews with Juanita Duggan, supra note 174; Stuart Pape, supra note 162.
191. Interview with Ed Scarborough, supra note 138.
192. See supra notes 97-103 and accompanying text for discussion of the dispute between the USDA and the FDA. Peter B. Hutt reports that the only other time a President was required to intervene to resolve an FDA matter was in 1908 when President Theodore Roosevelt overruled a decision to ban saccharin from food. Hutt, supra note 90. (quoting H.W. Wiley, An Autobiography 240-41 (1930) and H.W. Wiley, The History of a Crime Against the Food Law 160-63 (1929)).
rules were of concern to those who would be subject to the rules. Thus, the regulated community wanted to avoid the hammered final rules and they lobbied the White House to resolve the dispute between the FDA and the USDA. In its final effort to force resolution of its disputes with the USDA and the White House, the FDA was able to point to the "extraordinary statutory deadline" of the hammer, which required timely publication of the final rules in order to avert the unsatisfactory result of hammered final rules. One prominent FDA observer, in fact, reports that the FDA thought the hammer enhanced its position to such a degree that it strengthened its resistance to any compromises in the negotiations leading up to the hammer date. This gamble did not work because the hammer did fall, but the resistance ultimately led to the need for Presidential resolution of the issues involved. Thus, had there not been pressure to avoid the hammer, the issue might have been passed to the next administration.

The pressure to continue the negotiations and resolve the matter continued past the date when the hammer fell. There still was uncertainty about the flexibility the FDA might have to change the hammered final rules and there also was a desire to resolve the issue before the next administration took office.

In many ways, then, the hammer altered the rulemaking process, primarily due to the unique, pressured environment that the hammer created. That pressure accelerated the process, forced closure internally and externally, and enhanced the ability of the agency to reach a conclusion on difficult issues within the executive branch.

VI. LESSONS OF THE HAMMER

There is the possibility that the NLEA's hammer is an exceptional case. This type of hammer was utilized for the first time in 1990, and was attached to high-profile legislation. The FDA already had taken significant steps in the direction the law instructed it to go, the law was very prescriptive, and it included an extremely short compliance period. All of this had an impact on the rulemaking. The final resolution of the issues

193. Many agreed with the assessment that the White House resolution might not have occurred without the presence of the hammer. The combination of industry desire to avoid the uncertainty associated with the hammered final rules and the legal uncertainties helped push the White House to resolve the questions. This is not, of course, to say that these were the only factors.
194. Interviews with Stuart Pape, supra note 162; and Juanita Duggan, supra note 174.
195. See Memorandum for C. Boyden Gray from Secretary Sullivan (undated) (on file with author).
196. Hutt, supra note 90 ("[The FDA's strategy was to stall as long as it could, discuss controversial provisions but not compromise on them, and rely on the hammer provision . . . to force USDA, OMB, and the White House to accept its approach.")
197. A variety of factors other than the hammer played a role in this as well: the desire not to allow the issue to lapse into another administration, and the personal commitment of Secretary Sullivan to the issue.
associated with the NLEA was played out in the midst of a presidential election—an event whose outcome is often unpredictable.

Despite the unique circumstances of the hammer’s operation in this case, some broader lessons can be drawn from its impact on NLEA rulemaking. Perhaps the most obvious lesson is that the hammer came close to accomplishing its goal—implementing the objectives of the NLEA quickly. Although not the only force pushing in this direction, the hammer operated inside the agency to force closure and moved NLEA rulemaking to the top of the agency’s agenda. Furthermore, it strengthened the agency’s hand within the executive branch and in its dealings with the regulated community. All of these developments contributed (nearly) to accomplish the goals embodied in the law’s timetable.

Just as clearly, the hammer imposed costs. These are difficult to characterize and impossible to quantify, but it seems clear that other agency functions were neglected and that there is room for concern about the adequacy, wisdom, and coherence of certain aspects of the final regulations.

The pressured environment created by the hammer in the NLEA arguably had an effect on the deliberateness of the rulemaking product. Those frustrated by agency delay may applaud pressure toward closure and the ranking of objections that the hammer evoked, but such pressure can go too far. If the purpose of notice-and-comment rulemaking is to allow interested parties to comment and to attempt to persuade the agency, truncating this process dilutes this prerogative. If—and this is contested—the agency deliberately took positions in the proposal stage that it knew to be extreme because of the hammer, then the hammer distorted the rulemaking process by inviting strategic action on the part of the agency.

The other costs of the hammer are less concrete, but are perhaps of more general application because they reflect the systematic problems with the use of hammers. Hammers can produce fictive announcements from the agency when they fall. In each case, the agency announces that the proposed rules are “now final rules as a matter of law.” This incantation has little meaning because, at the same time, the agency states that the docket on the proposed rule remains open and that it intends to supersede the hammered final rules.

This new “hammered final” stage of rulemaking presents problems. First, rulemaking effectively is converted into a three-stage process: the proposed rule, the hammered final rule, and the superseding of the hammered final rule. The two-stage process is sometimes cumbersome, and adding another layer—even one that is automatic—is unwise. Much uncertainty is associated with steps two and three. It is not clear when the agency must act in order to supersede the hammered final rules and still maintain that its superseding rules are the “logical outgrowth” of the
original proposal. If there are significant developments in the interim that would have an impact on the rules, it would seem that superseding the hammered final rules without comment would meet with disapproval in the courts.

Legal obligations arise from final rules, and this presumably applies to hammered final rules. In the case of the NLEA, the effective date of the law came after the hammered final rules were announced. The lead time involved in changing labels, however, meant that industry had to know what the real final rules were long before the effective date. As a matter of enforcement discretion, the FDA could refrain from enforcing the hammered final rules, but the agency could not prevent the states—which the NLEA authorized to carry out enforcement functions—from enforcing the federal standards. It is true that the agency attempted to address this problem in its rulemaking by providing early notice that the agency intended to supersede the hammered final rules. Nonetheless, if the three-stage process was delayed and the agency did not supersede the final rules with dispatch, the potential uncertainty about the real standards seems intolerable.

There is also the unsettling prospect that a hammer frees the agency from the underlying constraints of administrative law; two cases illustrate this point. In the medical device tracking rule, after the labyrinthine route the rules travelled, the agency allowed hammered final rules to remain as final rules. In this case, months after the rule had been hammered final but before the effective date, the agency responded to the major comments it had received. The agency might be applauded for doing what it said it was not required to do under the dictates of the hammer; conversely, a mechanism that turns an agency’s response to comment into an academic and discretionary function is problematic.

The Dietary Supplement Act's hammered final regulations of January 1994 provide another example of this difficulty. There, the agency transformed the proposed regulation authorizing a health claim with respect to folic acid and neural tube defects into a hammered final regulation. This regulation applied only to dietary supplements containing folic acid. The agency thus had authorized an important health claim, one not permitted on conventional foods, through a hammered final regulation. Of course, the rule was hammered final before the effective date and other factors intervened to overrule the FDA’s action. In addition, the agency

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198. See supra notes 131-37 and accompanying text.
199. The rules were hammered final in November 1992. The agency’s response to comments came in August 1993. See supra note 137.
200. See supra notes 119-23 and accompanying text for discussion of agency action on this rule.
could have superseded the hammered final rule. Nonetheless, the hammered final rule was published without the usual administrative requirements of a final rule, particularly a substantive defense of the reasons for the agency’s action.

The medical device tracking rules provide a stark illustration of another cost of the hammer. The agency’s actions there stretch the very concept of notice-and-comment rulemaking.²⁰² The agency’s initial proposal, issued after the deadline for the proposed rule and two months prior to the hammer deadline, was heavily criticized. The agency withdrew its original proposal and issued a revised proposed rule. Then, one day later, the revised proposed rule was hammered final as required by law. Congress quickly intervened, turning the hammered final rule into a proposed rule, and attached another hammer. But the identical rule ultimately was hammered final again under this law. Only then did the agency respond to significant comments on the rule. Withdrawing a proposed rule, issuing a revised proposed rule, and hammering it into a final rule within two days raises serious procedural questions. Congress acted quickly in this case, but such intervention is not a reliable remedy for breakdowns created by hammers’ artificial deadlines.

The real message of the FDA’s maneuvering in the short history of this type of hammer is that the fear of a falling hammer has diminished because the agency has discovered ways to escape its apparent demands. That is, the gamble the FDA took in January 1993 of replacing and revoking its previously hammered final rules has paid off because the action was not challenged. The agency may rely on this rationale to replace and revoke future hammered final rules. In short, the strong incentive to promulgate final rules by the hammer date—perhaps the most salutary effect of the hammer—has diminished. It is important to observe, however, that even while these incentives imposed on the agency to act within the prescribed timeframe may have diminished, the costs associated with hammers have not decreased.

Finally, the influence that accrues to the agency as a result of a hammer will remain a characteristic of this sort of legislative device. This is the case because the underlying premise of the hammer is uncommonly powerful in the face of uncertainty or dissension, the hammer dictates action. A conventional assumption about agency behavior is that discord or uncertainty are impediments to action. The hammer flips that on its head, a fact that can be used to strengthen the hand of an agency considerably.

VII. CONCLUSION

The FDA’s experience with the NLEA hammer provides an illuminating window on the modern regulatory state. The choice of the hammer

²⁰² See supra notes 131-37 and accompanying text for description of events.
itself reflects legislative frustration with, and suspicion of, modern agency rulemaking. The legislative answer is to be ever more specific in statutory requirements. In the NLEA hammer, Congress found a way to require action automatically without specifying the precise contours of that automatic action. The disjunction between what was thought by Congress to be a realistic deadline and the fact that the rulemaking required such an intense expenditure of agency effort (in the wake of which the deadline was missed anyway), demonstrates that the many requirements of modern rulemaking are understood differently by Congress and the executive branch. This disjunction is a common observation about the congressional-executive branch relationship, but when Congress seized upon a tool that required automatic action, this difference in perception shaped the rulemaking process. The key role the hammer played in the NLEA rulemaking is one reason the gap must be narrowed between congressional and agency perceptions of rulemaking requirements.