JUSTIFYING DELAY: WHY AGENCIES DELAY COMPLIANCE DATES AND HOW THEY DO IT

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"Delay is preferable to error"[1]
–Thomas Jefferson

Every administration since President Reagan has used compliance delays[2] to postpone the implementation of midnight rules promulgated by the outgoing administration.[3] Recent cases involving the Trump Administration's delay of Obama Administration rules have reinvigorated courts' interests in whether such delays require notice and an opportunity for comment under the Administrative Procedure Act ("APA").[4] Some scholars have written about why incoming administrations use compliance delays to prevent implementation of the previous administration's "midnight rules."[5] These delays are often cast as a precursor to repeal,

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[1] Letter from Thomas Jefferson to George Washington (May 16, 1792), https://founders.archives.gov/documents/Washington/05-10-02-0253.

[2] "Compliance delays" are the delay of the effective or compliance date of a previously promulgated final rule. Although carrying different legal effects, a compliance delay may delay either the effective date or compliance date of the rule. Throughout, I use "compliance date" as shorthand for both effective and compliance dates, except where legally relevant.

[3] Memorandum from Mark Sandy, Acting Director, Implementation of Regulatory Freeze (Jan. 24, 2017), https://www.whitehouse.gov/the-press-office/2017/01/24/implementation-regulatory-freeze; Memorandum, Rahm Emanuel, Assistant to the President and Chief of Staff, Regulatory Review (Jan. 20, 2009); Memorandum, Andrew H. Card, Jr., Assistant to the President and Chief of Staff, Regulatory Review Plan (Jan. 20, 2001); Memorandum, Leon E. Panetta, Director, Regulatory Review (January 22, 1993); Memorandum, Ronald Reagan, Postponement of Pending Regulations (Jan. 29, 1981).

[4] *See, e.g.*, Air Alliance Houston v. EPA, No. 17-1155 (D.C. Mar. 23, 2018), ECF. No. 1723664. Open Communities Alliance v. Carson, 286 F. Supp. 3d 148, 162-78 (D.D.C. 2017); Nat'l Venture Capital Assoc. v. Duke, No. 17-1912 (JEB), 2017 WL 5590122 (D.D.C. Dec. 1, 2017).

[5] *See generally* Kathryn A. Watts, *Regulatory Moratoria*, 61 DUKE L.J. 1883, 1885–86 (2012); William M. Jack, *Take Care that Presidential Oversight of Regulatory Process is Faithfully*

engendering fears that the now-postponed final rule will be reversed.[6] Yet a more overarching discussion of compliance delays is largely absent from the literature.[7]

This Article seeks to fill the literary void with two arguments. First, I argue that compliance delays serve a healthy role in the regulatory process. Part I provides a case study of the Food and Drug Administration's ("FDA") Menu-Labeling Rule. Using this case study and other examples, Part II builds a typology of five justifications used by agencies when implementing compliance delays. Part III recognizes that an agency's *justification* may not equate to its *reason* for delay and, therefore, briefly examines how external pressures may distort these justifications. In a brief interlude, I conclude that compliance delays are a valuable procedural tool[8] that leads to additional transparency and responsive governance.

Second, I consider what procedures agencies should be required to use to delay compliance dates. Part IV presents two options—"delay rules" and "enforcement delays"—and the drawbacks of each. Delay rules officially amend compliance dates. However, recent case law suggests that delay rules must be implemented through notice-and-comment rulemaking. In contrast, an agency using an enforcement delay will allow the compliance date to elapse but choose not to enforce the rule for a certain period of time. Courts are critical of enforcement

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Executed, 54 ADMIN. L. REV. 1479 (2002); Scott R. Furlong, *The 1992 Regulatory Moratorium: Did It Make a Difference?*, 55 PUB. ADMIN. REV. 254 (1995).

[6] *See* Watts, *supra* note 5, at 1886–87.

[7] For examples of studies of compliance delays, see Peter D. Holmes, *Paradise Postponed: Suspensions of Agency Rules*, 65 N.C. L. REV. (1987).

[8] I intentionally use the phrase "procedural tool" rather than "procedural rule." By "procedural tool," I mean a tool used by an agency to improve its decisionmaking process. For example, procedural tools may increase information, enhance public participation, or allow the agency more time for consideration. I do not mean to suggest that all procedural tools qualify as procedural rules under the APA.

delays, which may lead agencies to implement the policy secretly, only allowing its existence to be leaked in ex parte communications. Part IV concludes by suggesting that agencies will choose enforcement delays over delay rules to avoid the resource costs of notice-and-comment rulemaking.

The conclusion synthesizes these two arguments and suggests that the choice between delay rules and enforcement delays is one of procedure or transparency. If agencies select enforcement delays, the benefits of increased transparency and responsive governance disappear. I argue in favor of transparency, concluding that delay rules should be exempt—in one form or another—from APA rulemaking requirements.

Three caveats: First, this Article is about whether we should exempt delay rules from notice-and-comment rulemaking as a matter of *policy* and not whether courts should find them exempt under Section 553. Throughout, I assume that delay rules are substantive rules subject to APA rulemaking requirements because delay rules amend the compliance date of the final rule. Second, this is a qualitative analysis meant to identify perceived trends and begin a conversation. Further quantitative research would allow for a more complete understanding of delays, their frequency, and agency's justifications for them. Third, policy-based delays are understandably contentious, but a necessary part of this conversation. Nevertheless, I reserve judgment on whether policy-based delays benefit the regulatory process and focus my efforts on the other justifications.

I. CASE STUDY: FDA MENU-LABELING RULE

For two decades, policymakers have pursued various initiatives to combat rising obesity levels in the United States. Studies have shown that this health crisis is correlated with increased

calorie consumption outside the home and consumer misinformation about nutrition.[9] In 2006, state and local governments began enacting laws requiring disclosure of nutritional information on menus.[10] As more laws were enacted, industry groups began fearing inconsistent regulations, calling upon Congress to enact uniform, federal standards.[11]

In 2010, the Affordable Care Act ("ACA") was signed by President Obama. Section 4205 of the ACA directs the FDA to establish rules requiring restaurants and retail food establishments with twenty or more locations to disclose certain nutritional information on menus.[12] In April 2011, the FDA published its notice of proposed rulemaking for the Menu-Labeling Rule.[13] The final Menu-Labeling Rule was promulgated on December 1, 2014, with a compliance date of December 1, 2015.[14] The rule regulates a variety of different food-related businesses, including chain restaurants, grocery stores, convenience stores, concession stands,

[9] *See generally* AMALIA K. CORBY-EDWARDS, CONG. RESEARCH SERV., NUTRITION LABELING OF RESTAURANT MENUS 1-4 (2012) (describing federal and state law efforts to reduce obesity).

[10] *See* Brent Bernell, *The History and Impact of the New York City Menu Labeling Law*, 65 FOOD & DRUG L.J. 839, 839 (2010); Christine Cusick, *Menu-Labelling Laws: A Move from Local to National Regulation*, 51 SANTA CLARA L. REV. 989 (2011).

[11] *New Coalition Advocates National Nutrition Standard for Chain Restaurants*, NAT'L RESTAURANT ASS'N (Oct. 21, 2008), http://www.restaurant.org/Pressroom/Press-Releases/New-Coalition-Advocates-National-Nutrition-Standar ("When different rules exist in various parts of the country, it makes it difficult for consumers to compare options. Consumers deserve a federal standard that provides access to the same nutrition information no matter where they are or where they live.").

[12] Patient Protection & Affordable Care Act § 4205(H), Pub. L. 111-148, 124 Stat. 119, 573-76 (2010).

[13] Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, Proposed Rule, 76 Fed. Reg. 19,192 (Apr. 6, 2011).

[14] Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, Final Rule, 79 Fed. Reg. 71,155, 71,1156 (Dec. 1, 2014) [hereinafter Final Menu-Labeling Rule].

and any other establishment that sells "restaurant-type food."[15] These entities are required to display nutritional information on menus for "restaurant-type food," defined as food "eaten on the premises, while walking away, or soon after arriving at another location."[16]

The Menu-Labeling Rule covers a large breadth of businesses with different operational models, stirring confusion about how its provisions apply to specific entities. In an effort to remedy these initial problems, FDA issued three rules—all without pursuing notice-and-comment rulemaking—to delay the compliance date.

A. *July 2015 Delay*

Since its promulgation, Congress has expressed concerns about the Menu-Labeling Rule. On May 15, 2015, thirty-two senators sent a bipartisan letter requesting that FDA delay the compliance date by one year.[17] The senators argued that "the lack of clear and consistent guidance from the agency will make it difficult, confusing, and burdensome for businesses."[18] Additionally, the House considered (but did not include) a provision in the 2015 appropriations bill that would delay the compliance date until at least December 1, 2016.[19]

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[15] *Id.* at 71,157.

[16] *Id.* at 71,157-158, 71,254.

[17] *32 Senators Urge FDA to Provide Clarify to Businesses Before Enforcing Menu Labeling Rule*, U.S. SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR & PENSIONS (May 18, 2015), https://www.help.senate.gov/chair/newsroom/press/32-senators-urge-fda-to-provide-clarity-to-businesses-before-enforcing-menu-labeling-rule.

[18] *Id.*

[19] *See* STAFF OF H. COMM. ON APPROPRIATIONS, 114TH CONG., MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES 84-85 (Comm. Print. 2015) ("None of the funds made available by this Act may be used to implement, administer, or enforce the final rule entitled 'Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments' . . . until the later of— (1) December 1, 2016; or (2) the date that is one year

On July 10, 2015, FDA published a rule delaying the compliance date until December 1, 2016.[20] FDA offered two justifications for the delay. First, FDA acknowledged "numerous requests" for clarification about "whether specific practices would be acceptable for purposes of complying with the rule."[21] FDA referred businesses to its Small Entity Compliance Guide and announced that it was "considering what additional guidance might be helpful."[22] Second, FDA cited several comments from a larger retailer and trade organizations stating that industry would not be able to develop the technologies necessary to comply with the rule by December 1, 2015.[23] FDA stated the delay would allow regulated entities sufficient time to develop "software, information systems, and other technologies for providing nutrition information."[24]

In an accompanying statement, FDA acknowledged the "extensive input" it received from stakeholders and reassured that it was "committed to working collaboratively with those establishments covered by the menu labeling final rule." [25] FDA agreed that it needed more time

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after the date on which the Secretary of Health and Human Services publishes Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants . . . .").

[20] Nutritional Labeling of Standard Menu Items in Restaurant and Similar Retail Food Establishments; Extension of Compliance Date, 80 Fed. Reg. 39,675, 39,675-676 (July 10, 2015) [hereinafter Menu-Labeling Rule–July 2015 Delay].

[21] *Id.*

[22] *Id.*

[23] The July 2015 Delay states, "Since February 2015, we have received four requests asking us to extend the compliance date of the final rule based on concerns that covered establishments do not have adequate time to fully implement the requirements of the rule by the compliance date." *Id.* In April 2018, I submitted a Freedom of Information Act request to FDA for the four comments referenced in this rule. Curiously, after extensive conversations with FDA, FDA was not able to identify these four comments.

[24] *Id.*

[25] *Id.*

"to provide further clarifying guidance to help facilitate efficient compliance across all covered businesses and for covered establishments to come into compliance with the final rule."[26] In furtherance of this goal, FDA announced that it would release guidance and provide "educational and technical assistance" to regulated entities.[27]

In September 2015, FDA released its draft Level 1 Guidance.[28] Despite assurances by FDA that the guidance "responds to many of the most frequently asked questions,"[29] regulated entities demanded further clarification. For example, the Food Marketing Institute ("FMI") – an organization of nearly 40,000 retail food stores — commented that "as of November 2, 2015, the agency has yet to provide clear guidance on FDA's enforcement considerations."[30] FMI called for an additional one-year delay of the compliance date.[31] Other regulated entities expressed concerns that compliance with some provisions was impossible or overly burdensome. Numerous commenters, including the Alcohol and Tobacco Tax and Trade Bureau,[32] worried

[26] Statement by Michael R. Taylor, FDA Deputy Commissioner for Foods and Veterinary Medicine, *Menu Labeling Extension of Compliance Date* (July 9, 2015), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm515020.htm.

[27] *Id.*

[28] A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part II, 80 Fed. Reg. 55,564 (Sept. 16, 2015).

[29] Statement by Dr. Susan Mayne, Director of Center for Food Safety and Applied Nutrition, *Release of Menu Labeling Guidance* (Sept. 11, 2015), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm515020.htm.

[30] Letter from Stephanie K. Barnes, Regulatory Counsel, Food Marketing Institute, to FDA, at 2 (Nov. 2, 2015).

[31] *Id.*

[32] John J. Manfreda, Administrator, Alcohol and Tobacco Tax and Trade Bureau, to FDA (Nov. 2, 2015), https://www.regulations.gov/document?D=FDA-2011-F-0172-0605.

that restaurants would incur significant laboratory-testing costs to provide nutritional information of alcoholic beverages because manufacturers are not required to provide this information.[33] Yet other commenters, including some members of Congress,[34] called for the swift implementation of the rule without further delay.[35]

B. *May 2016 Delay*

In the 2016 Consolidated Appropriations Act, Congress barred FDA from using funds to implement or enforce the Menu-Labeling Rule until the later of (1) December 1, 2016, or (2) one year after FDA published its Level 1 Guidance.[36] On March 6, 2016, FDA released its Level 1 Guidance, responding to comments with examples and explanations about how the rule applies to various situations.[37] FDA acknowledged the limitations placed on the agency by Congress and delayed the compliance date until May 7, 2017.[38]

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[33] *See, e.g.*, Letter for Joy Dubost, Sr. Director of Scientific & External Affairs, Beer Institute, to FDA (Nov. 2, 2015); Letter from Joan McGlockton, Vice President, Nat'l Restaurant Ass'n, to FDA, at 2 (Nov. 2, 2015),; Letter from Lynne J. Omlie et al., to FDA (Nov. 2, 2015).

[34] Letter from Patty Murray, U.S. Senator, and Rosa L. De Lauro, Member of Congress, to FDA (Oct. 30, 2015), (calling for FDA to "finalize the guidance quickly and move forward with implementation" and for clarification that the rule covers "concession stands in movie theaters, amusement parks, and other venues.").

[35] Letter from Deirde McGinley-Gieser, Sr. Vice President, Am. Inst. For Cancer Research, to FDA, at 1 (Nov. 2, 2015); Letter from Barbara J. Moore, President and CEO, Shape Up America!, to FDA (Nov. 2, 2015); Letter from Margo G. Wootan, Director, Ctr. for Sci. in Pub. Interest, to FDA (Nov. 2, 2015).

[36] 2016 Consolidated Appropriations Act § 747, Pub. L 144-113, 129 Stat. 2242, 2282 (Dec. 18, 2015).

[37] A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods–Part II, 81 Fed. Reg. 27,067, 27,068 (May 5, 2016) [hereinafter Menu-Labeling Rule–May 2016 Delay].

[38] *Id.* FDA confirmed the delay in a subsequent publication in December 2016. Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date, 81 Fed. Reg. 96,364 (Dec. 30, 2016).

Following the delay, FDA announced a series of public workshops to help regulated entities comply with the rule.[39] At these workshops, FDA presented on the rule's requirements and offered individual consultations for businesses.[40] Yet comments suggest that FDA did not have answers to remaining questions and instead informed regulated entities that it "had not determined all of those types of compliance questions."[41]

C. *May 2017 Delay*

In January 2017, President Trump took office, joined by a Republican-controlled Congress that had campaigned on repeal of the ACA's menu-labeling requirements.[42] In April, members of Congress called on FDA to "delay, withdraw (or stay), and rewrite the [Menu-Labeling Rule]."[43] These members justified delay, in part, on the premise that Congress planned to enact the Common Sense Nutrition Disclosure Act to provide statutory relief to regulated entities.[44]

Regulated entities, particularly grocers, seized the opportunity. In early 2016, the National Association of Convenience Stores and the National Grocers Association ("NGA")

[39] Menu Labeling Public Workshops; Public Meeting, 81 Fed. Reg. 39,056 (June 15, 2016); Menu Labeling Public Workshop; Public Meeting, 81 Fed. Reg. 63,776 (Sept. 16, 2016).

[40] *Id.*

[41] Letter from Jon Taets, Director, Nat'l Ass'n of Convenience Stores, to Tom Price, Secretary, Dep't of Health & Human Servs. at 1-2 (Feb. 24, 2017) [hereinafter Nat'l Ass'n of Convenience Stores Letter].

[42] REPUBLICAN NATIONAL COMMITTEE, REPUBLICAN PLATFORM 2016 17 (2016) (stating that "menu labeling should be ended as soon as possible"); Kevin Hardy, *With Trump in Office, Where Does Food Policy Go Now?*, QSR (Mar. 2017), https://www.qsrmagazine.com/restaurant-operations/trump-office-where-does-food-policy-go-now.

[43] Letter from Members of Congress to Thomas E. Price, Secretary, Dep't of Health & Human Servs. (Apr. 7, 2017).

[44] *Id.* at 1-2.

asked FDA to delay the rule pending further clarification.[45] NGA expressed confusion about whether independently-owned grocery stores that market as part of an alliance constitute food establishments with twenty or more locations.[46] NGA also claimed that the distinction between menus and advertisements was unclear, questioning whether "a sign-spinner outside of the supermarket" would be required to display nutritional information.[47] Separately, FMI wrote to OIRA asking that FDA revise its "overly burdensome regulations."[48]

On May 1, 2017—just days before the compliance date was set to take effect—FDA delayed the compliance date until May 2, 2018.[49] Expressing doubts about the rule's efficacy, FDA alleged that the rule would undermine efforts to provide consumers with nutritional information because it was too inflexible given the diverse business models of regulated entities.[50] FDA also stated that it needed to reconsider and clarify "complex" questions about advertising, calorie disclosure for self-service foods, and natural calorie variations.[51]

Beyond claims of ineffectiveness and obscurity, FDA implied that the rule required amending to lessen the burden on businesses. Citing Executive Order 13777 ("Enforcing the

[45] Letter from Peter J. Larkin, President and CEO, Nat'l Grocers Ass'n, to Stephen Ostroff, Acting Commissioner, FDA at 1 (Mar. 28, 2017) [hereinafter Nat'l Grocers Ass'n Letter]; Nat'l Ass'n of Convenience Stores Letter, *supra* note 41, at 2.

[46] Nat'l Grocers Ass'n Letter, *supra* note 45.

[47] *Id.* at 2.

[48] Letter from FMI et al., to Dominic J. Mancini, Acting Administrator, Office of Information & Regulatory Affairs (Feb. 10, 2017).

[49] Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retain Food Establishments; Extension of Compliance Date, 82 Fed. Reg. 20,825, 20,826 (May 4, 2017) [hereinafter Menu-Labeling Rule–May 2017 Delay].

[50] *Id.* at 20,827 (emphasis added).

[51] *Id.*

Regulatory Reform Agenda"),[52] FDA stated the delay would allow it to "consider what opportunities there may be to address these fundamental and complex questions and reduce the cost and enhance the flexibility of these requirements beyond those reflected in the final rule." Further justifying the delay, FDA explained "it would not make sense to require establishments . . . to come into compliance with the rule (for which compliance is not yet required), as well as incur additional ongoing costs to maintain or update compliance, when these requirements may change as a result of our reconsideration of the rule."[53]

For the first time, FDA requested comments on the delay of the compliance date. Still, FDA issued the delay rule without notice and opportunity for comment, invoking the procedural-rule exemption and the good-cause exception.[54]

Not all regulated entities were pleased with the delay. The delay came just days before compliance was expected, meaning many restaurants had already begun compliance.[55] The National Restaurant Association announced, "This delay upends plans that have been in motion for years throughout the food industry."[56] On the other hand, FMI applauded the delay, proclaiming that "[i]t is wholly appropriate and necessary for FDA and the Trump administrative

[52] Executive Order 13777, Enforcing the Regulatory Reform Agenda, 82 Fed. Reg. 12,285 (Feb. 24, 2017) (requiring agencies to consider how to alleviate "unnecessary regulatory burdens").

[53] May 2017 Delay, 82 Fed. Reg. at 20,827.

[54] *Id.*

[55] Helena Bottemiller Evich, *Trump's Delay of Calorie-Posting Rule Jolts Restaurants*, POLITICO (May 27, 2017), https://www.politico.com/story/2017/05/27/trump-restaurant-calorie-posting-rule-238873.

[56] *Id.*

to review this rule and its corresponding burdens using the common sense and logic that has been absent in the process thus far."[57]

In August 2017, FDA announced that it would provide additional guidance by the end of 2017, but would maintain the May 7, 2018 compliance date.[58] In November 2017, FDA released draft Supplemental Guidance, clarifying some of the remaining questions surrounding the rule.[59] Convenience stores and grocers continued to call for further delay or complete withdraw of the rule.[60] In contrast, the National Restaurant Association advocated for implementation of the rule on May 7, 2018,[61] and other stakeholders went so far as to call for revocation of the delay.[62]

D. *Litigation*

Following the May 2017 delay, proponents of the Menu-Labeling Rule grew tired of waiting. Mayor Bill de Blasio announced that New York City would begin enforcing its own

[57] *Food Retail Industry Welcomes Extension of Burdensome FDA Menu Labeling Compliance Date*, FOOD MARKETING INSTITUTE (May 1, 2017), https://www.fmi.org/newsroom/news-archive/view/2017/05/01/food-retail-industry-welcomes-extension-of-burdensome-fda-menu-labeling-compliance-date.

[58] *Statement from FDA Commission Scott Gottlieb*, U.S. FOOD & DRUG ADMIN. (Aug. 25, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm573277.htm.

[59] Menu Labeling; Supplemental Guidance for Industry, 82 Fed. Reg. 52,036 (Nov. 9, 2017).

[60] *Comment from Greg Scriver*, REGULATIONS.GOV (Jan. 8, 2018), https://www.regulations.gov/document?D=FDA-2011-F-0172-2877 (calling for delay); Letter from Douglas S. Kantor, Counsel to NACS and SIGMA, to Anna K. Abraham, Deputy Comm'r for Policy, Planning, Legislation, and Analysis, FDA at 1-2 (Jan. 8, 2018) (calling for withdraw); Letter from Greg Ferrara, Senior Vice President, Nat'l Grocers Ass'n, to Scott Gottlieb, Commissioner, FDA at 1-2 (Jan. 4, 2018).

[61] Cicely Simpson, Executive Vice President, Nat'l Restaurant Ass'n, to FDA at 1 (Jan. 8, 2018).

[62] Takako Tagami, President, Ass'n of State Pub. Health Nutritionists, to FDA at 3 (Jan. 8, 2018).

menu-labeling regulations.[63] Trade organizations challenged NYC's regulations in federal court, arguing that regulations were preempted by federal law.[64] NYC argued that the latest delay was not entitled to preemptive effect because FDA failed to comply with APA rulemaking requirements.[65] The United States intervened on behalf of the trade organizations.[66] Shortly thereafter, the parties stipulated that NYC would not enforce its regulations against regulated entities covered under the FDA Menu-Labeling Rule until May 7, 2018, and the case would be dismissed if the rule went into effect on that date.[67] But NYC's Health Commissioner warned, "Should the FDA fail to live up to this commitment, this case remains before the court. The city is prepared to defend its right, independent of FDA action, to enforce its requirements that give New Yorkers the information they need to make informed dietary decisions."[68]

[63] *De Blasio Administration Announces New Calorie Labeling Rules*, NYC (May 18, 2017), https://www1.nyc.gov/site/doh/about/press/pr2017/calorie-label-rules.page.

[64] Complaint, Nat'l Ass'n of Convenience v. NYC Dep't of Health & Mental Hygiene, No. 17 Civ. 5324 (S.D.N.Y. July 14, 2017), ECF No. 1.

[65] Def.'s Mem. Of Law in Supp. of Cross-Mots. to Dismiss at 22-25, Nat'l Ass'n of Convenience v. NYC Dep't of Health & Mental Hygiene, No. 17 Civ. 5324 (S.D.N.Y. Aug. 9, 2017), ECF No. 42.

[66] Statement of Interest of the United States of America, Nat'l Ass'n of Convenience v. NYC Dep't of Health & Mental Hygiene, No. 17 Civ. 5324 (S.D.N.Y. Aug. 14, 2017), ECF No. 45.

[67] Stipulation ¶¶ 4, 7, Nat'l Ass'n of Convenience Stores v. NYC Dep't of Health & Mental Hygiene, No. 17 Civ. 5324 (S.D.N.Y. Aug. 25, 2017), ECF No. 50.

[68] Dan Goldberg, *New York City Won't Begin Enforcing New Menu Labeling Rule, Agrees to Wait for FDA*, POLITICO (Aug. 25, 2017), https://www.politico.com/states/new-york/albany/story/2017/08/25/new-york-city-wont-begin-enforcing-new-menu-labeling-rules-agrees-to-wait-for-fda-114157.

On June 7, 2017, consumer groups sued FDA over its failure to undergo notice-and-comment rulemaking before promulgating the May 2017 delay.[69] Following FDA's statement that it would maintain the current compliance date, the district court granted a stay until the earlier of (1) May 7, 2018, (2) a subsequent delay, (3) a failure to confirm the May 7, 2018 compliance date by December 31, 2017, or (4) a failure to publish guidance by December 31, 2017.[70]

As planned, the Menu-Labeling Rule went into effect on May 7, 2018.[71] Both the trade organization's case and the consumer group's case were dismissed.[72]

E. *Forthcoming Statutory Amendment and Delay?*

Although the Menu-Labeling Rule has gone into effect, consumer groups face an additional hurdle: Congress. On February 6, 2018, the House passed the Common Sense Nutrition Disclosure Act.[73] The bill's author, Representative Cathy McMorris Rodgers, described the Menu-Labeling Rule as "fundamentally impractical and unnecessarily expensive," complaining that compliance would "cost American businesses more than $1 billion and 500,000

[69] Complaint, Ctr. for Sci. in the Pub. Interest v. Price, No. 17-cv-1085, (D.D.C. June 7, 2017), ECF No. 1.

[70] Minute Order, Ctr. for Sci. in the Pub. Interest, No. 17-cv-1085 (D.D.C. Sept. 26, 2017); Joint Motion for Stay ¶ 8, Ctr. for Sci in the Pub. Interest, No. 17-cv-1085 (D.D.C. Sept. 15, 2017).

[71] *Statement from FDA Commissioner Scott Gottlieb, M.D., on the Public Health Benefits From Enactment of Menu Labeling*, FDA (May 7, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm606694.htm.

[72] *See* Stipulation of Dismissal, Nat'l Ass'n of Convenience v. NYC Dep't of Health & Mental Hygiene, No. 17 Civ. 5324 (S.D.N.Y. May 9, 2018), ECF No. 54; Notice of Voluntary Dismissal, Ctr. for Sci. in the Pub. Interest v. Price, No. 17-cv-1085, (D.D.C. May 9, 2018), ECF No. 19.

[73] Final Vote Results for Roll Call 56, OFFICE OF THE CLERK, U.S. HOUSE OF REPRESENTATIVES, http://clerk.house.gov/evs/2018/roll056.xml (last visited Apr. 17, 2018).

hours of paperwork."[74] The purpose of the Act is to "improve and clarify certain disclosure requirements for restaurants and similar retail food establishments."[75] The Act would allow certain regulated entities to provide nutritional information online instead of on in-store menus.[76] It would also provide regulated entities ninety days to correct a violation before FDA could take an enforcement action.[77] Moreover, the Act would prohibit enforcement until FDA promulgated new regulations pursuant to the Act.[78] In effect, the Act would substantially weaken the ACA's requirements and, in turn, weaken FDA's Menu-Labeling Rule.

II. A DELAY TYPOLOGY

FDA justified its delays of the Menu-Labeling Rule on various grounds. I label these justifications (1) clarification-based delays, (2) industry-based delays, and (3) policy-based delays. Two additional types of justifications sometimes invoked by agencies—(4) litigation-based delays and (5) agency-based delays—are not (yet) reflected in the history of the Menu-Labeling Rule. Of these five types of delays, policy-based delays are the most worrisome and, therefore, are considered last.

A. *Clarification-Based Delays*

Ambiguity often pervades regulations—either from poor draftsmanship or unexpected situations—and carries significant costs. First, ambiguity results in increased litigation costs for

[74] *Smarter Menu Legislation Passed Committee,* CONGRESSWOMAN CATHY MCMORRIS RODGERS (Nov. 18, 2015), https://mcmorris.house.gov/smarter-menu-legislation-passed-committee.

[75] Common Sense Nutrition Disclosure Act, H.R. 772, 115th Cong. (2d Sess. 2018).

[76] *Id.* § 2(a)(1)(C).

[77] *Id.*§ 2(a)(7)

[78] *Id.* § 2(a)(5).

both the agency and the challenger, which in turn consumes unnecessary judicial resources.[79] Second, ambiguity creates uncertainty and unpredictability. Regulated entities may fail to comply with the rule due to misunderstandings about what the law requires, what it prohibits, or even whether they are subject to the rule.[80] In the context of the Menu-Labeling Rule, individually-owned grocers repeatedly sought clarity on whether they were regulated if they marketed as a collective.[81] Ambiguity may result in ineffective compliance—either over- or under-compliance—due to misinterpretation of the rule's requirements. Prior to FDA's clarification, restaurants feared that the Menu-Labeling Rule would require laboratory testing of alcoholic beverages, which, absent clarification, would have resulted in costly over-compliance. Third, if corrected later rather than sooner, ambiguity can render regulated entities' existing compliance efforts obsolete. Fourth, ambiguity can result in inconsistent or discriminatory enforcement due to different interpretations by agents about the law's requirements.

Ambiguity is unavoidable,[82] but interpretative guidance is an invaluable tool for remedying this barrier to compliance. From the regulated entities' perspective, interpretative guidance shields from unequal treatment, provides better information than case-by-case adjudications, and strengthens the integrity of the regulatory program.[83] From the agency's

[79] Gregory E. Maggs, *Reducing the Costs of Statutory Ambiguity: Alternative Approaches and the Federal Courts Study Committee*, 29 HARV. J. ON LEGIS. 123, 127 (1992).

[80] *Id.*

[81] *See* Nat'l Grocers Ass'n Letter, *supra* note 45.

[82] *See* Nicholas R. Bednar & Kristin E. Hickman, *Chevron's Inevitability*, 85 GEO. WASH. L. REV. 1392, 1446–51 (2017) (describing the inevitability of ambiguity).

[83] NICHOLAS R. PARRILLO, FEDERAL AGENCY GUIDANCE: AN INSTITUTIONAL PERSPECTIVE 28-37 (Oct. 12, 2017), https://www.acus.gov/sites/default/files/documents/parrillo-agency-guidance-final-report.pdf.

perspective, interpretative guidance allows for more responsive changes in ever-evolving fields, addresses compliance in an accessible way compared to the legalese of the final rule, and takes less time to enact than legislative rules. [84] And even though notice-and-comment rulemaking is often not required for guidance documents, agencies frequently seek public comment in one form or another.[85] Indeed, FDA published both draft guidances for notice and opportunity for comment and elicited responses from regulated entities, consumer groups, members of Congress, and other federal agencies.[86]

Interpretative guidance takes time to draft, approve, and release. Clarification-based delays afford agencies an opportunity to publish guidance and consider amendments to rules. The Menu-Labeling Rule is no exception. With each delay, FDA announced its intent to draft guidance, actually issued guidance, or solicited comments for particular questions. FDA also provided public workshops to answer questions particular to certain businesses.

FDA is not the only agency to use clarification-based delays. In 1990, the Environmental Protection Agency ("EPA") promulgated a final rule requiring certain facilities to install controls for benzene emissions.[87] Eventually, EPA acknowledged that the rule was "poorly understood by affected facilities" and plagued by "widespread misunderstanding of many basic provisions of

[84] *Id.*

[85] *Id.* at 139-46.

[86] Of course, regulated entities' interests in the opportunity for comment for guidance can be nefarious and create obstacles for agency policymaking. *Id.* at 165-66. Industry may weaponize notice-and-comment rulemaking to further delay rules through "scare tactics" and "the invocation of 'extreme' fact situations." *Id.* at 165. One certainly sees some of these tactics reflected in the comments to FDA's guidance for the Menu-Labeling Rule. *E.g.*, Nat'l Grocers Ass'n Letter, *supra* note 45, at 2 (questioning whether a sign-spinner is subject to the rule).

[87] National Emission Standards for Hazardous Air Pollutants, 55 Fed. Reg. 8292 (Mar. 7, 1990).

the rule."[88] At least three lawsuits were filed against EPA due to the lack of clarity.[89] Rather than allow the rule to go into effect, the EPA chose to stay and clarify the rule to avoid "penaliz[ing] facilities for being confused about the original rule language."[90]

B. *Industry-Based Delays*

Agencies sometimes miscalculate how long it will take regulated entities to develop technologies and procedures to comply with regulations.[91] When regulated entities demonstrate that compliance is not possible within the allotted time, agencies may delay the compliance date. For example, FDA justified its July 2015 delay on the need for regulated entities to develop new technologies. In cases where state governments are expected to comply with regulations, the agency may delay the rule to allow states to amend laws and establish new regulatory infrastructure.[92] Industry-based delays appear common among agencies that regulate public health, the environment, and other technology fields.[93]

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[88] National Emission Standards for Hazardous Air Pollutants; Benzene Waste Operations, 57 Fed. Reg. 8012, 8012 (Mar. 5, 1992).

[89] *Id.*

[90] *Id.*

[91] Sidney A. Shapiro & Thomas O. McGarity, *Not So Paradoxical: The Rationale for Technology-Based Regulation*, 1991 Duke L.J. 729, .

[92] Limitations on the Issuance of Commercial Driver's Licenses With a Hazardous Materials Endorsement, 68 Fed. Reg. 63,030, 63,032 (Nov. 7, 2003) (delaying rule to allow states to purchase fingerprinting equipment).

[93] Approval and Promulgation of Air Quality Implementation Plans; Nevada; Regional Haze Federal Implementation Plan; Extension of BART Compliance Date for Reid Gardner Generating Station, 78 Fed. Reg. 53,033 (Aug. 28, 2013) (delaying compliance date for specific generating station to allow Nevada Public Utilities Commission to approve the plan); Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates, 77 Fed. Reg. 27,591, 27,592 (May 11, 2012) (delaying a rule subjecting sunscreen to certain labeling and testing requirements after industry groups complained of "complex label redesign issues" and "required broad spectrum testing").

Industry-based delays can benefit consumers when implementation of the rule without delay would result in the removal of necessary products from the market. In 2000, FDA published a rule that limited the aluminum content for certain drugs used in total parental nutrition (TPN)—a therapy used to feed patients whose digestive tracts do not function.[94] Industry participants met with FDA to voice concerns that the rule required total reformulation of TPN drugs to lower aluminum content and reformulation was not feasible by the compliance date.[95] The FDA extended the effective date of the rule by two years because it was "concerned that some products unable to reformulate by the existing effective date are medically necessary and without alternatives thus potentially putting certain patients at great risk."[96]

However, not every concern of infeasibility warrants delay, particularly when based on a misunderstanding of regulatory requirements. For example, restaurants expressed concerns that they could not provide nutritional information for alcohol without laboratory analysis. In its draft Supplemental Guidance, FDA clarified that "laboratory analysis is simply one of many methods—rather than the *only* method—that could be used."[97] FDA's response in this instance suggests agencies are less likely to institute an industry-based delay when the request is based on an ambiguity in the rule. Clarification may be all that is needed. Indeed, agencies should approach claims that compliance is infeasible—rather than costly—with skepticism.

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[94] Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition; Delay of Effective Date, 66 Fed. Reg. 7864, 7864 (Jan. 26, 2001) (delaying a rule limiting aluminum content in certain drugs because reformulation of a medically necessary drug was impossible by the compliance date).

[95] *Id.* at 7864-65.

[96] *Id.* at 7865.

[97] FDA, MENU LABELING: SUPPLEMENTAL GUIDANCE FOR INDUSTRY 35-36 (Apr. 2016)

C. *Litigation-Based Delays*

Unlike other delays, litigation-based delays are expressly sanctioned by the APA. Under Section 705, an agency may postpone the "effective date" of a rule pending judicial review when it finds that "justice so requires."[98] The APA does not require the agency to undergo notice-and-comment rulemaking to implement a delay under Section 705, but courts have been strict with its application. In *Becerra v. Department of Interior,* a district court concluded that the Department of Interior could not invoke Section 705 to delay the *compliance date* of an already-effective rule without notice-and-comment rulemaking.[99] According to the court, "The plain language of the statute authorizes postponement of the 'effective date,' not 'compliance dates.'"[100]

D. *Agency-Based Delays*

An agency may choose to delay the compliance date of a rule because of its need to develop internal procedures to implement the rule. Agency-based delays appear most common when the rule requires the regulated entity to interact with the agency—perhaps for billing, licensing, or inspection. In May 2013, the Department of Veteran Affairs ("VA") amended its regulations to apply the Center for Medicare and Medicaid fee schedule to non-VA providers.[101] The VA delayed the rule twice,[102] stating that the delays were "necessary to accommodate

[98] 5 U.S.C. § 705 (2012).

[99] Becerra v. U.S. Dep't of Interior, 276 F. Supp. 3d 953, 963-66 (N.D. Cal. 2017).

[100] *Id.* at 964.

[101] Payment for Home Health Services and Hospice Care to Non-VA Providers, 78 Fed. Reg. 26,250 (May 6, 2013).

[102] Payment for Home Health Services & Hospice Care to Non-VA providers; Delay of Effective Date, 79 Fed. Reg. 16,200 (Mar. 25, 2013) [hereinafter "VA Delay March 2013]; Payment for Home Health Services & Hospice Care to Non-VA Providers; Delay of Effective Date, 78 Fed. Reg. 68,364 (Nov. 14, 2013).

difficulties in the outreach and implementation of standardized processes for VA staff."[103] Additionally, the VA needed to address "difficulties regarding information technology systems necessary to use the CMS rate."[104]

However, my research has not produced an example where an agency has implemented an agency-based delay for a rule that did not require direct communication between the agency and regulated entities. The absence of examples makes sense. When a rule does not require regular communication between the agency and regulated entities, the only necessary interaction between the agency and regulated entities is enforcement. Even if the agency cannot yet enforce the rule, regulated entities can still comply with its requirements. An agency has no reason to afford regulated entities reprieve from compliance in this situation. Rather, the agency can quietly delay enforcement while expecting that regulated entities will still come into compliance.

E. *Policy-Based Delays*

After promulgation, an agency may realize that the final rule does not comport with the desired policy outcome because either (1) the new administration has different policy goals than the administration that enacted the rule, or (2) the rule was promulgated based on an erroneous assumption underlying the reason for the rule. Agencies implement policy-based delays to afford time to amend or repeal the final rule.

During periods of presidential transition, agencies may delay compliance dates if the rule conflicts with the new administration's objectives. Agencies cite regulatory-freeze memoranda

[103] VA Delay March 2013, *supra* note 102.

[104] *Id.*

and the need for reconsideration as justification for these delays.[105] As a result, the incoming administration is afforded time to reconsider the previous administration's rule.

Proponents argue policy-based delays promulgated during presidential transitions promote democratic accountability by allowing the new administration to stave off lame-duck midnight rules and to align regulatory policymaking with its goals.[106] However, other commentators believe that presidents may weaponize delays to create de facto repeals without undergoing APA rulemaking requirements.[107] In one of the earliest cases involving a delay rule, Judge Harry T. Edwards expressed in dissent:

> Certainly a decision to suspend indefinitely regulations that are the product of exhaustive study and comprehensive rulemaking, in order to allow wholesale revaluation of a major regulatory program, cannot be viewed as a temporary measure for preserving the status quo. . . . The advent of a new Administration cannot justify the Government's complete and continued disregard of the APA's rulemaking requirements.[108]

[105] *See, e.g.*, Fisheries of the Caribbean; Gulf of Mexico, and South Atlantic; Dolphin and Wahoo Fishery off the Atlantic States; Regulatory Amendment 1, 82 Fed. Reg. 8820 (Jan. 31, 2017) ("In accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff . . . this action stays the final rule NMFS published on December 30, 2016 in order to delay its effective date."); Endangered and Threatened Wildlife and Plants; Revisions to the Regulations for Candidate Conservation Agreements with Assurances, 82 Fed. Reg. 8501 (Jan. 26, 2017); Importation of Lemons from Northwest Argentina; Stay of Regulations, 82 Fed. Reg. 8353 (Jan. 25, 2017).

[106] *See* Anne Joseph O'Connell, *Agency Rulemaking and Political Transitions*, 105 NW. U. L. REV. 471, 527-30 (2011); Watts, *supra* note 5, at 1936-39.

[107] Nat. Res. Def. Council, Inc. v. EPA, 683 F.2d 752, 762 (3d Cir. 1982) ("If the effective date were not part of an agency statement such that material alternations in that date would be subject to the rulemaking provisions of the APA, . . . an agency could guide a rule through the rulemaking process, promulgate a final rule, and then effectively repeal it, simply by indefinitely postponing its operative date.").

[108] Public Citizen Health Res. Grp. v. Dep't of Health & Hum. Servs., 671 F.2d 518, 520 (1981) (Edwards, J., dissenting).

Opponents of the incoming administration may challenge delay rules implemented absent notice-and-comment rulemaking to protect the policies of a prior administration.[109]

Some agencies make little effort to conceal the political impetus of delay. At the start of the Obama Administration, the Department of Labor ("DOL") delayed a Bush Administration rule pertaining to the filing of financial reports by labor organizations "to permit unions to delay costly development and implementation of any necessary new accounting and recordkeeping systems and procedures" while the agency considered repeal.[110] Two Congressmen commented that the delay "suggests political favoritism to a select constituency rather than regulatory integrity."[111] DOL balked at the allegations, stating that it was not acting pursuant to "political favoritism" but rather instructions from OMB to delay rules to "permit their review for matters of law and policy before taking effect."[112] DOL highlighted other comments that "acknowledged that this review was necessary to provide the new Administration an opportunity to review rules issued in the waning days of the Bush Administration in order to prevent agencies from publishing rules that fail to meet the regulatory standards that OMB articulated in its guidance."[113] In a bizarre remark, DOL critiqued its own process, claiming that "the final rule

[109] Plaintiff's Mot. for Preliminary Injunction at 3-4, California v. U.S. Bureau of Land Mgmt., No. 3:17-cv-07186-LB (N.D. Cal. Jan. 19, 2018), ECF No. 3 ("Using this rationale, any agency could serially or indefinitely postpone compliance with an already-effective rule solely on the grounds that the agency is considering promulgating revisions); Complaint ¶ 7, Nat'l Venture Capital Ass'n v. Duke, No. 17-cv-1912 (D.D.C. Sept. 19, 2017), ECF No. 1 ("[T]his 'delay' is nothing more than a *de facto* repeal of the Rule.").

[110] Labor Organization Annual Financial Reports, 74 Fed. Reg. 18,132, 18,132 (Apr. 21, 2009).

[111] *Id.* at 18,134.

[112] *Id.*

[113] *Id.*

did not reflect proper consideration of all relevant facts and was not based on reasonable judgment about the legally relevant policy considerations."[114]

But not all policy-based delays occur during transition. An agency may delay a compliance date if it determines that the rule is inefficacious. For example, after EPA amended the limits of nonmetal residues for exempted burners, EPA realized that its limits "are extremely conservative to the point that they replicate an unrealistic scenario."[115] EPA explained that its estimates were created as a result of poor experimental design:

> To establish the [health-based limits] for nonmetals, the Agency converted drinking water limits . . . to total concentrations simply by mathematically converting the milligram per liter drinking water limits to milligram per kilogram units. In the rush to promulgate the BIF rules under a stringent court-ordered deadline, the Agency failed to note that this approach continues to assume that the hypothetical exposed individual is ingesting two liters (two kilograms) per day of the media—that is, two kilograms or 4.4 pounds of residue. Clearly, this was not the Agency's intent. In previous risk assessments, the Agency has often assumed that an individual ingests 0.2 grams of soil per day.[116]

EPA concluded, "What is certain is that the existing regulation values are mistaken."[117]

Yet, as Part III discusses, it can be difficult to distinguish between situations where the rule is actually ineffective and situations where the agency seeks to legitimize a political decision with a more palatable justification.

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[114] *Id.*

[115] Burning of Hazardous Waste in Boilers and Industrial Furnaces, 58 Fed. Reg. 59,598 (Nov. 9, 1993).

[116] *Id.* at 59,599.

[117] *Id.* Indeed, I certainly hope that no individual is consuming more than four pounds of soil in a day.

III. FORCES FOR DELAY

An agency's *justification* for delay is not necessarily synonymous with its *reason* for delay.[118] The justification may merely sanitize for the public a political decision resulting from pressures exerted by government and non-government entities. In delaying the Menu-Labeling Rule, FDA was pressured by two presidential administrations, Congress, litigants, state governments, regulated entities, and consumer groups. The notion that agency action is shaped by these institutions is not novel.[119] The scope of this article does not permit a full analysis of the pressures that influence agency decisionmaking. I therefore limit my discussion to how pressures exerted by litigation, Congress, and the president give reasons to doubt FDA's justifications for delay and engender concerns that FDA acted in accordance with political pressures.

A. *Litigation*

Litigation—or the threat of it—can influence agency behavior. Opponents may litigate rules for two reasons. Most simply, opponents may simply seek judgment of the rule as legally impermissible.[120] Other times, regulated entities may leverage judicial review to delay implementation of regulations where the cost of compliance outweighs the cost of litigation. For example, trade associations challenged OSHA's air-contaminants standard knowing that

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[118] Jerry L. Mashaw, *Small Things Like Reasons Are Put in a Jar: Reason and Legitimacy in the Administrative State*, 70 FORDHAM L. REV. 17 (2001).

[119] The literature on this point is too expansive for review. For just a few sources, see JAMES Q. WILSON, BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT 235-94 (1989); Christopher R. Berry & Jacob E. Gersen, *Agency Design and Political Control*, 126 YALE L. J. 1002, 1010-14 (2017); Joshua D. Clinton, David E. Lewis, & Jennifer L. Selin, *Influencing the Bureaucracy: The Irony of Congressional Oversight*, 58 AM. J. OF POL. SCI 387 (2014); Terry M. Moe, *Control and Feedback in Economic Regulation: The Case of the NLRB*, 79 AM. POL. SCI. REV. 1094, 1095 (Dec. 1985).

[120] *See* Ronald M. Levin, *"Vacation" at Sea: Judicial Remedies and Equitable Discretion in Administrative Law*, 53 DUKE L.J. 291 (2003).

continued litigation cost less than the annual cost of compliance for the rule.[121] Judicial review delayed implementation of OSHA standards by two years, affording regulated entities a brief reprieve from compliance.[122] In these types of cases, the agency itself may delay the rule under Section 705 or the court may issue an injunction preventing the agency from enforcing the rule.

While no opponent of the Menu-Labeling Rule has sued FDA, stakeholders have used litigation to *prevent* further delay. While litigation forced FDA to maintain the May 8, 2018 compliance date, this concession does not mean that FDA will *enforce* the rule starting May 8, 2018. Given the political pressures exerted by Congress and the president, it is possible that FDA acquiesced to consumer-group demands to avoid litigation, knowing that it could exercise its enforcement discretion while determining how best to "reduce the burdens" of the Menu-Labeling Rule.[123]

B. *Congress*

Agency officials identify Congress as the institution having the greatest influence on policymaking.[124] Herbert Kaufman once described agency chiefs as "constantly looking over their shoulders . . . at the elements of the legislative establishment relevant to their agencies—taking stock of moods and attitudes, estimating reactions to contemplated decisions and actions,

[121] Shapiro & McGarity, *supra* note 91, at 737-38.

[122] Elinor P. Schroeder & Sidney A. Shapiro, *Responses to Occupational Disease: The Role of Markets, Regulation, and Information*, 72 GEO. L.J. 1231, 1257-58 (1984).

[123] Menu-Labeling Rule–May 2017 Delay, *supra* note, at

[124] Scott R. Furlong, *Political Influence on the Bureaucracy: The Bureaucracy Speaks*, 8 J. OF PUB. ADMIN. RES. & THEORY 39, 48 (1998).

trying to prevent misunderstandings and avoidable conflicts, and planning responses when storm warnings appeared on the horizon."[125]

What Congress giveth, Congress can taketh away. Congress has various tools to exert influence over agency policymaking. Congress can override agency action through the passage of legislation. It can leverage the appropriations process to prevent agencies from using funds to enforce regulations.[126] Informally, members of Congress individually threaten action if the agency does not align its policies with the legislator's desires.[127]

Congress and its members leveraged all of these tools in pressuring FDA to delay the Menu-Labeling Rule, consistently framing its concern as one of clarity. Whether Congress's concerns were sincere is questionable. Of the thirty-two senators who signed the May 2015 letter, fourteen were democrats, including eight who voted for the ACA.[128] The presence of these ACA proponents suggests that Congress's clarity concerns were sincere, at least before FDA published its Level 1 guidance. But later congressional involvement appears politically motivated. In campaigning to constituents, Republicans have focused not on the rule's lack of clarity, but rather the harms they believe it will cause businesses.

FDA has reasons to fear further legislative action meant to hinder the Menu-Labeling Rule. By the May 2017, Congress had already stripped appropriations for enforcement of the

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[125] HERBERT KAUFMAN, THE ADMINISTRATIVE BEHAVIOR OF FEDERAL BUREAU CHIEFS 164 (1981).

[126] Jack M. Beermann, *Congressional Administration*, 43 SAN DIEGO L. REV. 61, 84-85 (2006)

[127] Zachary S. Price, *Reliance on Nonenforcement*, 57 WM. & MARY L. REV. 937, 1010-11 (2017).

[128] *Compare*, *32 Senators Urge FDA to Provide Clarify to Businesses Before Enforcing Menu Labeling Rule*, *supra* note 17, *with Roll Call Vote 111th Congress – 1st Session*, U.S. SENATE, https://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=111&session=1&vote=00396 (last visited Apr. 17, 2018).

Menu-Labeling Rule once and was considering legislation that would amend the ACA's menu-labeling requirements. One must question whether FDA implemented the May 2017 delay to avoid either expending resources while Congress considered the Common Sense Nutrition Disclosure Act or retributive action from the Republican Congress.

C. The President

The president is often cast as the leader of the bureaucracy and shepherd of agency decisionmaking.[129] Yet the White House intervenes in agency decisionmaking selectively and often without transparency.[130] The White House is most likely to intervene in "significant" rulemakings (i.e., having an annual economic effect of $100 million)—like the Menu-Labeling Rule—to pursue changes favoring regulated entities.[131]

Early in his term, the president is incentivized to engage in more intervention. Since President Clinton, the presidency has seesawed between parties, and each incoming president has advocated repeal of certain policies of his predecessor.[132] An incoming president has the best chance of achieving his policy goals—including repeal of undesirable rules—in the first year of

[129] Cynthia R. Farina, *The "Chief Executive" and the Quiet Constitutional Revolution*, 49 ADMIN. L. REV. 179, 180 (1997).

[130] Lisa Schultz Bressman & Michael P. Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control*, 105 MICH. L. REV. 47, 50, 82 (2006)

[131] Bressman & Vandenbergh, *supra* note 130, at 67-68, 90.

[132] *See, e.g.*, Patrick Parenteau, *Anything Industry Wants: Environmental Policy Under Bush II*, 14 DUKE ENVT'L L. & POL'Y FORUM 364 (2004) (describing the "Anything But Clinton" rule); Amy Goldstein & Jenna Johnson, *Trump: If Obamacare Is Not Repealed, It 'Will Destroy Health Care in America*," WASH. POST (Nov. 1, 2016), https://www.washingtonpost.com/news/post-politics/wp/2016/11/01/trump-if-obamacare-is-not-repealed-it-will-destroy-health-care-in-america/?utm_term=.a2b39979190d; Jeff Zeleny, *Obama Weighs Quick Undoing of Bush Policy*, N.Y. TIMES (Nov. 9, 2008), https://www.nytimes.com/2008/11/10/us/politics/10obama.html

his administration.[133] In many circumstances, undesirable regulations must be repealed, amended, or delayed shortly after inauguration if the president hopes to prevent regulated entities from expending resources on compliance.[134] Delay affords the administration time to amend or repeal undesirable rules.

It is hard to ignore the political undertones of FDA's May 2017 delay. President Trump and the Republican Party ran on a platform that included repeal of menu-labeling requirements.[135] The delay expressly invokes President Trump's Executive Order, which requires agencies "to consider how [they] might further reduce the regulatory burden." FDA announced it would delay the rule while reconsidering it in accordance with this Executive Order because it would not "make sense" for regulated entities to incur costs pending changes to the rule. [136] This proclamation signals that FDA intended to amend the Menu-Labeling Rule to lessen requirements for regulated entities. Moreover, FDA's unexplained claim that the rule "lacks flexibility"[137] is belied by previous assertions that the rule "provides flexibility for covered establishments in order to minimize costs while also helping to ensure that calorie and

[133] RICHARD BRODY, ASSESSING THE PRESIDENT: THE MEDIA, ELITE OPINION, AND PUBLIC SUPPORT 27-44 (1991); Casey Byrne Knudsen Dominguez, *Is it a Honeymoon? An Empirical Investigation of the President's First Hundred Days*, 31 CONG. & THE PRESIDENCY: A J. OF CAPITAL STUDS. 63 (20045).

[134] *See* Jack M. Beermann, *Presidential Power in Transitions*, 83 B.U. L. REV. 947, 983-85 (2003) (describing these tools as solutions to combating midnight rules).

[135] *See supra* text and accompanying notes at 42-44.

[136] Menu-Labeling Rule–May 2017 Delay, 82 Fed. Reg. at 20,827.

[137] *Id.*

other nutrition information is made available to consumers."[138] There can be little doubt that the delay was pursued, in part, as part of President Trump's efforts to repeal Obama-era regulations.

Yet the May 2017 delay avoids describing the Menu-Labeling Rule as antithetical to the incoming administration's agenda and, instead, reiterates FDA's commitment "to provide consumers with nutrition information."[139] FDA appears to have offered such statements to legitimize its actions. Bureaucratic governance is founded on notions of agency expertise and insulation from the political tides. Purely political explanations delegitimize agency action and subject the agency to the risk of litigation.[140] Courts expect social, scientific, or economic facts—not the political environment—to support agency decisionmaking.[141]

In light of pressures to appear legitimate, FDA's clarification-based justification of the May 2017 delay is dubious. The FDA invoked the good-cause exception to evade notice-and-comment rulemaking, arguing that the complex questions and cost of compliance warranted immediate delay.[142] Yet the delay came four days before the compliance date, meaning many regulated entities were prepared to comply despite purported ambiguities. Moreover, FDA had already released detailed guidance documents and conducted workshops. True, the Supplemental Guidance is evidence that the Menu-Labeling Rule required further clarification. But additional

[138] Final Menu Labeling Rule, 79 Fed. Reg. at 71,178.

[139] Menu-Labeling Rule May 2017 Delay, 82 Fed. Reg. at 20,827.

[140] Jerry L. Mashaw, *Small Things Like Reasons Are Put in a Jar: Reason and Legitimacy in the Administrative State*, 70 FORDHAM L. REV. 17-22 (2018) ("[I]t is a rare case in which an administrator called upon to justify a decision can respond simply, 'The President made me do it,' or 'The Congress said so.'")

[141] *See Motor Vehicles Manufacturers Assoc. v. State Farm Automobile Ins. Co.*, 463 U.S. 29 (1983)

[142] Menu-Labeling Rule–May 2017 Delay, 82 Fed. Reg. at 20,827-828.

guidance will always be needed. At some point, one must question whether the agency's justifications are merely legitimizing facades covering political reasons.

Broadened to the entire regulatory process, these observations are of limited value. The Menu-Labeling Rule is unique in how much political attention it garnered. Most rules and their respective delays are mundane and apolitical. For example, the VA's final billing-methodology rule received one comment, which was supportive of the rule,[143] and there is no reason to believe the subsequent agency-based delay masked political pressures.[144] Even when institutions pressure agencies to select certain policy choices, empirical studies suggest that the influence is often less significant than expected.[145] Ultimately, context is key. Skepticism of justifications for any agency action—whether for delay, repeal, or rulemaking—is warranted when context suggests that the agency is pressured by political interests. While the identified justifications in Part II may be used to legitimize political action, it is overbroad to suggest that all delays are political.

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Good-governance requires agencies to pursue action in ways that promote transparency and public participation.[146] Transparency provides the public with information about the

[143] Payment for Home Health Services and Hospice Care to Non-VA Providers, 78 Fed. Reg. 26,250 (May 6, 2013).

[144] Payment for Home Health Services and Hospice Care to Non-VA Providers; Delay of Effective Date, 79 Fed. Reg. 16,200.

[145] Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2255-60 (2001) B. Dan Wood, *Principals, Bureaucrats, and Responsiveness in Clean Air Enforcements*, 82 AM. POLI. SCI. REV. 213, 227-28.

[146] Cary Coglianese, Heather Kilmartin, & Evan Mendelson, *Transparency and the Public Participation in the Federal Rulemaking Process: Recommendations for the New Administration*, 77 GEO. WASH 924 (2009).

agency's decisionmaking process and reasons for action. Public participation provides stakeholders a voice in an otherwise insulated process. Together, transparency and public participation facilitate oversight, produce more informed policy decisions, and legitimize agency action.[147]

Litigants, critics, and courts err by casting compliance delays as substantive decisions rather than a procedural tool. Certainly, an amendment to a final rule's compliance date is a substantive change to the rule. But the agency's goal is rarely the delay for the sake of delay. Underlying delay is a substantive problem with the rule. Delay is the procedural tool that resolves the substantive problem. Sometimes that problem is solved by the delay itself—such as the case with industry-based delays. Other times, delay provides the agency with time to craft the necessary solution, such as the publishing of interpretative guidance. Delay rules allow for responsive governance by providing the agency time to remedy problems.

When sincerely pursued, delays foster a rulemaking environment that allows for *more* transparency and public participation. The delay itself is the product of public participation. Even when the rule is not open for comment, stakeholders notify agencies of the problems they have identified with the rule. When the agency announces the delay, it notifies the public that the agency has identified a problem with the rule. From there, the agency may take additional action that leads to public participation. When the agency adopts interpretative guidance, it often does so through notice and opportunity for comment or, at the very least, through informal channels of communication with stakeholders. This transparency also benefits opponents of the delay, who serve as government watchdogs. If these groups suspect that the delay is a de facto repeal, they may seek judicial review, arguing that the agency's decision to delay is arbitrary and capricious.

[147] *Id.* at 927

Haste makes waste. Carelessly drafted rules create ambiguities that result in inadequate (and, eventually, obsolete) compliance efforts and inconsistent enforcements. In other instances, failure to delay may result in egregious policy outcomes, such as the removal of medically-necessary drugs from the market. An agency may even create a rule that does nothing to advance the policy objective, because the agency's reasoning is irredeemably flawed.

In sum, compliance delays can result in more legitimate and more informed policy decisions, while preventing economic waste.

IV. DELAY RULES V. ENFORCEMENT DELAYS

If delays are a beneficial tool in the bureaucrat's toolbox, the question becomes: What procedures should be required to delay compliance dates? Every compliance delay examined in Parts I-III was implemented as a delay rule. While delay rules are the formalistic method to amend the compliance date, agencies can achieve similar results by not enforcing rules until a later date. Ultimately, the rulemaking requirements of delay rules incentive agencies to pursue enforcement delays to avoid rulemaking costs associated with delay rules.

A. *Delay Rules*

In promulgating a delay rule, the agency officially amends the compliance date of the final rule. Typically, the APA requires agencies to undergo notice-and-comment rulemaking to amend the substance of a final rule.[148] While agencies sometimes follow these procedures,[149] agencies have generally avoided notice-and-comment rulemaking in implementing delay rules.

[148] 5 U.S.C. §§ 551(5), 553(b)-(c) (2012).

[149] *See, e.g.*, Extension of BART Compliance Date for Reid Gardner Generating Station, 78 Fed. Reg. 53,033 (Aug. 28, 2013); Prohibition on Financing Credit Insurance Premiums; Delay of Effective Date, 78 Fed. Reg. 32,547 (May 31, 2013); Medicaid Program: State Flexibility for Medicaid Benefit Packages and Premiums and Cost Sharing, 74 Fed. Reg. 62,501 (Nov. 30, 2009).

Instead agencies invoke Executive Orders,[150] the good-cause exception,[151] or the procedural-rule exemption to avoid rulemaking costs.[152] Other times, agencies offer no excuses and promulgate the rule without opportunity for comment.

In *Council of Southern Mountains, Inc. v. Donovan*, the D.C. Circuit concluded that the Secretary of Labor had good cause to dispense with APA rulemaking requirements in implementing a delay rule, but stated the court did "so guardedly, based on the totality of the special circumstances presented."[153] Yet *Southern Mountains* was decided before courts began affirming procedural challenges to delay rules.[154] In more recent cases, courts regularly vacate delay rules promulgated without notice and opportunity for comment.[155] Despite the persistent

[150] Fisheries of the Caribbean; Gulf of Mexico, and South Atlantic; Dolphin and Wahoo Fishery off the Atlantic States; Regulatory Amendment 1, 82 Fed. Reg. 8820 (Jan. 31, 2017); Endangered and Threatened Wildlife and Plants; Revisions to the Regulations for Candidate Conservation Agreements with Assurances, 82 Fed. Reg. 8501 (Jan. 26, 2017); Importation of Lemons from Northwest Argentina; Stay of Regulations, 82 Fed. Reg. 8353 (Jan. 25, 2017).

[151] *See, e.g.*, Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations; Delay of Effective Date, 82 Fed. Reg. 10,855 (Feb. 16, 2017); Delay of Effective Date for Importations of Certain Vehicles and Engines Subject to Federal Antipollution Emission Standards, 82 Fed. Reg. 8589, 8590 (Jan. 27, 2017); Delay of Effective Date for 30 Final Regulations Published by the Environmental Protection Agency Between October 28, 2016 and January 17, 2017, 82 Fed. Reg. 8499, 8499-8501 (Jan. 26, 2017); *cf.* 5 U.S.C. 553(b)(B) (2012) (good-cause exception).

[152] *See, e.g.*, Recognition of Triable Organizations for Representation of VA Claimants; Delay of Effective Date, 82 Fed. Reg. 11,151, 11,152 (Feb. 21, 2017); Energy Conservation Program: Energy Conservation Standards for Ceiling Fans, 82 Fed. Reg. 8806 (Jan. 31, 2017); Civil Penalties, 82 Fed. Reg. 8694 (Jan. 30, 2017); *cf.* 5 U.S.C. 553(b)(A).

[153] 653 F.2d 573, 582 (D.C. Cir. 1981).

[154] Holmes, *supra* note 7, at 652-53.

[155] *See* Nat. Res. Def. Council v. Abraham, 355 F.3d 179, 204-06 (2d Cir. 2004) (rejecting use of good-cause exception and procedural-rule exemption); Envtl. Def. Fund, Inc. v. EPA, 716 F.2d 915, 920-21 (D.C. Cir. 1983) (rejecting good-cause exception); Nat. Res. Def. Council v. EPA, 683 F.2d (3d Cir. 1982); Open Communities Alliance v. Carson, 286 F. Supp. 3d 148, 162-78

invocation of Section 553 exceptions and exemptions, courts are foreclosing the use of these exceptions and exemptions in the delay-rule context.

The benefits of notice-and-comment rulemaking should not be undersold. Rulemaking procedures constrain agency discretion, encourage transparency, increase the quality of agency decisions, and promote democratic participation.[156] Pursuant to the text of the APA, notice-and-comment rulemaking is a simple affair: the agency publishes the proposed rule in the *Federal Register*;[157] interested parties are given "an opportunity to comment on the rule; and the agency issues the rule with a concise statement of purpose.[158]

What the statutory text fails to explain is how onerous notice-and-comment rulemaking has become. In an effort to control agencies, each branch of government has formally and informally expanded the APA's procedural requirements.[159] Scholars have long argued that increased procedural requirements have "ossified" the rulemaking process.[160] Court reversals of agency decisionmaking for (sometimes minor) procedural flaws have caused agencies to become

(D.D.C. 2017); Nat'l Venture Capital Ass'n v. Duke, No. 17-1912, 2017 WL 5990122, at *7-11 (D.D.C. 2017) (rejecting good-cause exception).

[156] *See* Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 69, 59-60 (1995).

[157] *Id.* 5 U.S.C. § 553(b) (2012).

[158] *Id.* § 553(c).

[159] Mathew D. McCubbins, Roger G. Noll, & Barry R. Weingast, *Administrative Procedures as Instruments of Political Control*, 3 J. L. ECON & ORG. 243 (1987).

[160] *See* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1385 (1992); Richard J. Pierce, Jr., *Rulemaking Ossification is Real: A Response to Testing the Ossification Thesis*, 80 GEO. WASH. L. REV. 1493 (2012).

skittish about rulemaking.[161] Meanwhile, Congress and the White House engage in a competitive game of micromanagement, each attempting to exercise influence over agency policymaking to prevent deviations from the desired outcome.[162] The White House requires agencies to submit proposed rules to OMB for review and has increased the number of considerations agencies must assess before proposing a rule.[163] For its part, Congress has enacted laws requiring the agency to consider whether the rule results in an undesirable impact on the public, such as paperwork reduction and environmental impacts.[164] While the empirical wisdom of the ossification thesis has come under attack,[165] even critics acknowledge that "it seems clear that the life of a bureaucrat is a difficult one."[166]

Rulemaking has become harder and agencies have become inventive in circumventing its requirements. As Peter Strauss astutely summarized:

> The more costly it becomes to generate regulations, and the fewer resources agencies have available to pay those costs, the greater

[161] *Id.* at 1400-03 (explaining how analytical requirements affect agency behavior); *see also* JAMES Q. WILSON, BUREAUCRACY 282 (1989) ("Agency heads that face the prospect of frequent legal challenge become even more risk averse than they already are, and thus institute rule-making procedures that are far more complex than anything required by the Administrative Procedure Act.."); Sidney A. Shapiro, *Political Oversight and the Deterioration of Regulatory Policy*, 46 ADMIN. L. REV. 1, 4 (1994).

[162] Shapiro, *supra* note 161.

[163] Jason Webb Yackee & Susan Webb Yackee, *Testing the Ossification Thesis: An Empirical Examination of Federal Regulatory Volume and Speed, 1950-1990*, 80 GEO. WASH. L. REV. 1414, 1429-30 (summarizing the evolution of Executive Order 12,291); *see, e.g.*, Executive Order 13771 (Jan. 30, 2017) (requiring agencies to (1) identify two existing regulations to be repealed and (2) to not promulgate new regulations unless the final incremental cost of all new regulations is zero).

[164] Yackee & Yackee, *supra* note 163 at 1430-31.

[165] *Id.* at 1475.

[166] Yackee & Yackee, *supra* note 163 at 1467.

> will be the temptation to find other means to generate policy—shortcoming a desirable, even necessary public process.[167]

Rulemaking avoidance increases political autonomy while preserving time and resources.[168] When agencies perceive a low risk of a procedural challenge, agencies are much more likely to engage in rulemaking avoidance.[169] Between 1995 and 2012, agencies avoided notice-and-comment rulemaking when promulgating 52% of rules.[170] The apparent frequency at which delay rules are promulgated without notice and opportunity for comment suggests that agencies remain invested in avoiding rulemaking for delay rules.

Incentives to avoid rulemaking procedures create an odd game with respect to compliance delays. Assuming (1) the agency refuses to use APA rulemaking procedures and (2) Section 553 exceptions and exemptions are foreclosed by case law, the agency has two choices to implement the compliance delay. If the agency believes that the delay rule is unlikely to draw a procedural challenge, the agency may simply promulgate the rule in the *Federal Register* without notice and opportunity for comment. FDA adopted this strategy in promulgating the July 2015 and May 2016 delays of the Menu-Labeling Rule. But if the agency believes that the delay rule is likely to be challenged, the agency can still avoid APA rulemaking procedures by adopting an enforcement delay.

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[167] Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 808 (2001).

[168] Connor Raso, *Agency Avoidance of Rulemaking Procedures*, 67 ADMIN. L. REV. 65, 68 (2015).

[169] *Id.* at 91-93

[170] *Id.*

B. *Enforcement Delays*

An enforcement delay is a policy of prosecutorial discretion in which the agency decides not to enforce the rule for a period of time even though the compliance date has gone into effect. Enforcement delays are a form of categorical nonenforcement. Categorical nonenforcement is not uncommon and has been used in the marijuana, immigration, and environmental contexts.[171]

Section 701(a)(2) of the APA precludes judicial review of actions "committed to agency discretion."[172] In *Heckler v. Chaney*, the Supreme Court held that the "decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion."[173] According to the Court, the agency is in the best position to balance whether an enforcement action fits the agency's overall policies and whether the agency has enough resources to devote to the particular enforcement action.[174] Moreover, the Court emphasized that "when an agency refuses to act it generally does not exercise its *coercive* power over an individual's liberty or property right, and thus does not infringe upon areas that courts often are called upon to protect."[175]

Scholars often overstate the breadth of *Heckler*.[176] Courts have become much more willing to review nonenforcement when litigants characterize it as an affirmative rule or

[171] Zachary S. Price, *Enforcement Discretion and Executive Duty*, 67 VAND. L. REV. 671, 756-62 (2014).

[172] 5 U.S.C. § 702(a)(2); *see also* Lincoln v. Vigil, 508 U.S. 182, 191 (1993).

[173] Heckler v. Chaney, 470 U.S. 821, 831 (1985).

[174] *Id.* at 831-32.

[175] *Id.* at 832 (emphasis added).

[176] *See* Daniel E. Walter, *The Judicial Role in Constraining Presidential Nonenforcement Discretion: The Virtues of an APA Approach*, 164 U. PA. L. REV. 1911, 1926-27 (2016) (stating that much of the literature "prematurely considers inaction review a dead letter").

policy.[177] Categorical nonenforcement often looks like an informal policy susceptible to judicial review. For good reason. Categorical nonenforcement is often a deregulatory tool that conflicts with statutory mandates.[178] Some scholars have gone as far to suggest that categorical nonenforcement is unconstitutional absent congressional approval.[179]

As such, courts are becoming increasingly skeptical of categorical nonenforcement. In *Crowley Caribbean Transport, Inc. v. Peña*, the D.C. Circuit stated that while an agency's "*single-shot* enforcement decision" is nonreviewable, "an agency's statement of a *general enforcement policy* may be reviewable for legal sufficiency where the agency has expressed the policy as a formal regulation after the full rulemaking process . . . or has otherwise articulated it in some form of universal policy statement."[180] In *Texas v. United States*, the Fifth Circuit dismissed the Department of Homeland Securities' invocation of *Heckler* to defend its memorandum instructing immigration agencies to exercise prosecutorial discretion with respect to undocumented immigrations who are the parents of a U.S. citizen child ("DAPA").[181] The Fifth Circuit agreed that "[p]art of DAPA involves the Secretary's decision—at least temporarily—not to enforce the immigration laws as to a class of what he deems to be low-

[177] *Id.* at 1929 ("At some point, patterns of nonenforcement start to resemble rules, particularly when a memorandum, guidance document, or policy statement guides the exercise of nonenforcement discretion and qualifies as final agency action.")

[178] Price, *supra* note 171 at 750.

[179] Leigh Osofsky, *The Case for Categorical Nonenforcement*, 69 TAX L. REV. 77-78 (2015) (describing literature on this point).

[180] 37 F.3d 671, 676 (D.C. Cir. 1994).

[181] Memorandum from Jeh Johnson, Sec'y, Dep't of Homeland Sec., at 3-4 (Nov. 20, 2014), https://www.dhs.gov/sites/default/files/publications/14_1120_memo_deferred_action.pdf. "DAPA" stands for "Deferred Action for Parents of Americans and Lawful Permanent Residents" [hereinafter DAPA Memo]; United States v. Texas, 809 F.3d 134, 146 (5th Cir. 2015).

priority illegal immigrants."[182] However, the Fifth Circuit concluded that deferred action was "much more than nonenforcement" because it would "affirmatively confer 'lawful presence' and associated benefits on a class of unlawfully present aliens."[183] Additionally, the Fifth Circuit found that DHS had to undergo notice-and-comment rulemaking to implement DAPA and could not rely on the rulemaking exceptions under the APA.[184]

However, this skepticism has not provided a bright-line rule for when an agency engages in reviewable categorical nonenforcement. Recently, the Ninth Circuit has expressed interest in establishing clearer jurisprudence on this issue. On May 1, 2018, the Ninth Circuit requested supplemental briefing in *Regents of the University of California v. California*,[185] on whether *Heckler* bars judicial review of DHS's rescission of DACA. Citing *Crowley*, the Ninth Circuit also stated that "[t]he parties should consider whether the rescission is judicially reviewable as a general enforcement policy, rather than as a single-shot non-enforcement decision."[186]

Even if this case law prohibits categorical nonenforcement, agencies may still engage in categorical nonenforcement. In order for courts to distinguish between "single-shot" and categorical nonenforcement, they need evidence that the agency has actually adopted an informal policy against enforcement. As a result, agencies can still pursue enforcement delays if they avoid announcing the policy. Transparency is lost.

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[182] *United States v. Texas*, 809 F.3d at 166.

[183] *Id.*

[184] *See id.* at 171-77 (rejecting DHS's policy-statement exception, procedural-rule exception, and public-benefits exception arguments).

[185] No. 18-15068, at 2 (9th Cir. May 1, 2018), ECF No. 157

[186] *Id.*

For obvious reasons, documenting unspoken policies of categorical nonenforcement is difficult. Yet scholars have managed to identify a few cases where agencies have furtively engaged categorical nonenforcement.[187] In 2003, the Bush Administration published a rule that expanded the scope of certain Clean Air Act exemptions to ease regulatory burdens on power plants.[188] In 2006, the D.C. Circuit vacated the rule.[189] However, scholars believe that the Bush Administration nevertheless implemented the rule through an "unspoken, informal enforcement policy" because violations for specific Clean Air Act all but disappeared.[190]

The facts in *Public Citizen v. Department of Health and Human Services* exemplify how an agency might silently delay enforcement while still managing to notify regulated entities of the delay.[191] In 1980, FDA published a rule requiring that inserts be distributed with certain prescription drugs.[192] After promulgation, FDA met with a pharmaceutical-industry representative to seek comments on a proposed delay of the rule.[193] In February 1981, FDA notified regulated entities through the "trade press" that it was going to stay the effective date.[194]

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[187] *See* Osofsky, *supra* note **Error! Bookmark not defined.**, at 80-87 (describing categorical nonenforcement by the IRS); Daniel T. Deacon, Note, *Deregulation Through Nonenforcement*, 85 N.Y.U. L. Rev. 795, 811-812 (2010) (describing the George W. Bush Administration's efforts to ease enforcement of the Clean Air Act).

[188] Deacon, *supra* note 187; *see also* Jonathan Remy Nash & Richard L. Revesz, *Grandfathering and Environmental Regulation: The Law and Economics of New Source Review*, 101 NW. U. L. REV. 1677, 1678-84 (2007).

[189] *New York v. EPA*, 443 F.3d 880, 890 (D.C. Cir. 2006).

[190] Deacon, *supra* note 187.

[191] 671 F.2d 518, 520 (D.C. Cir. 1981).

[192] *Id.* at 519.

[193] Holmes, *supra* note 7, at 651.

[194] *Pub. Citizen*, 671 F.2d at 520.

But FDA waited until April 1981 to publish the delay in the *Federal Register* and did so without notice and opportunity for comment.[195] While FDA ultimately published its delay, it is easy to imagine a scenario where an agency would notify regulated entities without telling other stakeholders. Absent the agency's decision to publish in the *Federal Register*, all other stakeholders would have suffered from an information deficit.

As exemplified by *Public Citizen*, agencies and regulated entities engage in ex parte communications. These ex parte communications occur "off the record" and prevent public participation. In the rulemaking context, Susan Webb Yackee argues that this lack of transparency restricts the public's ability to respond to communications, increases the influence of regulated entities, runs counter to the idea of accountability, and creates an imbalance between stakeholders during other agency proceedings.[196] *Public Citizen* suggests that agencies have the ability to use ex parte contact to communicate an enforcement delay to regulated entities, accomplishing the goal of both delay and rulemaking avoidance.

Even if an agency did not inform regulated entities directly, regulated entities could identify categorical nonenforcement through patterns of individual enforcement. As Lori Richardson Pelliccioni described in the first panel of this Symposium, industry officials regularly share information about enforcement decisions. If regulated entities come to realize that the agency has no intent to enforce the rule, they may stop complying with the rule altogether.

I concede that this fear is speculative. However, without empirical testing, it is hard to assess whether enforcement delays are an observable phenomenon. Researchers might be able to observe enforcement delays by examining how long after the compliance date it takes the agency

[195] *Id.*

[196] Susan Webb Yackee, *The Politics of* Ex Parte *Lobbying: Pre-Proposal Agenda Building and Blocking During Agency Rulemaking*, J. OF PUB. ADMIN. RES. & THEORY 4 (2011).

to start enforcing the regulation. Such a study clearly falls beyond this Article's purview. For now, anecdotal evidence of hidden categorical nonenforcement is enough to suggest that, perhaps, agencies might implement enforcement delays.

CONCLUSION

Compliance delays are a procedural tool that promotes transparency and public participation in the rulemaking process. These benefits are only achieved when the agency implements the compliance delay through a delay rule. But delay rules—like all substantive rules—require the onerous process of notice-and-comment rulemaking. Seeking an alternative, agencies may gravitate toward enforcement delays. Unfortunately, regulated entities are the only stakeholders likely to be informed of an agency's enforcement delay in order to prevent procedural challenges to the delay. All stakeholders must be informed if the compliance delay is to produce optimal transparency and public participation.

If we wish to preserve compliance delays as a procedural tool for agencies, we must exempt compliance delays from APA rulemaking procedures. Congress recognizes that notice-and-comment rulemaking is not always worthwhile. Section 553 recognizes exemptions for interpretative rules and procedural rules, both of which may affect the rights of stakeholders far more than the delay of a compliance date. In particular, interpretative guidance has become the bread-and-butter of regulatory policymaking and can be even more important than the final rule's text.

Moreover, the primary purposes of notice-and-comment rulemaking are to encourage transparency, increase the quality of agency decisions, and promote democratic participation.[197] Delay rules accomplish all of these goals even absent APA rulemaking requirements. The Menu-

[197] *See* Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 69, 59-60 (1995).

Labeling Rule exemplifies that stakeholders communicate their concerns to agencies at all times, even absent formal invitation. These concerns led FDA to create more opportunities for public participation, such as a series of public workshops to address stakeholder questions and comments for draft guidance. And finally, perhaps to the agency's detriment, the transparency inherent in delay rules allowed consumer groups to challenge the May 2017 delay rule as arbitrary and capricious. Challenges like this may be impossible when the agency obfuscates its actions through an enforcement delay.

In sum, notice-and-comment rulemaking is necessary for many agency actions. Delay rules are not among them.