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Intractable Delay and the Need To Amend the Petition Provisions of the FDCA

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Intractable Delay and the Need To Amend the Petition Provisions of the FDCA

DIANA R. H. WINTERS*

Private party oversight has proven to be ineffective at countering inaction by the Food and Drug Administration (FDA). Inaction when regulation is warranted can put the public at continued and increasing risk of harm, but the failure of private enforcement to compel action reverberates beyond this harm to the interests of individuals. It also diminishes the transparency of agency decision making, lessens the opportunity for public participation, and reduces the interaction between the institutions that oversee agencies. Moreover, the benefits afforded to the administrative process by judicial review are weakened.

This Article analyzes two examples of FDA inertia and compares private enforcement under the Food, Drug, and Cosmetic Act (FDCA) to more successful private party activity under several environmental statutes. These comparisons highlight several weak spots in the FDCA that contribute to the difficulties faced by private party oversight in attempting to compel FDA action. The Article then proposes solutions suggested by these problems. Congress should amend the Act to include more specific petition provisions with statutory deadlines and to strengthen the general citizen petition provision of the FDCA. Interested parties should also be able to petition the Office of Information and Regulatory Affairs (OIRA) for the review of the denial of rulemakings. These steps will restore the vitality of a critical part of the administrative enforcement scheme—private party oversight—and thereby benefit both the public health and the regulatory state.

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INTRODUCTION

Inaction by federal agencies in the realms of health, safety, and environmental regulation causes as much or more harm than excessive action, or misdirected action.¹ A failure to regulate when regulation is warranted puts the public at continued and increasing risk of harm. The administrative state relies on private enforcement to remedy deficiencies in agency action, including the problem of inaction. Agencies are also overseen by the executive branch and by Congress, but private enforcement provides a critical check on the influence of political vicissitude on an agency’s divergence from its statutory mandate.² Moreover, congressional or presidential action addressing agency inertia is unreliable.³

This Article is concerned with oversight of agency inaction and looks at why mechanisms of private enforcement are ineffective under certain circumstances but succeed under others. Agency inaction takes many forms, but the focus of this Article

1. See *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) (“[D]elays that might be reasonable in the sphere of economic regulation are less tolerable when human health or welfare are at stake . . .”).

2. The Administrative Procedure Act, which prescribes the structure of agency proceedings, emphasizes the oversight of private parties as the main constraint on agency action or inaction. See, e.g., Edward Rubin, *It’s Time To Make the Administrative Procedure Act Administrative*, 89 CORNELL L. REV. 95, 101 (2003) (The Administrative Procedure Act’s basic provisions “rely on a single method for controlling the actions of administrative agencies, namely, participation by private parties.”).

3. See Sidney A. Shapiro & Richard W. Murphy, *Eight Things Americans Can’t Figure Out About Controlling Administrative Power*, 61 ADMIN. L. REV. 5, 28 (2009).

is not an agency's failure to directly enforce its statutory mandates, over which it has much discretion, or the failure of an agency to engage in nondiscretionary duties, over which it has little. Instead I explore situations where an agency fails to respond to a rulemaking petition or denies a rulemaking petition. In particular, I look at the Food and Drug Administration's (FDA) activities. By "ineffective," I do not mean that the Agency has failed to act as a private entity desires, but rather that the Agency has failed to engage with or respond to the issues raised. The situations addressed here are evidence of a stalled system and a failure of the checks and balances built into the administrative state.

More specifically, this Article analyzes the difficulty that private enforcement faces in forcing action by FDA.⁴ Inaction by FDA—which has responsibility over eighty to ninety percent of our food supply⁵ and authority over products that represent twenty-five cents of every consumer dollar⁶—imperils the public and decreases public confidence in our regulatory system more generally. In this Article, I look at two high-profile incidences of FDA inaction—the failure of FDA to withdraw approval for the subtherapeutic use of certain antibiotics in animal feed, and the Agency's recalcitrance in switching emergency contraception to over-the-counter (OTC) status for all women. I will also examine two less prominent incidences of inaction.⁷

In both the high-profile and less prominent incidences, private parties petitioned FDA to take a certain action, brought suit when FDA refused to do so, and in some cases, prevailed in court with a judicial opinion admonishing FDA for contravening its statutory mandate by not acting sooner. These cases can be seen as illustrations of private enforcement working as it should—stakeholders mobilized to enforce a federal agency's tendency to stray from its statutory mandate and supported by judicial decree. But even if this is a system working properly, it is not a system working well.

The cases are striking because of the immense delay. Especially in areas of health and safety regulation, FDA's delay undermines regulatory goals and has a detrimental effect on the public health.⁸ Moreover, FDA's inaction in these cases is an example of arbitrary decision making where "conclusions . . . do not follow logically from the evidence," and this kind of decision making affects statutorily provided rights.⁹

4. By "private enforcement," I mean agency-forcing suits, or suits brought by private entities against administrative agencies to force specific action. I am not addressing suits brought under citizen suit provisions, although these are discussed *infra* Part I.A., nor do I refer to suits brought under state tort law.

5. See RENÉE JOHNSON, CONG. RESEARCH SERV., RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 4 (2012), available at <http://www.fas.org/sgp/crs/misc/RS22600.pdf> (basing this estimate on information supplied by the Government Accountability Office and the Department of Agriculture).

6. RENA STEINZOR & SIDNEY SHAPIRO, THE PEOPLE'S AGENTS AND THE BATTLE TO PROTECT THE AMERICAN PUBLIC 24 (2010).

7. I do not look here at cases brought to accelerate the new drug approval process. This subset of agency inaction is governed by a distinct statutory scheme and is beyond the scope of this Article.

8. Telecomms. Research & Action Ctr. v. FCC, 750 F.2d 70, 80 (D.C. Cir. 1984) ("[D]elays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake . . .").

9. Lisa Schultz Bressman, *Judicial Review of Agency Inaction: An Arbitrariness*

In contrast, there are certain areas where private enforcement has been very effective in forcing agencies to act pursuant to their statutory mandates. Private actors and judicial review have spurred action under the Clean Air Act (CAA)¹⁰ and the Clean Water Act (CWA),¹¹ and have initiated the listing of many species under the Endangered Species Act (ESA).¹² Although these suits have been subject to the delay inherent to judicial review, they have nevertheless resulted in some spectacular successes.¹³

Why is oversight by private parties, one of the bedrock supports of the administrative state, effective in some contexts but not in others? Although each episode of inaction reflects a unique confluence of factors, specifically drawn citizen petition provisions, as are found in some environmental laws, allow for meaningful and (more) timely judicial review. In contrast, many citizen actions before FDA are brought under a weak general citizen petition provision.

When it is clear that action should be taken, FDA delay undermines its statutorily mandated goals. For instance, there has been a consensus for over three decades that the subtherapeutic use of antibiotics in animal feed harms the public health,¹⁴ and FDA, as the agency with responsibility over animal feed, should regulate the use of these medicines. Inaction and the failure of private enforcement also have implications beyond their specific substantive context. Episodes of arbitrary decision making resulting in inaction can, as Lisa Schultz Bressman writes, “affect individual liberty in a collective sense.”¹⁵

Inaction is rarely documented, and the failure of private enforcement contributes to the opacity of agency decision-making processes. Public participation in the regulatory process is lessened, which is a detriment in itself,¹⁶ and reduced

Approach, 79 N.Y.U. L. REV. 1657, 1687 (2004) (citing Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461, 496 (2002)).

10. See Emily Hammond Mezell, *Deference and Dialogue in Administrative Law*, 111 COLUM. L. REV. 1722, 1764–72 (2011) (discussing serial litigation under the CAA).

11. See Robert L. Glicksman, *The Value of Agency-Forcing Citizen Suits To Enforce Nondiscretionary Duties*, 10 WIDENER L. REV. 353, 373 (2004) (discussing citizen suit litigation under the CWA).

12. See Eric Biber & Berry Brosi, *Officious Intermeddlers or Citizen Experts? Petitions and Public Production of Information in Environmental Law*, 58 UCLA L. REV. 321 (2010) (discussing success of citizen petitions under the ESA).

13. Private enforcement and judicial review do not always have a positive effect on the regulatory environment. For criticism, see Nicholas Bagley, *The Puzzling Presumption of Reviewability*, 127 HARV. L. REV. 1285, 1331–36 (2014); Biber & Brosi, *supra* note 12, at 323–24 (discussing criticism of citizen petitions).

14. See *Natural Res. Def. Council, Inc. v. FDA*, 872 F. Supp. 2d 318, 341–42 (S.D.N.Y. 2012) (“For over thirty years, the Agency has been confronted with evidence of the human health risks associated with the widespread subtherapeutic use of antibiotics in food-producing animals, and, despite a statutory mandate to ensure the safety of animal drugs, the Agency has done shockingly little to address these risks.”), *rev’d on other grounds*, 760 F.3d 151 (2d Cir. 2014).

15. Bressman, *supra* note 9, at 1687.

16. See David Markell, “Slack” in the Administrative State and Its Implications for Governance: The Issue of Accountability, 84 OR. L. REV. 1, 10 (2005) (“Proponents of increases in transparency and citizen participation in environmental or other aspects of governance internationally have invoked reasons similar to those offered by proponents of

participation also permits agency capture by special interests or at least the appearance thereof.¹⁷ Additionally, the failure of existing private enforcement mechanisms means the regulatory process does not receive the benefits provided by judicial review.

In addition, if the oversight function of private enforcement is not working satisfactorily, the relationship between the agency and its various principals, which is already complex,¹⁸ becomes even more tangled. Without the effective oversight of the public and review by the judiciary, special-interest influence can thwart congressional will or block executive priorities, administrative pressure can interfere with legislative priorities, and/or legislative inertia can interfere with agency work to protect the public health and safety.

This Article looks closely at these episodes of inaction by FDA and the failure of private oversight in forcing Agency action. It then offers some solutions suggested by the sources of the problem, although the complexity of the problem precludes a simple answer. Part I presents a typology of mechanisms for bringing suit against agencies to force action, and Part II looks at some specific instances of agency inaction in both the food and drug and environmental contexts. Part III discusses the problems resulting from the inadequacy of private enforcement to force agency action in these circumstances, and Part IV puts forward some solutions, including a call for Congress to write more specific standards for FDA to follow.

I. SUING AGENCIES TO FORCE ACTION

The Administrative Procedure Act (APA) supports the architecture of the regulatory state by prescribing general procedural mechanisms with which all agencies must comply. Passed in 1946, one of the Act's purposes was to "introduce greater uniformity of procedure and standardization of administrative practice among the diverse agencies."¹⁹ In addition to the general provisions of the APA, agencies must comply with their specific implementing statutes. For example, FDA must follow the mandates of the FDCA but also ensure that its actions comply with the APA's prescriptions.

With regard to oversight by private parties, the APA permits citizens to petition agencies for rulemaking and provides for the judicial review of agency action.²⁰ The FDCA also contains a general provision allowing private parties to petition the Agency for rulemaking, as well as specific provisions allowing for petitions under certain circumstances.²¹ This Part describes these rules, as well as an example of their

similar developments domestically, including increasing the fairness of the workings of international regimes; improving the information available to international decision-makers; enhancing prospects for compliance; and strengthening the legitimacy of the institutions involved."); Richard B. Stewart & Cass R. Sunstein, *Public Programs and Private Rights*, 95 HARV. L. REV. 1193, 1238 (1982) (describing the public values rationale for regulatory law).

17. See *infra* Part IV.B.

18. See STEINZOR & SHAPIRO, *supra* note 6, at 39–41.

19. *Wong Yang Sung v. McGrath*, 339 U.S. 33, 41 (1950).

20. 5 U.S.C. § 553(e) (2012).

21. See 21 U.S.C. § 360k (2012) (medical devices); *id.* § 360ss (radiation emissions); *id.* § 379r (OTC drugs); *id.* § 379s (cosmetics).

counterpart in one of the major environmental statutes, the ESA, and explains how these provisions define the contours of the private enforcement of agency action. Next, it discusses the judicial review of agency *inaction*, which has a distinct and convoluted history.

A. Provisions Permitting Citizens To Petition for Rulemaking

The APA's provision on rulemaking provides that agencies must allow any "interested person" the right to petition the agency for the "issuance, amendment, or repeal of a rule."²² Agencies must provide "prompt notice" if they deny a petition, and this denial must be "accompanied by a brief statement of the grounds for denial" unless the agency is "affirming a prior denial" or "the denial is self-explanatory."²³

The FDCA and various environmental statutes also contain petition provisions providing for interested parties to petition FDA, the Environmental Protection Agency (EPA), or any other relevant agency to take particular action. For example, a substance defined as a "food additive" can only be used in food after an interested party has petitioned FDA to issue a regulation prescribing the conditions under which the additive can be safely used.²⁴

FDA has issued regulations prescribing the procedures by which citizen petitions—petitions to the Agency requesting that the Agency take a certain action—should be filed. For instance, any interested party can petition FDA to "establish, amend, or repeal a regulation" that prohibits a certain substance from use in human food.²⁵ Any petitions submitted to FDA must comply with the requirements of the petition provision, 21 C.F.R. § 10.30, which also details procedures for FDA's response. Under this provision, FDA must respond to any petition within 180 days, either denying the petition, approving the petition, or "[p]rovid[ing] a tentative response, indicating why the agency has been unable to reach a decision on the petition."²⁶ In issuing a ruling, FDA has much discretion and is instructed to take into account "available agency resources" and "the priority assigned to the petition

22. 5 U.S.C. § 553(e). For examples of parties petitioning agencies for the repeal or amendment of a final rule issued by the agency pursuant to notice and comment rulemaking, see *Natural Res. Def. Council v. Abraham*, 355 F.3d 179, 203 (2d Cir. 2004); *S. Hills Health Sys. v. Bowen*, 864 F.2d 1084, 1087 (3d Cir. 1988).

23. 5 U.S.C. § 555(e) (2012). See Biber & Brosi, *supra* note 12, for a discussion of the APA's requirement that agencies respond promptly to citizen petitions. They point out that the APA also requires an agency to "conclude a matter presented to it" within "a reasonable time," 5 U.S.C. § 555(b), and allows courts to "compel agency action 'unreasonably delayed,'" Biber & Brosi, *supra* note 12, at 327 n.19 (quoting 5 U.S.C. § 706(1)).

24. "Food additive" is defined as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food," but excludes pesticide chemicals, color additives, animal drugs, dietary supplements, and foods generally recognized as safe. 21 U.S.C. § 321(s) (2012). A petitioner must show that the food additive for which a regulation is requested is safe. *Id.* § 348(b).

25. 21 C.F.R. § 189.1(c) (2013).

26. 21 C.F.R. § 10.30(e)(2) (2014).

considering both the category of subject matter involved and the overall work of the agency,” among other things.²⁷

Many environmental laws contain specific petition provisions too.²⁸ The Toxic Substances Control Act allows “[a]ny person [to] petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule,” under various sections of the Act.²⁹ The ESA details the procedures by which interested persons can petition the Secretary of the Interior or the Secretary of Commerce to add or remove a species from the endangered species list or the threatened species list.³⁰

Citizen petition provisions are different than citizen suit provisions, which many environmental statutes also contain. Citizen suit provisions generally allow any person or entity to sue a violator of the relevant statute or the agency in charge of the statute for failing to perform a nondiscretionary action.³¹ The FDCA does not contain a citizen suit provision or a private right of action.³² Without a citizen suit provision, a party may be unable to sue another private party for violation of the statute at issue, although a suit against the Agency is possible under the judicial review provisions of the APA.

B. The Judicial Review of Agency Action

Under the APA, “final agency action for which there is no other adequate remedy in a court [is] subject to judicial review,” and “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.”³³ When reviewing agency action, courts can “compel agency action unlawfully withheld or unreasonably delayed” or “set aside” agency action found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” among other things.³⁴ In 1967, the Supreme Court stated a strong presumption in favor of

27. *Id.* § 10.30(e)(1).

28. Congress enacted many petition provisions during the 1970s. *See* Biber & Brosi, *supra* note 12, at 327.

29. 15 U.S.C. § 2620(a) (2012).

30. 16 U.S.C. § 1533(b)(3) (2012). The ESA is administered by the U.S. Fish and Wildlife Service and the National Marine Fisheries Service.

31. *See, e.g.*, Clean Water Act § 505, 33 U.S.C. § 1365(a) (2012) (“[A]ny citizen may commence a civil action on his own behalf—(1) against any person . . . who is alleged to be in violation of (A) an effluent standard or limitation under this chapter or (B) an order issued by the Administrator or a State with respect to such a standard or limitation, or (2) against the Administrator where there is alleged a failure of the Administrator to perform any act or duty under this chapter which is not discretionary with the Administrator.”); *see also* 42 U.S.C. § 7604 (2012) (citizen suit provision of the CAA).

32. Private parties can only sue violators if there is a private right of action or a citizen suit provision in the statute. *See* Matthew C. Stephenson, *Public Regulation of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91 VA. L. REV. 93, 107–08 (2005). The FDCA does not contain a private right of action. *See* Bailey v. Johnson, 48 F.3d 965, 968 (6th Cir. 1995).

33. 5 U.S.C. §§ 702, 704 (2012). The APA also contains exceptions to reviewability, explained *infra* Part I.C. *See* 5 U.S.C. § 701 (2012).

34. 5 U.S.C. § 706 (2012).

judicial review of agency action,³⁵ and one commentator has noted that our society has a “deeply ingrained commitment to the availability of judicial review as a check on administrative action.”³⁶

The APA’s judicial review provisions apply in the absence of a specific statutory judicial review provision, which many statutes contain. Statutory judicial review provisions may designate which level of court should hear the claim, specify whether administrative exhaustion is necessary, or prescribe alternative methods of relief.³⁷ Such provisions may also contain standards of review that differ from those of the APA. For example, the Occupational Safety and Health Act of 1970 provides for judicial review of standards issued by the Occupational Safety and Health Administration (OSHA), and it directs that “[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.”³⁸

Other statutes contain judicial review provisions as well, although some of these mirror the APA’s language. For example, the CAA provides that a court may reverse an agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”³⁹ The FDCA “contains no single, overarching provision governing judicial review. Instead, discrete agency actions are subject to specialized review provisions,” which prescribe in which court (district or circuit court) appeals from Agency action will be heard.⁴⁰

C. The Judicial Review of Agency Inaction

As one commentator noted, “[f]rom a cursory reading of the APA’s statutory text, it is not obvious that the APA would set a higher standard for judicial review of agency inaction than for review of agency action.”⁴¹ Indeed, the definition of “agency action” in the APA includes the “failure to act,”⁴² and the Act’s judicial review provision allows courts to “compel agency action unlawfully withheld or unreasonably delayed,”⁴³ in addition to reviewing agency action. Action and inaction are reviewed differently, however.

There are various types of agency inaction, and some are less susceptible to judicial review than others. “The notion of agency inaction might encompass any

35. See *Abbott Labs. v. Gardner*, 387 U.S. 136, 140–41 (1967), *partially abrogated by* *Califano v. Sanders*, 430 U.S. 99 (1977).

36. Ronald M. Levin, *Understanding Unreviewability in Administrative Law*, 74 MINN. L. REV. 689, 702 (1990). In *The Puzzling Presumption of Reviewability*, Bagley questions this commitment. See Bagley, *supra* note 13.

37. See, e.g., 29 U.S.C. § 660(a) (2012) (provision of the Occupational Safety and Health Act providing for judicial review in the “court of appeals for the circuit in which the violation is alleged to have occurred or where the employer has its principal office, or in the Court of Appeals for the District of Columbia Circuit”).

38. *Id.* § 655(f).

39. 42 U.S.C. § 7607(d)(9)(A) (2012).

40. *In re Natural Res. Def. Council*, 645 F.3d 400, 404 (D.C. Cir. 2011) (citing *Cutler v. Hayes*, 818 F.2d 879, 887 (D.C. Cir. 1987)).

41. Eric Biber, *The Importance of Resource Allocation in Administrative Law*, 60 ADMIN. L. REV. 1, 8 (2008).

42. 5 U.S.C. § 551(13) (2012).

43. *Id.* § 706(1).

instance in which an agency fails to take desired or desirable action.”⁴⁴ An agency may choose not to prosecute an alleged violator, may deny a citizen petition to initiate rulemaking,⁴⁵ may fail to respond to a citizen petition calling for action,⁴⁶ or may fail to comply with a specific statutory mandate or deadline.⁴⁷ Each of these decisions not to act correlates differently with agency discretion and the extent of judicial review. Courts see the former as almost entirely discretionary and thus presumptively unreviewable, while the failure to respond to a mandate or meet a deadline is a failure to fulfill a nondiscretionary duty, which is more susceptible to judicial review. The courts treat each type of inaction along this spectrum with varying levels of deference, and I address each below.

First, as noted, agency decisions not to prosecute specific violators or to take enforcement action against specific parties are treated as presumptively unreviewable.⁴⁸ The APA contains two exceptions to the reviewability of agency action which exclude agency action from judicial review if “(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law.”⁴⁹ In *Heckler v. Chaney*, a 1985 Supreme Court case involving a challenge by death row inmates to FDA’s decision not to prohibit the use of certain drugs to administer the death penalty, the Court held that section 701(a)(2) of the APA immunized “an agency’s decision not to take enforcement action” from judicial review.⁵⁰

In *Heckler*, the Court explained that such actions were unsuitable for judicial review for several reasons, including the following:

First, an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency’s overall policies, and, indeed, whether the agency has enough resources to undertake the action at all.⁵¹

44. Bressman, *supra* note 9, at 1664.

45. *See Farmworker Justice Fund, Inc. v. Brock*, 811 F.2d 613 (D.C. Cir.), *vacated as moot*, 817 F.2d 890 (D.C. Cir. 1987).

46. *See Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127 (S.D.N.Y. 2012) (plaintiffs filed suit against FDA seeking to compel responses to citizen petitions filed years earlier).

47. *See, e.g., Scott v. City of Hammond, Ind.*, 741 F.2d 992, 996 (7th Cir. 1984) (citizen suit brought against EPA for failing to promulgate waterway pollutant standards as required by statute); *Sierra Club v. EPA*, 850 F. Supp. 2d 300, 304 (D.D.C. 2012) (suit brought against EPA for failing to meet statutory deadline to promulgate certain emissions standards).

48. *Heckler v. Chaney*, 470 U.S. 821, 832 (1985).

49. 5 U.S.C. § 701(a) (2012).

50. *Heckler*, 470 U.S. at 832.

51. *Id.* at 831.

Although courts have construed section 701(a)(2) narrowly,⁵² agency decisions not to take enforcement actions against violators remain unreviewable.⁵³ On the other hand, judicial review is generally available for agency noncompliance with nondiscretionary duties. For example, the Food Safety and Modernization Act of 2010 set mandatory deadlines for FDA to accomplish certain responsibilities, including promulgating several food safety regulations.⁵⁴ FDA missed many of these deadlines, and two consumer advocacy groups, the Center for Food Safety and the Center for Environmental Health, sued FDA under section 702 of the APA to force compliance.⁵⁵ Section 702 provides that “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof,” and the APA’s definition of “agency action,” includes the failure to act.⁵⁶ Plaintiffs argued that FDA had unreasonably delayed action by not promulgating the required regulations and the court should therefore compel action.⁵⁷

The district court agreed, explaining that courts can compel “discrete agency action” under section 706(1) of the APA when it is “demanded by law.”⁵⁸ FDA argued that the reasonableness of its administrative timeline was the key factor in determining whether there had been “unreasonable delay” under section 706(1), and that the court should evaluate its timetable under the “TRAC test,” a six-factor balancing test set out by the D.C. Circuit in 1984.⁵⁹ The court, however, held that noncompliance with the

52. See Rachel E. Barkow, *The Ascent of the Administrative State and the Demise of Mercy*, 121 HARV. L. REV. 1332, 1338–39 & n.23 (2008); see also *Kenney v. Glickman*, 96 F.3d 1118 (8th Cir. 1996) (finding that the Secretary of Agriculture’s decision to inspect meat and poultry products differently was not a presumptively unreviewable enforcement action under *Heckler*); *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) (finding that a decision not to ban interstate sales of raw milk was not an enforcement decision committed to agency discretion).

53. See *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993) (“Over the years, we have read § 701(a)(2) to preclude judicial review of certain categories of administrative decisions that courts traditionally have regarded as ‘committed to agency discretion.’ . . . In *Heckler* itself, we held an agency’s decision not to institute enforcement proceedings to be presumptively unreviewable under § 701(a)(2).” (citations omitted)); Bressman, *supra* note 9, at 1669.

54. See, e.g., 21 U.S.C. § 350g(n)(1)(A) (2012) (“Not later than 18 months after January 4, 2011, the Secretary shall promulgate regulations—(A) to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under this section . . .”).

55. Complaint for Declaratory and Injunctive Relief, *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. 2013) (No. C 12-4529 PJH), available at http://www.centerforfoodsafety.org/files/2012-08-29-fsma-complaint-filed_78450.pdf.

56. 5 U.S.C. §§ 551(13), 702 (2012).

57. See 5 U.S.C. § 706(1) (2012); Complaint for Declaratory and Injunctive Relief, *supra* note 55.

58. *Ctr. for Food Safety*, 954 F. Supp. 2d at 968.

59. *Id.* at 969–70 & n.3 (“Under the TRAC test, the court should consider (1) whether the time agencies take to make decisions is governed by a ‘rule of reason’ that governs the analysis; (2) whether Congress provided a timetable in the statute; (3) whether the delays have more or less of an impact on human health and welfare (as opposed to simply having an impact in the area of economic regulation); (4) whether expediting agency action would have an effect on agency actions of a higher or competing priority; (5) the nature and extent of the interests

mandatory deadlines set by the statute required a finding of unreasonable delay and granted declaratory relief.⁶⁰ After the parties were unable to come to an agreed-upon timetable, the court granted injunctive relief a few months later.⁶¹

In short, an agency's noncompliance with a mandatory statutory duty is reviewable and remediable.⁶² This is in marked contrast to the unreviewability of an agency's failure to take enforcement action. Between these two poles, however, is the judicial review of an agency's denial of a petition for rulemaking.

In this situation, the agency is being urged to take action, and it refuses. For example, in 2010, the Corn Refiners Association petitioned FDA "to authorize 'corn sugar' as an alternate common or usual name for high fructose corn syrup."⁶³ FDA denied the petition.⁶⁴ And in 1999, nineteen organizations filed a rulemaking petition with EPA requesting that EPA "regulate 'greenhouse gas emissions from new motor vehicles under § 202 of the Clean Air Act.'"⁶⁵ The denial of this petition was the basis for *Massachusetts v. EPA*,⁶⁶ a case with implications for both the regulation of greenhouse gases and the judicial review of petitions for rulemaking.

In *Massachusetts v. EPA*, the Court clarified that judicial review of the denial of rulemaking petitions is permitted, but highly deferential to the agency's decision, explaining that "[t]here are key differences between a denial of a petition for rulemaking and an agency's decision not to initiate an enforcement action" and that "[r]efusals to promulgate rules are thus susceptible to judicial review, though such review is 'extremely limited' and 'highly deferential.'"⁶⁷

Although a court's review of an agency's decision on a rulemaking petition is highly deferential, its ability to assess the appropriateness of that decision is modulated by the statutory requirements of the provision under which the petition was made. Specific requirements create tangible markers to assess whether the agency has adhered to its duty. For example, under the ESA, any interested person

prejudiced by the delay; and (6) whether there is any impropriety 'lurking behind agency lassitude' (although such a finding is not essential to a determination that agency action has been unreasonably delayed)." (citing *Telecomms. Res. & Action Ctr. v. FCC*, 750 F.2d 78, 80 (D.C. Cir. 1984)).

60. *Id.* at 970.

61. *Ctr. for Food Safety v. Hamburg*, No. C 12-4529 PJH (N.D. Cal. June 21, 2013). Pursuant to a settlement extending and staggering these deadlines, FDA dropped its appeal to the Ninth Circuit in February 2014. See Lydia Zuraw, *FSMA Gets New Deadlines for Final Rules*, FOOD SAFETY NEWS (Feb. 21, 2014), <http://www.foodsafetynews.com/2014/02/fsma-gets-new-deadlines-for-final-rules/#.UwgdAKCRjww>.

62. See *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1177 n.11 (9th Cir. 2002) (providing that if Congress provides a specific deadline, "no balancing of factors is required or permitted").

63. Letter from Michael M. Landa, Director, Ctr. for Food Safety & Applied Nutrition, FDA, to Audra Erickson, President, Corn Refiners Ass'n (May 30, 2012) (response to petition from Corn Refiners Association to authorize "corn sugar" as an alternate common or usual name for high fructose corn syrup (HFCS)), available at <http://www.fda.gov/aboutFDA/CentersOffices/OfficeofFood/CFSAN/CFSANFOIAElectronicReadingRoom/ucm305226.htm>.

64. *Id.*

65. *Massachusetts v. EPA*, 549 U.S. 497, 510 (2007).

66. *Id.*

67. *Id.* at 527–28 (citations omitted).

can petition the relevant secretary to add a species to the endangered or threatened lists under the statute.⁶⁸ After receiving the petition, the relevant agency must respond “[t]o the maximum extent practicable, within 90 days,” with a preliminary finding about whether further action is warranted.⁶⁹ If further action is necessary, the agency must make findings regarding the petition within twelve months.⁷⁰ A missed deadline provides the opportunity for an interested party to sue for action, and provides a court with delineated criteria on which to order action, even if such action is procedural.⁷¹

Certain provisions of the FDCA work similarly. For example, in 1958, the Food Additives Amendment to the FDCA put into place a process whereby new ingredients had to be tested and approved before they could be used.⁷² Any person may file a petition with the Secretary of Health and Human Services to regulate the safe use of a food additive.⁷³ The relevant statute prescribes specific information that the petition must contain, as well as specific deadlines for a response.⁷⁴ If a party is seeking the repeal or amendment of a food additive regulation, it can file a food additive petition under 21 C.F.R. § 171.1. The petitioner is required to provide information on the changes, and FDA must follow the statutory deadlines for responding to a new additive petition.⁷⁵

Parties can also petition for a change to an existing food additive regulation using the citizen petition provision of the FDCA, 21 C.F.R. § 10.30.⁷⁶ This route entails “far less supporting data than the food additive petition, and the petitioner does not bear the burden of establishing that an additive is safe or unsafe.”⁷⁷ FDA is required to respond to a citizen petition within 180 days, but may file a “tentative response” explaining why it could not reach a decision.⁷⁸

There is also a specific petition provision within the Medical Device Amendments of 1976. Pursuant to 21 U.S.C. § 360g, “any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order.”⁷⁹ The provision includes a detailed list of the actions that may be challenged under this provision, including the denial of a request for reclassification of a device and the issuance of a

68. 16 U.S.C. § 1533(b)(3)(A) (2012). The ESA is administered by both the Department of the Interior and the Department of Commerce, and the relevant secretary depends on the species to be protected.

69. *Id.*

70. *Id.* § 1533(b)(3)(B).

71. *See, e.g.,* *Or. Natural Res. Council, Inc. v. Kantor*, 99 F.3d 334 (9th Cir. 1996) (petitioner sued Secretary of Commerce for not responding to its petition to list coho salmon as an endangered or protected species in certain states).

72. The definition of “food additive” excludes many categories of ingredients, including ingredients approved before 1958. 21 U.S.C. § 321(s) (2012).

73. *Id.* § 348(b)(1).

74. *Id.* § 348(b)(2), (c)(2).

75. 21 C.F.R. §§ 171.1(c), 171.100 (2013).

76. *See supra* Part I.A.

77. *In re* Natural Res. Def. Council, 645 F.3d 400, 403 (D.C. Cir. 2011).

78. *See supra* Part I.A.

79. 21 U.S.C. § 360g(a) (2012).

regulation banning a device.⁸⁰ If, however, a petitioner's claim does not fall into one of the categories outlined in § 360g, she must file her claim in district court.⁸¹

District courts may require petitioners challenging FDA inaction that does not fall within the requirements of a specific petition provision of the FDCA to first utilize 21 C.F.R. § 10.30, the citizen petition provision.⁸² Courts, however, can waive this requirement because “the citizen petition procedure is a regulatory rather than a statutory creation.” In fact, courts have specifically waived this nonstatutory exhaustion requirement because of FDA delay in responding substantively to citizen petitions.⁸³

The availability of a statutory specific provision can provide petitioners and courts with specific benchmarks to gauge an agency's response or a specific route to judicial review. When a challenged action or inaction falls outside of the bounds of these specific provisions, petitioners must use the APA's unreasonable delay provision or a general citizen petition provision to bring suit, which provide courts with less concrete markers to review an agency's performance.

II. WHEN PRIVATE ENFORCEMENT IS NOT ENOUGH

This Part turns to cases where private enforcement has failed to effectively oversee FDA, an agency with vital importance to health and safety. In each of these cases, a private party sought action from FDA and moved, either by petitioning the Agency or by bringing suit, to compel action. And in each of these cases, the mechanism of private enforcement has not been effective in countering intolerable delay or arbitrary decision making. As noted above, this Article does not characterize private enforcement as having failed because the private party has not achieved the particular outcome sought. In fact, in several of these cases the particular outcome desired *has* been achieved, but after too much time has passed. Private party oversight is simply not effectively overcoming agency inertia. The Article then compares these episodes with areas where private enforcement has been extremely effective in compelling agency action.

80. *Id.* § 360g(a)(3), (5).

81. *See Moms Against Mercury v. FDA*, 483 F.3d 824, 827 (D.C. Cir. 2007) (“If judicial review of an FDA action or inaction is not provided for in the Act, challenges to such actions may be brought only in the district court.”). This case settled a year after petitioners were denied relief in the court of appeals when FDA acceded to their request and agreed to classify mercury fillings.

82. *See, e.g., Cody Labs., Inc. v. Sebelius*, 446 F. App'x 964, 970 (10th Cir. 2011) (“Cody argues that it will be unduly prejudiced if forced to exhaust because the FDA is sometimes dilatory in substantively responding to citizen petitions. . . . [But] [i]t is clear that Cody would not be unduly—or even significantly—prejudiced by following FDA regulations and filing a citizen petition.”).

83. *See, e.g., Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 30–31 (D.D.C. 1997) (“The FDA regulations require the agency to respond to a Citizen Petition within 180 days of its receipt, *see* 21 C.F.R. § 10.30(e)(2), in Bracco's case, by the end of June 1997. The Court was advised during oral argument, however, that a ‘response’ might consist only of a letter advising a petitioner that the agency needs more time to consider the matter. Forcing plaintiffs to await the FDA's response to their Citizen Petitions would permit the FDA to continue the disparate treatment of plaintiffs' products that is causing them to spend millions of dollars in testing fees and costs.”).

A. Antibiotics in Animal Feed

In 2011, after decades of inertia and delay by FDA, five consumer advocacy groups filed suit against FDA for failing to withdraw the approval of certain antibiotics used in animal feed for the purpose of increasing food production.⁸⁴

FDA approved new animal drug applications for penicillin and two kinds of tetracycline in the 1950s, after it was discovered that certain antibiotics improved food production when they were fed to animals at levels below those necessary to cure disease (subtherapeutic levels).⁸⁵ In the mid-1960s, FDA began to consider whether the use of antibiotics in animals at subtherapeutic levels might lead to antibiotic resistance in organisms that cause human disease; and, in 1970, the Agency convened a task force consisting of scientists from FDA, the National Institutes of Health, the U.S. Department of Agriculture (USDA), the Centers for Disease Control, and representatives from academia and industry to study this and related issues.⁸⁶

In 1972, the FDA task force issued its report.⁸⁷ It found that antibiotic-resistance prevalence has increased in humans; that the use of antibiotics, especially at subtherapeutic levels, leads to antibiotic-resistant organisms; that animals receiving antibiotics in feed may serve as reservoirs of antibiotic-resistant pathogens that can produce human infections; and that antibiotic-resistant organisms have been found on meat and meat products.⁸⁸

The task force recommended that antibiotics used as human medicine, including penicillin and tetracyclines, be prohibited from use in animal feed for subtherapeutic purposes.⁸⁹ In 1973, FDA issued a regulation “propos[ing] to revoke currently approved subtherapeutic (increased rate of gain, disease prevention[,] etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975,” and allowing for the submission of material by industry supporting the continued approval of these drugs along a specified timeline.⁹⁰

84. *Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127 (S.D.N.Y. 2012).

85. *Id.* at 131; Eugene Lambert & Jeannie Perron, *Veterinary Food and Drugs*, in *FOOD AND DRUG LAW AND REGULATION* 247, 269 (David G. Adams et al. eds., 2d ed. 2011).

86. *Natural Res. Def. Council*, 884 F. Supp. 2d at 129. The other issues include whether antibiotic-resistant strains of organisms, if they were created by the use of subtherapeutic doses of antibiotics in animals, could be transferred from animals to humans, and whether a resistance “carrier” would affect other antibiotics besides those specifically used in animal feed. Lambert and Perron comment that these questions are “perhaps impossible to answer.” Lambert & Perron, *supra* note 85, at 274.

87. *Antibiotic and Sulfonamide Drugs in Animal Feeds*, 37 Fed. Reg. 2444–45 (proposed Feb. 1, 1972) (to be codified at 21 C.F.R. pt. 135).

88. *Id.*

89. *Id.* At the same time, the Swann Committee in Great Britain came to similar conclusions, and restrictions were placed on antibiotic use in animal feed in England. Lambert & Perron, *supra* note 85, at 274. The Task Force noted that “[a]ntimicrobial agents used in human clinical medicine” that met certain safety guidelines in regard to growth promotion and subtherapeutic use could be used, but proposed shifting the burden to manufacturers to show the drugs’ safety and efficacy. *Antibiotic and Sulfonamide Drugs in Animal Feeds*, 37 Fed. Reg. at 2444–45.

90. 21 C.F.R. § 558.15 (2013).

The revocation did not take place, and in 1977, a subcommittee of FDA's National Advisory Food and Drug Committee recommended the withdrawal of approval for the subtherapeutic use of penicillin and that restrictions be made on the subtherapeutic use of tetracyclines in animal feed.⁹¹ The Director of the Bureau of Veterinary Medicine, a subdivision of FDA, issued notices of an opportunity for a hearing (NOOHs) on the withdrawal of approvals for the subtherapeutic use of penicillin and certain tetracyclines.⁹²

A number of drug firms and agricultural groups requested hearings, and FDA issued a statement that "a notice of hearing will be published in the [Federal Register] as soon as practicable."⁹³ Subsequently, Congress made several statements requesting that FDA wait for more information before withdrawing these antibiotics,⁹⁴ and FDA continued to research the risk of using subtherapeutic levels of antibiotics in animal feed.⁹⁵ The hearings were not held.

In 1983, FDA denied several petitions by industry requesting withdrawal of the 1977 NOOHs proposing the withdrawal of approval for antibiotics in animal feed, but also began allowing the approval of new animal drug applications for the subtherapeutic use of penicillin and tetracyclines in animal feed.⁹⁶ FDA concluded that new approvals should not be denied while its research was ongoing.⁹⁷

Fast forward two decades to when FDA published a notice proposing to rescind the sections in the Code of Federal Regulations from 1973 calling for the withdrawal of approval for the subtherapeutic use of penicillin and tetracyclines in animal feed.⁹⁸

91. Penicillin-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 43,772 (Aug. 30, 1977); Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56,264 (Oct. 21, 1977).

92. *Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127, 134–36 (S.D.N.Y. 2012).

93. Penicillin and Tetracycline in Animal Feeds, Notice of Hearing, 43 Fed. Reg. 53,827–28 (Nov. 17, 1978).

94. The nature of these requests is unclear. The federal district court opinion states that "none of these recommendations was adopted by the full House or Senate, and none was passed as law," *Natural Res. Def. Council*, 884 F. Supp. 2d at 135, implying that FDA should have acted anyway, but a notice in the Federal Register states that the House Appropriations Committee has "mandated that FDA withhold any restriction on the use of penicillin and the tetracyclines (chlortetracycline and oxytetracycline) used in animal feeds until the National Academy of Sciences has studied the matter," Committee To Study the Human–Heath [sic] Effects of Subtherapeutic Antibiotic Use in Animal Feeds; Public Meeting, 44 Fed. Reg. 36,479 (June 22, 1979). Even if the congressional statements were binding, the information requested by Congress was not two decades in coming. FDA could have moved to acquire the necessary studies and to hold the hearings during the early 1980s.

95. *Natural Res. Def. Council*, 884 F. Supp. 2d at 136.

96. Drugs for Human Use; Drug Efficacy Study Implementation; Certain Anticholinergic Drugs Containing Tridihexethyl Chloride; Withdrawal of Approval, 48 Fed. Reg. 4554 (Feb. 1, 1983); New Animal Drugs for Use in Animal Feeds; Penicillin and Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 48 Fed. Reg. 4490 (proposed Feb. 1, 1983) (to be codified at 21 C.F.R. pt. 558).

97. New Animal Drugs for Use in Animal Feeds; Penicillin and Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 48 Fed. Reg. at 4490.

98. New Animal Drugs; Removal of Obsolete and Redundant Regulations, 68 Fed. Reg. 47,272 (proposed Aug. 8, 2003) (to be codified at 21 C.F.R. pts. 510, 558).

The notice explained that these sections should be removed because they “long ago fulfilled [their] stated purpose of requiring sponsors to submit data regarding the subtherapeutic use of antibiotics on the market at the time of its publication,” and because “over time FDA developed a new strategy and concept to deal with the issue of antimicrobial resistance.”⁹⁹

This 2003 notice is striking in two regards. First is its far-fetched justification for proposing the withdrawal of the sections calling for the withdrawal of approval for antibiotics in animal feed.¹⁰⁰ It is clear from the face of the original call for hearings that its purpose was not information gathering, but rather the withdrawal of approval for antibiotics. The first sentence of the notice FDA proposed to withdraw is,

The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention[,] etc.) uses in animal feed of antibiotic and sulfonamide drugs . . . unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration.¹⁰¹

This leads to the second striking aspect of the notice, which is the description of the history of the “antimicrobial resistance issue” included by FDA.¹⁰² This history shows a consistent account of numerous studies, conducted over decades by various national and international bodies, finding that the subtherapeutic use of antibiotics in animal feed is dangerous to human health.¹⁰³

In 2010, FDA released a draft guidance titled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” recommending that antibiotics used for human medicine not be used for growth promotion in animals¹⁰⁴—the same recommendation FDA had made four decades earlier.

In May 2011, the Natural Resources Defense Council (NRDC), the Center for Science in the Public Interest, the Food Animal Concerns Trust, Public Citizen, and the Union of Concerned Scientists, Inc. brought suit against FDA, alleging that FDA had “withheld agency action,” and had therefore violated the FDCA and the APA.¹⁰⁵ Plaintiffs alleged that FDA had violated section 512 of the FDCA,¹⁰⁶ which provides for the withdrawal of an approved animal drug if the drug is found to be unsafe, and that the court should “compel agency action unlawfully withheld or unreasonably delayed” under the authority granted by APA section 706(1).¹⁰⁷ Furthermore, plaintiffs argued that the FDCA required the Agency to withdraw approval of penicillin and tetracyclines for subtherapeutic use in animal feed once it was found

99. *Id.* at 47,274.

100. *See id.*

101. 21 C.F.R. § 558.15 (2013).

102. New Animal Drugs; Removal of Obsolete and Redundant Regulations, 68 Fed. Reg. 47,272.

103. *Id.*

104. Natural Res. Def. Council, Inc. v. FDA, 884 F. Supp. 2d 127, 136 (S.D.N.Y. 2012).

105. *Id.* at 130.

106. 21 U.S.C. § 360b(e)(1) (2012).

107. 5 U.S.C. § 706(1) (2012).

that they had not been shown to be safe for humans, unless the drug sponsors could demonstrate the drugs' safety.¹⁰⁸

In their complaint, plaintiffs also moved to compel responses to two citizen petitions they had filed in 1999 and 2005 requesting withdrawal of approval for these antibiotic uses, to which the Agency had never replied.¹⁰⁹ During the suit, FDA issued denials to these petitions and plaintiffs amended their complaint to argue that the denials were arbitrary and capricious.¹¹⁰

In response to the complaint, FDA argued that the FDCA's provision on withdrawing approval for animal drugs¹¹¹ only required the Agency to withdraw approval of an unsafe animal drug if the Secretary made a finding after a formal hearing.¹¹² FDA did not, of course, hold the hearings for which it had given notice and did not, therefore, make those findings. It argued that it was not required to do either.¹¹³

The district court disagreed with FDA's interpretation of its statute, finding that the "plain meaning of § 360b(e)(1) requires the Secretary to issue notice and an opportunity for a hearing whenever he finds that a new animal drug is not shown to be safe."¹¹⁴ The district court granted summary judgment for plaintiffs in March 2012, finding that FDA must "re-issue a notice of the proposed withdrawals (which may be updated) and provide an opportunity for a hearing to the relevant drug

108. *Natural Res. Def. Council*, 884 F. Supp. 2d at 140–41.

109. These petitions were most likely filed under the general citizen petition provision, 21 C.F.R. § 10.30 (2014), as 21 U.S.C. § 360b (2012), the statutory section regarding new animal drugs, does not contain a petition provision for the withdrawal of animal drugs.

110. *Natural Res. Def. Council*, 884 F. Supp. 2d at 137 n.6; *see* 5 U.S.C. § 706(2) (2012).

111. In relevant part, the provision reads:

The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) of this section with respect to any new animal drug if the Secretary finds—

(A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved or the condition of use authorized under subsection (a)(4)(A) of this section

21 U.S.C. § 360b(e)(1).

112. *Natural Res. Def. Council*, 884 F. Supp. 2d at 140–41. An article written by Lisa Heinzerling discusses FDA's insistence on the need to hold a formal hearing, which she argues is unnecessary and anachronistic, and the Agency dysfunction that led to this position. Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VT. L. REV. 1017 (2013).

113. *Natural Res. Def. Council*, 884 F. Supp. 2d at 141.

114. *Id.* at 143. When a court reviews an agency's interpretation of a statute, it "must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984). If the court finds the language of the statute unambiguous, its inquiry stops there. If the intent of Congress is not clear, the "court will defer to an agency's interpretation of the statute, so long as it is 'reasonable.'" *Natural Res. Def. Council*, 884 F. Supp. 2d at 141 (citing *Chevron*, 467 U.S. at 843–44). Here, the court determined that the plain language of the statute was unambiguous, but even if it was not, FDA's own regulations contradicted the stance that they were taking in the immediate litigation. *Id.* at 143–44.

sponsors If, at the hearing, the drug sponsors fail to show that the use of the drugs is safe, the Commissioner must issue a withdrawal order.”¹¹⁵

As to plaintiffs’ claims that FDA’s denials of their 1999 and 2005 citizen petitions were arbitrary and capricious, the district court agreed in June 2012, granting plaintiffs summary judgment on this claim as well. The court wrote,

[T]he Court finds the Agency’s denial of the Petitions to be arbitrary and capricious. For over thirty years, the Agency has been confronted with evidence of the human health risks associated with the widespread subtherapeutic use of antibiotics in food-producing animals, and, despite a statutory mandate to ensure the safety of animal drugs, the Agency has done shockingly little to address these risks. Now, in responding to this litigation and two Petitions that have been pending for years, requesting that the Agency comply with its statutory mandate, the Agency has refused to make any findings and instead intends to adopt a voluntary program that is outside the statutory regulatory scheme.¹¹⁶

The case was appealed,¹¹⁷ and, in the interim, FDA announced a new voluntary plan to reduce the use of nontherapeutic antibiotics in animal feed.¹¹⁸ On July 24, 2014, the Second Circuit overturned the district court’s decision. The Second Circuit was persuaded by FDA’s reasoning, holding that plaintiffs’ reasoning would have required FDA to make two findings, while the statute only called for one. The court also found this interpretation to be consistent with the provision’s statutory context and background legal concepts.¹¹⁹

On September 18, 2014, President Barack Obama released an executive order titled “Combating Antibiotic-Resistant Bacteria.”¹²⁰ The accompanying national strategy “recognizes that resistance can arise in humans, animals, and the environment.”¹²¹ One of its objectives is to “[e]liminate the use of medically

115. *Natural Res. Def. Council*, 884 F. Supp. 2d at 151. FDA had withdrawn the NOOHs issued in 1977 for the withdrawal of the approval for antibiotics during the suit, arguing that the NOOHs were obsolete. *Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed*, 76 Fed. Reg. 79,697 (Dec. 22, 2011).

116. *Natural Res. Def. Council, Inc. v. FDA*, 872 F. Supp. 2d 318, 341 (S.D.N.Y. 2012), *rev’d*, 760 F.3d 151 (2d Cir. 2014).

117. *Natural Res. Def. Council v. FDA*, 884 F. Supp. 2d 108 (S.D.N.Y. 2012).

118. *See Phasing Out Certain Antibiotic Use in Farm Animals*, FDA (Dec. 11, 2013), <http://www.fda.gov/forconsumers/consumerupdates/ucm378100.htm>.

119. *Natural Res. Def. Council, Inc. v. FDA*, 760 F.3d 151 (2d Cir. 2014). The dissent points out that any reading of the provision in its larger context would show that once FDA had made a preliminary finding that the drugs were unsafe, it was required to hold hearings on their withdrawal. *Id.* at 177 (Katzmann, J., dissenting). The plaintiffs’ argument was the better one because the primary purpose of the FDCA is to protect the public, because the statute’s provisions regarding human drugs have always been construed to assume that withdrawal hearings would follow a preliminary finding, and because administrative practice comports with this sequence of events. *Id.* at 176–79.

120. Executive Order No. 13,676, 79 Fed. Reg. 56,931 (Sept. 18, 2014).

121. THE WHITE HOUSE, NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA 5 (2014), *available at* http://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf.

important antibiotics for growth promotion in animals.”¹²² However, the strategy also relies on FDA’s voluntary programs to accomplish this in the United States.¹²³

B. Making Emergency Contraception Available to All Women over the Counter

The decade-long saga concerning the provision of emergency contraception to women without a prescription, which included a public, and very controversial, dispute between the secretaries of the Department of Health and Human Services (HHS) and FDA,¹²⁴ seems finally to be drawing to a close. In April 2013, a federal judge ordered FDA to “make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days,”¹²⁵ and in June 2013, the government indicated to the court that it would comply with this order and would not appeal.¹²⁶ On June 20, 2013, FDA approved the OTC sale of emergency contraception with no age restrictions.¹²⁷

Plan B One-Step is an emergency contraceptive that can be taken within seventy-two hours of sexual intercourse to prevent pregnancy.¹²⁸ In 1999, FDA approved a new drug application (NDA) for Plan B, which became available by prescription.¹²⁹ Before a new drug can be sold in the United States, the drug’s sponsor must submit an NDA to the Secretary of HHS.¹³⁰ Each NDA is based on extensive clinical testing and must demonstrate the new drug’s safety and effectiveness.¹³¹ If a

122. *Id.* at 8.

123. *Id.*

124. The dispute garnered much media attention and speculation regarding the political nature of the HHS Secretary’s action. See Gardiner Harris, *F.D.A. Overruled on Availability of After-Sex Pill*, N.Y. TIMES, Dec. 8, 2011, at A1 (“For the first time ever, the Health and Human Services secretary publicly overruled the Food and Drug Administration The decision avoided what could have been a bruising political battle over parental control and contraception during a presidential election season.”); Rob Stein, *Obama Administration Refuses To Relax Plan B Restrictions*, WASH. POST, Dec. 8, 2011, at A1; Matthew Herper, *Did the Obama Administration Throw the FDA Under the Bus?*, FORBES (Dec. 9, 2011), <http://www.forbes.com/sites/matthewherper/2011/12/09/did-the-obama-administration-throw-the-fda-under-the-bus/>. Incidentally, HHS previously overruled FDA in 1985. See *infra* Part III.C.

125. *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 197 (E.D.N.Y. 2013).

126. *Tummino v. Hamburg*, No. 12–CV–763 (ERK)(VVP), 2013 WL 2631163, at *2 (E.D.N.Y. June 12, 2013).

127. Press Release, FDA, FDA Approves Plan B One-Step Emergency Contraceptive for Use Without a Prescription for All Women of Child-Bearing Potential (June 20, 2013), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082.htm>. In March 2014, FDA expanded access to emergency contraception over the counter with no age restrictions to generic contraceptive pills. Julie Rovner, *FDA To Increase Access to Generic Morning-After Pills*, NPR (Mar. 2, 2014), <http://www.npr.org/blogs/health/2014/03/02/284397995/fda-to-increase-access-to-generic-morning-after-pills>.

128. Plan B works by preventing eggs from becoming fertilized, as opposed to RU-486, which acts on implanted embryos. See Pam Belluck, *No Abortion Role Seen for Morning-After Pill*, N.Y. TIMES, June 6, 2012, at A1.

129. *Tummino v. Torti*, 603 F. Supp. 2d 519, 525 (E.D.N.Y. 2009).

130. 21 U.S.C. § 355 (2012).

131. See 21 C.F.R. § 314.50 (2013).

drug “is not safe for use except under the supervision of a practitioner licensed by law to administer such drug,” it must be categorized as a prescription drug.¹³²

It is not uncommon for a new drug to be approved as a prescription drug and then be considered for a switch to OTC status.¹³³ A drug’s sponsor can request that a drug be switched from prescription to OTC status by supplementing its NDA, or FDA can promulgate a rule changing the drug’s status.¹³⁴ Such a rulemaking can be initiated by a citizen petition or by FDA itself.¹³⁵ A switch to nonprescription status is based on FDA’s finding that “the drug is safe and effective for use in self-medication as directed in proposed labeling.”¹³⁶

In early 2001, sixty-six petitioners filed a citizen petition with FDA requesting that FDA switch all emergency contraceptives from prescription to OTC status. FDA filed a “tentative response” to this petition pursuant to 21 C.F.R. § 10.30(e),¹³⁷ but issued no final ruling on the petition for five more years, when the Agency denied the petition.¹³⁸

Between 2001 and 2006, however, FDA had been working with the sponsor of the Plan B NDA on its submission of a supplemental new drug application (SNDA), requesting that Plan B be switched to OTC status.¹³⁹

This application was submitted in 2003, and FDA denied it in 2004.¹⁴⁰ The sponsor then submitted an amended application, requesting Plan B be made available OTC to women over the age of sixteen,¹⁴¹ which was amended again in 2006 to suggest OTC availability of Plan B to women over eighteen.¹⁴² This application was approved in August 2006.¹⁴³

In 2005, many of the original petitioners brought an action in district court seeking to compel FDA to respond to their citizen petition.¹⁴⁴ FDA denied the petition in June 2006, and the plaintiffs amended their suit to challenge FDA’s denial of their petition as arbitrary and capricious under the APA.¹⁴⁵ The basis for this claim was the allegation that “FDA’s decisions were made in bad faith because they were improperly influenced by political considerations wholly outside the scope of the FDA’s statutory authority.”¹⁴⁶

132. 21 U.S.C. § 353(b)(1)(A) (2012).

133. *Tummino*, 603 F. Supp. 2d at 525.

134. 21 C.F.R. § 310.200(b) (2013).

135. *Id.*

136. *Id.*

137. Recall that a “tentative response” only means that FDA must give a reason for its failure to respond. This reason may be “the existence of other agency priorities,” among other things. 21 C.F.R. § 10.30(e)(2)(iii) (2012).

138. *Tummino*, 603 F. Supp. 2d at 526.

139. *Id.* at 526–36.

140. *Id.* at 527–32.

141. *Id.* at 533.

142. *Id.* at 536.

143. *Id.*

144. The court noted that petitioners’ challenges to denials of citizen petitions are directly reviewable in district court because they were not covered under a specific FDCA petition provision providing for court of appeals jurisdiction. *Id.* at 539.

145. *Id.* at 538. Plaintiffs also filed constitutional challenges to the Agency’s denial of their petition.

146. *Id.*

In March 2009, the court agreed with plaintiffs, finding that plaintiffs “presented un rebutted evidence of the FDA’s lack of good faith regarding its decisions on the Plan B [OTC] switch applications.”¹⁴⁷ The court remanded the case and directed FDA to reconsider its decisions regarding the switch of Plan B to OTC use.¹⁴⁸

The court’s conclusion that FDA had not acted in good faith was based on evidence of:

- (1) repeated and unreasonable delays, pressure emanating from the White House, and the obvious connection between the confirmation process of two FDA Commissioners and the timing of the FDA’s decisions; and (2) significant departures from the FDA’s normal procedures and policies in the review of the Plan B switch applications as compared to the review of other switch applications in the past 10 years.¹⁴⁹

The evidence listed by the court to support its conclusions was extensive, and included (1) the fact that FDA’s scientific review staff and advisory committees recommended OTC availability of Plan B without age restrictions; (2) the evidence of White House pressure on FDA; (3) the arbitrary restriction of OTC availability to women over eighteen; (4) the inclusion of additional, unqualified members on an advisory committee; and (5) the refusal to extrapolate data in ways that had commonly been done in the past.¹⁵⁰

Notably, the court addressed concerns that remanding the issue to FDA would be futile. It commented that “circumstances have changed,” leading the court to believe that the Agency could be “trusted to conduct a fair assessment of the scientific evidence.”¹⁵¹

FDA, however, did nothing. In 2011, plaintiffs in the original suit sought to hold the Agency in contempt of court.¹⁵² Simultaneously, the manufacturer of Plan B submitted an SNDA to FDA for permission to market Plan B as a nonprescription drug for all ages.

147. *Id.* at 544. The court found the issue of FDA’s denial of the OTC switch applications to be “inextricably tied to its decision-making on the Citizen Petition.” *Id.* at 543.

148. The court remanded the issue of the Plan B OTC switch, but ordered FDA to allow women over the age of seventeen OTC access to Plan B under the same conditions that women over the age of eighteen were permitted access. The court found that here, “[a] remand would serve no purpose,” because

[t]he record is clear: the FDA’s justification for the denial of OTC access to Plan B for women over the age of 17—rather than 18—“runs counter to the evidence” and “is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”

Id. at 549 (citations omitted).

149. *Id.* at 544. The decision in this case provides a detailed and fascinating account of the events leading to the lawsuit, and beyond.

150. *Id.* at 545–47.

151. *Id.* at 549.

152. Reply in Support of Plaintiffs’ Motion for Civil Contempt, *Tummino v. Hamburg*, 2013 WL 865851 (E.D.N.Y. Mar. 6, 2013) (No. 05-CV-366 (ERK)(VVP)), 2011 WL 7166996.

During oral argument of the contempt action, the Commissioner of FDA issued a statement with her opinion that Plan B should be approved as an OTC medication for women of all ages.¹⁵³ Her opinion was based on research conducted by the Center for Drug Evaluation and Research, which “reviewed the totality of the data and agreed that it met the regulatory standard for a nonprescription drug and that Plan B One-Step should be approved for all females of child-bearing potential.”¹⁵⁴

The Commissioner also explained that the Secretary of HHS, who is responsible for executing the provisions of the FDCA,¹⁵⁵ had directed her to disapprove the application.¹⁵⁶ The Secretary of HHS issued her own memorandum, explaining that “the data submitted for this product do not establish that prescription dispensing requirements should be eliminated for all ages.”¹⁵⁷

In February 2012, plaintiffs to the original suit supplemented their complaint against FDA and HHS, thereby reopening the case,¹⁵⁸ and in April 2013, the judge hearing the case granted plaintiffs’ petition and ordered FDA to make Plan B available without a prescription to all ages. Explaining why he would not remand the action to the Agency to begin a rulemaking proceeding, the judge stated,

The FDA has engaged in intolerable delays in processing the petition. Indeed, it could accurately be described as an administrative agency filibuster. . . . The plaintiffs should not be forced to endure, nor should the agency’s misconduct be rewarded by, an exercise that permits the FDA to engage in further delay and obstruction.¹⁵⁹

Beyond the judge’s strong condemnation of FDA’s actions in this case, it is notable that in his decision he did not focus solely on the political ramifications of the case. Instead he noted, and emphasized, the mundane character of the nature of the case:

[T]he issue in this case involves the interpretation of a general statutory and regulatory scheme relating to the approval of drugs for over-the-counter sale. The standards are the same for aspirin and for contraceptives. . . . [T]he standard for determining whether contraceptives or any other drug should be available over-the-counter

153. *Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step*, FDA (Dec. 7, 2011), <http://www.fda.gov/NewsEvents/Newsroom/ucm282805.htm> [hereinafter *Hamburg Statement*].

154. *Id.*

155. 21 U.S.C. § 393(d)(2) (2012).

156. *Hamburg Statement*, *supra* note 153.

157. Memorandum from Kathleen Sebelius, Sec’y of Health & Human Servs., to Margaret A. Hamburg, M.D., Comm’r of Food & Drugs (Dec. 7, 2011), *available at* <http://online.wsj.com/public/resources/documents/20111207a.pdf>.

158. Rachel Slajda, *FDA Faces Renewed Battle over Plan B Age Restrictions*, LAW360 (Feb. 8, 2012, 2:50 PM), <http://www.law360.com/articles/307696/fda-faces-renewed-battle-over-plan-b-age-restrictions>; *Tummino v. Hamburg (NY)*, CENTER FOR REPROD. RTS. (Aug. 13, 2013), <http://reproductiverights.org/en/case/tummino-v-hamburg-ny>.

159. *Tummino v. Hamburg*, 936 F. Supp. 2d. 162, 198 (E.D.N.Y. 2013).

turns solely on the ability of the consumer to understand how to use the particular drug “safely and effectively.”¹⁶⁰

For this reason, the outcome of the case, according to the judge, depended on the judicial interpretation of the relevant statutory standards, which, according to the court, were clear.¹⁶¹ The case, however, took years to resolve.¹⁶²

C. A Historical Example: The Prohibition of the Interstate Sale of Raw Milk

We see that FDA can delay responding to petitions brought under the FDCA’s general petition provision and that judicial review of this delay only takes place when a petitioner sues to force action. This is not a recent phenomenon.

In 1973, pursuant to its authority to issue regulations regarding standards of quality for food,¹⁶³ FDA promulgated a regulation prohibiting the sale of all unpasteurized milk products in interstate commerce.¹⁶⁴ Due to questions regarding whether it was necessary to ban the interstate sales of certified raw milk to protect the public health, the Agency

160. *Id.* at 169.

161. *See id.*

162. It is hard to generalize about the trajectory of emergency contraception from prescription to OTC status because of the politically fraught environment in which this decision was made. Concerns about the sexual activity of teenagers and the public’s uncertainty regarding how emergency contraception actually works influenced the conversation regarding the switch of the drug from prescription to OTC status and FDA’s convoluted handling of the matter. The uniqueness of the issue was illustrated by the way in which the Agency repeatedly and markedly diverged from its usual practices and policies in making the switch. *See Tummino v. Hamburg*, 936 F. Supp. 2d. at 169 (FDA rode “roughshod over the policies and practices that it has consistently applied in considering applications for switches in drug status to over-the-counter availability.”); *Tummino v. Torti*, 603 F. Supp. 2d 519, 544–49 (E.D.N.Y. 2009) (discussing improper political influence on FDA’s decision-making process and “significant departures from the FDA’s normal procedures and policies in the review of the Plan B switch applications as compared to the review of other switch applications in the past 10 years”). This case is still instructive, however. FDA used its “tentative response” tool to delay answering a citizen petition requesting the drug’s status shift, and it took almost a decade for the case to be heard by a court. Moreover, even after finding that FDA had diverged from its normal policies and procedures in 2009, which indicated a susceptibility to political pressure, the court remanded the case to the Agency for disposition, *Tummino v. Torti*, 603 F. Supp. 2d at 549 (remanding decision to Agency because different decision makers were in place and because this decision was “best left to the expertise of the FDA”), which reflected a culture of deference to FDA. *Id.* Courts usually remand to agencies instead of granting affirmative relief. Nevertheless, the court here recognized serious impropriety in the decision-making process by FDA, and for this reason it may have been expected to forego a remand. On courts’ historical deference to FDA, see DANIEL CARPENTER, REPUTATION AND POWER 361 (2010).

163. 21 U.S.C. § 341 (2012).

164. *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1232 (D.D.C. 1986).

stayed the regulation.¹⁶⁵ “Certified raw milk” is unpasteurized milk that satisfies standards established by the American Association of Medical Milk Commissions.¹⁶⁶

FDA collected information from 1974 to 1982, and in 1982 wrote a proposed regulation banning the interstate sale of all raw milk based on evidence that the consumption of raw milk was linked to bacterial disease.¹⁶⁷ High-level officials at the Department of Health and Human Services (HHS) and the Centers for Disease Control supported this regulation, and statistical support was provided by the Chief of the Bureau of Foods Epidemiology and Clinical Toxicology Division in 1984.¹⁶⁸ The Agency, however, did not file the proposed regulations.

Public Citizen, a consumer advocacy organization, filed a citizen petition with FDA in 1984, seeking a ban on the sale of raw milk, both interstate and intrastate.¹⁶⁹ FDA did not respond to the petition, but sent letters in response to follow-up correspondence from Public Citizen. These letters stated that the matter was being considered and that hearings would be held, but detailed no schedule for action.¹⁷⁰ Public Citizen then filed a lawsuit in district court requesting that the court order FDA to respond to its petition.¹⁷¹

The district court ruled for Public Citizen, finding that “[t]he Department’s justification for its continued delay is lame at best and irresponsible at worst.”¹⁷² The court explained:

The facts here speak for themselves and need little elaboration. Officials at the highest levels of the Department of Health and Human Services have concluded that certified raw milk poses a serious threat to the public health. Leading health organizations are unanimous in proposing that sales of any raw milk should be banned. The Food and Drug Administration has twice proposed, in 1973 and 1983, that all milk in interstate commerce be pasteurized. Hundreds of cases of serious gastrointestinal infections have been reported since the ban on raw milk sales was first proposed.¹⁷³

Under its authority given by the APA to “compel agency action . . . unreasonably delayed,”¹⁷⁴ the court ordered FDA to rule on the petition within sixty days.¹⁷⁵

165. Milk and Cream, 38 Fed. Reg. 27,924 (Oct. 10, 1973) (to be codified at 21 C.F.R. pt. 18) (stayed by Identity Standards for Milk and Cream; Order Staying Certain Provisions, 39 Fed. Reg. 42,351 (Dec. 5, 1974)).

166. See *Public Citizen*, 653 F. Supp. at 1232.

167. *Id.*

168. *Id.* at 1233.

169. *Public Citizen v. Heckler*, 602 F. Supp. 611, 612 (D.D.C. 1985).

170. *Id.*

171. *Id.* at 613.

172. *Id.*

173. *Id.*

174. 5 U.S.C. § 706(1) (2012).

175. *Public Citizen*, 602 F. Supp. at 614.

In response to the court's ruling, FDA held hearings and, based on the findings from these hearings, recommended a proposed rule to the Secretary of HHS banning the interstate sale of raw milk.¹⁷⁶

The Secretary of HHS, however, rejected FDA's recommendation and directed the Agency to deny the petition.¹⁷⁷ While acknowledging the detrimental health effects of the consumption of raw milk, the Secretary reasoned that this was a matter better left to state control.¹⁷⁸

Public Citizen and other plaintiffs brought another action to challenge the denial of their petition, and in 1986, the court found the Secretary's action to be arbitrary and capricious, and directed FDA to ban the interstate sale of raw milk.¹⁷⁹ The court discussed the appropriateness of the judicial review of an agency's decision *not to* engage in rulemaking, finding that the policy reasons underlying deference to such an agency decision were not present in this case.¹⁸⁰ In particular, the decision did not implicate FDA's budget, as FDA already regulated noncertified raw milk; there were no indications of competing policy considerations; and there was a full administrative record for the court to review, which eliminated the concern that the judicial review would be based on hypotheticals.¹⁸¹

The court found that the Secretary's explanation for the decision to ban the petition "runs counter to the voluminous evidence to the contrary she had before her . . . [and] has no rational connection to the undisputed facts in the record."¹⁸² The court also found a remand to be unnecessary because the record itself was clear as to the scientific justification for banning interstate sales of raw milk.¹⁸³

The court in this case did not trace the decision by HHS to deny the citizen petition to any specific pressure from the administration, as did the court in the Plan B case. However, the availability and legality of raw milk has been tinged with controversy for decades.¹⁸⁴

176. *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1235 (D.D.C. 1986).

177. This is what happened during the Plan B decision making process, and it was viewed as shocking by commentators. *See, e.g.*, Sam Baker, *Left 'Speechless' as Sebelius Overrules FDA on Access to Morning-After Pill*, HILL (D.C.), Dec. 8, 2011, at P1.

178. *Public Citizen*, 653 F. Supp. at 1240.

179. *Id.* at 1242.

180. *Id.* at 1239–40.

181. *Id.*

182. *Id.* at 1240–41.

183. *Id.* at 1241.

184. *See, e.g.*, Elena Conis, *The Raw Milk Debate Rages On*, L.A. TIMES, Mar. 2, 2009, at F3, available at <http://articles.latimes.com/2009/mar/02/health/he-nutrition2>; Dana Goodyear, *Raw Deal*, NEW YORKER, Apr. 30, 2012, at 32. The tenor of the debate regarding the ban on interstate sales of raw milk may have been influenced by a 1985 foodborne illness outbreak in California, which killed dozens of people. This outbreak was traced tentatively to raw milk used in cheese, although this finding was disputed. *See* Ronald L. Soble, *Panel Blames Jalisco in Listeriosis Cases*, L.A. TIMES, Dec. 7, 1985, at A5; Sally Fallon Morell, *Is Raw Milk Safe for Babies?*, REAL MILK (Dec. 31, 2001), <http://www.realmilk.com/safety/is-raw-milk-safe-for-babies/> (tracing 1985 outbreak to pasteurized milk). Note that tracing mechanisms for foodborne illness outbreaks were undeveloped in the 1980s.

D. A Prospective Example: The Dispute over the Removal of Bisphenol A from Food Packaging

In 2008, NRDC filed a citizen petition with FDA requesting that FDA revoke all regulations permitting the use of bisphenol A (BPA) in food packaging.¹⁸⁵ BPA is a chemical that has been used in food packaging, including baby bottles, sippy cups, and formula containers, for decades.¹⁸⁶ Humans are exposed to BPA when it leaches into food from packaging.¹⁸⁷

BPA has been the subject of controversy for several years. In 2008, after the National Institute of Environmental Health Sciences and the National Toxicology Program wrote a report calling for research into BPA's potentially toxic effects, FDA began to study the chemical.¹⁸⁸ The tests done by FDA scientists showed that humans did not retain BPA in their bodies, that it was passed by pregnant mothers to the fetus only minimally, and that there was no evidence of toxicity at low doses in rodent studies.¹⁸⁹

Numerous other studies, however, found BPA to have harmful effects, and FDA has been criticized for relying on only a small sample of industry-funded studies.¹⁹⁰ In the petition, NRDC wrote that rodent studies have shown BPA to have numerous harmful effects, which occur at levels of exposure found in the general public. The group pointed to research showing a correlation between BPA exposure and adverse effects on human health, and concluded that “[t]he weight of the scientific evidence now shows that human exposure to BPA can not [sic] be confirmed safe.”¹⁹¹

NRDC petitioned FDA under section 409 of the FDCA, which regulates food additives,¹⁹² and under regulations issued by FDA regarding substances prohibited for use in human food. The group utilized the procedure for amending or repealing the standards approved for certain food additives and the procedure for submitting a citizen petition to FDA.¹⁹³

185. Natural Res. Def. Council, Citizen Petition 1 (Oct. 21, 2008), available at http://docs.nrdc.org/health/files/hea_08102001a.pdf.

186. Sabrina Tavernise, *F.D.A. Makes It Official: Chemical Can't Be Used in Baby Bottles and Cups*, N.Y. TIMES, July 18, 2012, at A15.

187. FDA, FDA CONTINUES TO STUDY BPA (2012), available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm297954.htm>.

188. *Id.*; Helena Bottemiller, *FDA Denies Petition To Ban BPA in Food and Beverage Containers*, FOOD SAFETY NEWS (Mar. 31, 2012), http://www.foodsafetynews.com/2012/03/fda-denies-petition-to-ban-bpa-in-food-and-beverage-containers/#.VBuYzqC8_ww.

189. FDA CONTINUES TO STUDY BPA, *supra* note 187. A new study also shows that the chemical has little to no effect in the amounts that humans are exposed to. See Jon Hamilton, *Maybe That BPA in Your Canned Food Isn't So Bad After All*, NPR (Feb. 26, 2014), <http://www.npr.org/blogs/thesalt/2014/02/26/283030949/government-studies-suggest-bpa-exposure-from-food-isn-t-risky>.

190. Lynn Harris, *BPA: How Bad Is It?*, BABBLE (Aug. 10, 2009), <http://www.babble.com/baby/baby-health-safety/bpa-plastic-to-avoid-bisphenol-a-safe-bottles/#fbConnectSection>.

191. Natural Res. Def. Council, *supra* note 185, at 7–9. The harmful effects seen in rodent studies include “reproductive defects, chromosomal damage, nervous system harm, increased rates of breast and prostate cancer, and metabolic changes including obesity and insulin resistance.” *Id.* at 2.

192. 21 U.S.C. § 348 (2012).

193. 21 C.F.R. §§ 10.30, 171.30, 189.1 (2013); see also *supra* Part I.A.

FDA responded to NRDC's petition with a "tentative response,"¹⁹⁴ stating that it could not reach a final decision because of the "limited availability of resources and other agency priorities."¹⁹⁵ After more than a year passed, NRDC filed suit seeking to compel a denial or acceptance of its petition.¹⁹⁶ In December 2011, NRDC and FDA settled. FDA agreed to make a decision whether to ban BPA from food packaging by March 31, 2012.¹⁹⁷

FDA denied NRDC's petition on March 30, 2012. The Agency found that the studies used by NRDC were limited, and the information in the petition "was not sufficient to persuade FDA, at this time, to initiate rulemaking to prohibit the use of BPA in human food and food packaging." FDA stated that it would continue to research BPA.¹⁹⁸

In July 2012, FDA banned the use of BPA in baby bottles and sippy cups. The Agency stated that it did not take this action in response to health concerns, but rather acted in response to a request by the chemical industry's main trade association, which had already stopped using it in these products and was interested in boosting consumer confidence and reducing confusion.¹⁹⁹ In July 2014, several legislators introduced a bill to ban BPA from food packaging.²⁰⁰ This bill, the Ban Poisonous Additives Act of 2014, failed in Congress.²⁰¹

194. This "tentative response" is permitted pursuant to the regulation issued by FDA regarding the procedure for submitting citizen petitions. 21 C.F.R. § 10.30; *see also supra* Part I.A.

195. *In re* Natural Res. Def. Council, 645 F.3d 400, 404 (D.C. Cir. 2011).

196. *Id.* at 400. NRDC initially filed suit in the District of Columbia Court of Appeals for an order directing FDA to respond to the petition. The court dismissed NRDC's suit, finding that the district court had exclusive jurisdiction over citizen petitions. *See id.* NRDC then brought suit in district court.

197. Ross Anderson, *FDA Agrees To Respond on BPA Risk by March 31*, FOOD SAFETY NEWS (Dec. 9, 2011), http://www.foodsafetynews.com/2011/12/fda-agrees-to-respond-on-bpa-risk-by-march-31/#.VBuZDqC8_wv.

198. Letter from David H. Dorsey, Acting Assoc. Comm'r for Policy & Planning, Dep't of Health & Human Servs., to Sarah Janssen & Aaron Colangelo, Natural Res. Def. Council (Mar. 30, 2012), *available at* http://docs.nrdc.org/health/files/hea_12033001a.pdf.

199. *See* Indirect Food Additives: Adhesives and Components of Coatings, 78 Fed. Reg. 41,840 (July 12, 2013) (to be codified at 21 C.F.R. pt. 175); Tavernise, *supra* note 186.

200. Chelsea Rice, *Congress Considering Bill To Ban BPA from Food Packaging*, BOSTON.COM (July 10, 2014, 1:54 PM), <http://www.boston.com/health/2014/07/10/congress-considering-bill-ban-bpa-from-food-packaging/JkXwdurEMLTkdpS30jJ/story.html>.

201. *H.R. 5033 (113th): Ban Poisonous Additives Act of 2014*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/113/hr5033>. It is worth noting that a government study published in early 2014 showed that there was no effect on rats of ingesting thousands of times what humans eat. *See* K. Barry Delclos, Luisa Camacho, Sherry M. Lewis, Michelle M. Vanlandingham, John R. Latendresse, Greg R. Olson, Kelly J. Davis, Ralph E. Patton, Gonçalo Gamboa da Costa, Kellie A. Woodling, Matthew S. Bryant, Mani Chidambaram, Raul Trbojevich, Beth E. Juliar, Robert P. Felton & Brett T. Thorn, *Toxicity Evaluation of Bisphenol A Administered by Gavage to Sprague Dawley Rats from Gestation Day 6 Through Postnatal Day 90*, TOXICOLOGICAL SCI., Feb. 24, 2014, at 9, 21; Hamilton, *supra* note 189.

E. The Inadequacy of Private Enforcement

In all of these examples, private parties petitioned FDA to take certain actions—hold hearings on the safety of the subtherapeutic antibiotics in animal feed, revoke the approval for BPA in food packaging, switch Plan B to OTC status, and ban the sale of certified raw milk—and brought suit to compel a response to their petitions and/or to contest the Agency’s denials. In the contexts of animal antibiotics, the Plan B switch, and the ban on raw milk, FDA itself had publicly acknowledged that the actions the petitioners sought would benefit the public health, and in regard to BPA, FDA actually took one of the steps suggested by petitioners even after denying the petition.

It may seem counterintuitive to characterize these cases as demonstrating the inadequacy of private enforcement when, in each, private entities achieved at least some measure of success. However, in each of these cases we see extensive delay, agency recalcitrance, evidence of arbitrary decision making, and repeated episodes of judicial review. These trajectories are unacceptable in the context of health and safety regulation.²⁰²

In some areas where private enforcement is more successful in compelling agency action, such as in the promulgation of standards under the CWA, or the listing of species under the ESA, political and economic interests are also implicated. The difference, however, is that the statutes under which private parties successfully move to compel regulation have more clearly articulated criteria and requirements, and contain more deadlines for action. The greater precision of these statutes has encouraged more litigation in these contexts, as well as less judicial deference to the relevant agencies.²⁰³

III. WHEN PRIVATE ENFORCEMENT IS SUCCESSFUL

This Part will describe two areas of law in the environmental context where private enforcement has been very effective in compelling agency action for the purpose of comparing the relevant statutory scheme to that used by citizens seeking to compel FDA action.²⁰⁴

A. A Comparison with EPA’s Role in Setting Water Quality Standards Under the Clean Water Act

The goal of the CWA is to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.”²⁰⁵ The CWA declares that the

202. See *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) (“[D]elays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake . . .”).

203. There are, of course, more reasons why there is more advocacy group litigation in the environmental context than the food and drug context. See Diana R. H. Winters, *Not Sick Yet: Food-Safety-Impact Litigation and Barriers to Justiciability*, 77 *BROOK. L. REV.* 905, 916–29 (2012).

204. For additional discussions of the success of private enforcement in these contexts, see, e.g., Biber & Brosi, *supra* note 12; Glicksman, *supra* note 11, at 373–80 (TMDLs); Meazell, *supra* note 10, at 1774–80 (various cases).

205. 33 U.S.C. § 1251(a) (2012).

elimination of “the discharge of pollutants into the navigable waters” is a national goal and the prohibition of “the discharge of toxic pollutants in toxic amounts” is a national policy.²⁰⁶

Under the CWA, each state must identify bodies of water that are more polluted and thus require additional limitations on effluent and thermal discharges than are required under other parts of the statute.²⁰⁷ The state must then establish a “total maximum daily load” (TMDL) of EPA-identified pollutants for these waters.²⁰⁸ States are required to submit the lists of waters and TMDLs to EPA for approval, and EPA then has to approve or disapprove each submission.²⁰⁹ The statute contains deadlines with which the states and EPA must comply.²¹⁰

After the passage of the CWA, many states did not meet their obligations to establish TMDLs, and EPA did not enforce the program.²¹¹ To enforce the program, environmental advocacy groups began to file lawsuits under the citizen suit provision of the CWA.²¹² Pursuant to this provision, “any citizen may commence a civil action on his own behalf,” against alleged violators of the CWA, and “against the Administrator where there is alleged a failure of the Administrator to perform any act or duty under this chapter which is not discretionary with the Administrator.”²¹³

Citizen suits to enforce the TMDL program were very successful. In *Scott v. City of Hammond, Indiana*, a citizen sued EPA for, among other things, its failure to set forth TMDLs for the discharge of pollutants into Lake Michigan.²¹⁴ EPA argued that it could not do so because Indiana had not submitted its list of TMDLs, as was statutorily required.²¹⁵ The Seventh Circuit held that the failure of the relevant states to submit TMDLs to EPA by the statutory deadline did not absolve EPA of its duty to promulgate TMDLs under the statute.²¹⁶ The court reasoned that the absence of a state submission should be read as a “constructive submission” of no TMDLs.²¹⁷ EPA could either approve this no-TMDL submission or disapprove it, in which case it was required to promulgate its own TMDLs.²¹⁸ Either decision could be challenged in court. In his article on the value of agency-forcing citizen suits, Robert L. Glicksman notes that this

206. *Id.* § 1251(a)(1), (3).

207. *See id.* § 1313(d)(1)(A), (B).

208. *Id.* § 1313(d)(1)(C); *see also id.* § 1314(a)(2).

209. *Id.* § 1313(d)(2).

210. *Id.* (providing that states have 180 days after EPA issues list of pollutants to submit list of bodies of water and TMDLs, and EPA has thirty days after this submission to respond).

211. Glicksman, *supra* note 11, at 374 (citing OLIVER A. HOUCK, *THE CLEAN WATER ACT TMDL PROGRAM: LAW, POLICY, AND IMPLEMENTATION* 51 (1999)).

212. *Id.* (“Against a background of federal environmental programs in which litigation has played a central role, it is hard to think of any program more precipitously driven by citizen suits from absolute zero toward its statutory destiny than TMDLs.” (quoting OLIVER A. HOUCK, *THE CLEAN WATER ACT TMDL PROGRAM: LAW, POLICY, AND IMPLEMENTATION* 75 (1999)).

213. 33 U.S.C. § 1365(a) (2012).

214. 741 F.2d 992, 996 (7th Cir. 1984).

215. *Id.* (“The district court agreed with the EPA that the EPA is not required to act unless and until the state submits a proposed TMDL.”).

216. *Id.* at 996–97.

217. *Id.* at 996.

218. *Id.* at 997.

“constructive submission” theory has been very influential, and that “TMDL citizen suits have already served as an important break on agency footdragging.”²¹⁹

Although the analogy is imperfect, we can compare FDA’s inaction in the field of animal antibiotics to EPA’s inaction in the context of promulgating TMDLs. In each case the agency did something that was supposed to lead to something else—in the case of antibiotics, FDA issued a notice for an opportunity for a hearing on the withdrawal of approval for certain antibiotics,²²⁰ and in the case of the TMDLs, EPA issued the statutorily required list of pollutants²²¹—but did not take the subsequent action. Similarly, in each of the above-cited examples,²²² members of the public attempted to compel FDA to act in an area implicating the public health, and each private party alleged that FDA had failed to take a statutorily mandated action. EPA was “footdragging” here in completing statutorily mandated steps toward the fulfillment of the statute’s ultimate purpose—the restoration and maintenance of the integrity of the nation’s waters.²²³ In contrast, though, the FDCA does not have a statement of purpose similar to that of the CWA. FDA’s stated purpose is to

protect[] the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices. The FDA is also responsible for the safety and security of most of our nation’s food supply, all cosmetics, dietary supplements and products that give off radiation,²²⁴

but the FDCA contains no statement such as this.

Moreover, the actions FDA was required to take in the examples are less clearly laid out than in the case of TMDLs. According to 21 U.S.C. § 360b(e)(1), the provision of the FDCA regarding the withdrawal of approval of an animal drug, the Secretary “shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval” of an animal drug if such drug was shown to be unsafe.²²⁵ Recall that FDA argued that it did not have to issue the withdrawal order if it never held a hearing and made findings pursuant to that hearing, regardless of any other findings it had made on the drug.²²⁶

The provision of the CWA governing TMDLs, which requires EPA to approve or disapprove state submissions, is less open to interpretation by either the Agency or a court. It also contains specific deadlines, which are easily reviewable by a court and signal that Congress supported prompt Agency action in this context. The provision reads:

219. Glicksman, *supra* note 11, at 374–75, 378.

220. *Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127, 133–34 (S.D.N.Y. 2012).

221. 33 U.S.C. § 1314(a)(2)(D) (2012); *Scott*, 741 F.2d at 996 n.10 (“EPA finally made the necessary identifications on December 28, 1978, apparently under court order.”).

222. *See supra* Part II.A–D.

223. *See supra* notes 214–215 and accompanying text.

224. *FDA Fundamentals*, FDA, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm> (last updated June 12, 2014).

225. 21 U.S.C. § 360b(e)(1) (2012).

226. *Natural Res. Def. Council*, 884 F. Supp. 2d at 140–41.

Each State shall submit to the Administrator from time to time, with the first such submission not later than *one hundred and eighty days* after the date of publication of the first identification of pollutants under section 1314(a)(2)(D) of this title, for his approval the waters identified and the loads established under paragraphs (1)(A), (1)(B), (1)(C), and (1)(D) of this subsection. The Administrator shall either approve or disapprove such identification and load *not later than thirty days* after the date of submission. If the Administrator approves such identification and load, such State shall incorporate them into its current plan under subsection (e) of this section. If the Administrator disapproves such identification and load, he shall *not later than thirty days* after the date of such disapproval identify such waters in such State and establish such loads for such waters as he determines necessary to implement the water quality standards applicable to such waters²²⁷

Granted, there is still ambiguity in the statute, as was litigated in the Seventh Circuit—that is, what happens if the state fails to submit its list for approval? Nevertheless, the existence of the deadlines better illustrates the wishes of Congress and better illuminates the Agency’s failure to fulfill these wishes than does a statute without deadlines.

Unlike the CWA, the FDCA does not contain a citizen suit provision. Petitioners in the animal antibiotics suit (*Natural Resources Defense Council, Inc. v. FDA*²²⁸) sued under 5 U.S.C. § 706(1), which gives courts the power to “compel agency action unlawfully withheld or unreasonably delayed.”²²⁹ As the court in *Natural Resources Defense Council* noted, “The Supreme Court has made clear that § 706(1) applies only when an [sic] ‘an agency failed to take a discrete agency action that it is required to take.’”²³⁰ In the animal antibiotics case, FDA contested both the “discrete action” prong and the “required to take” prong, arguing that because a hearing was a prolonged action, it was not a discrete action, and that it was not legally required to hold the withdrawal hearings in any event.²³¹ Similarly, under a citizen suit provision, petitioners can only sue an agency for the failure to take nondiscretionary action.²³² Suits under either provision are therefore functionally the same.²³³ The real difference here is the lack of statutory deadlines.

Even though the court disagreed with FDA’s arguments, the plaintiffs in *Natural Resources Defense Council* were more poorly equipped to force agency action than were those in the TMDL cases, where the statute contained deadlines.

227. 33 U.S.C. § 1313(d)(2) (2012) (emphasis added).

228. 884 F. Supp. 2d 127.

229. 5 U.S.C. § 706(1); *see also supra* Part II.A.

230. *Natural Res. Def. Council*, 884 F. Supp. 2d at 138 (emphasis omitted) (citing *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004)).

231. *See supra* Part II.A.

232. *See, e.g.*, 33 U.S.C. § 1365 (2012) (CWA citizen suit provision).

233. *See Glicksman, supra* note 11, at 369.

B. A Comparison with the Petition Provisions of the Endangered Species Act

Citizen petitions have been very influential in shaping the trajectory of the ESA.²³⁴ Any interested person can petition an agency for the issuance of a rule under the generic petition provision of the APA,²³⁵ and pursuant to this provision, any person can petition the Fish and Wildlife Service (FWS) or the National Marine Fisheries Service (NMFS) for a listing of a species as either endangered or threatened under the ESA.²³⁶ Under the ESA, the relevant agency then has ninety days to determine whether a filed petition should be investigated further, and then twelve months to determine whether the requested action is warranted.²³⁷

These strict deadlines supplement the petition provision of the APA, which itself only imposes a duty on the agency to respond within a reasonable time.²³⁸ The 1979 regulation,²³⁹ discussed above,²⁴⁰ detailing the procedure for the submission and receipt of citizen petitions to FDA, also supplements the APA's petition provision. Like the ESA, this provision contains deadlines for FDA to respond to citizen petitions.²⁴¹ However, this regulation allows FDA to respond with a "tentative response," which must

indicat[e] why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.²⁴²

The "tentative response" mechanism was used by FDA in three out of four of the examples above²⁴³ and allows FDA to comply with its regulatory duty while not actually furnishing an answer to the petition.

The strict deadlines in the ESA's petition provision force FWS or NMFS to respond to a citizen petition. In contrast, FDA can respond tentatively, and thus parry the request. The deadlines give citizen advocates a specific, nondiscretionary duty that can be litigated if the agency fails to respond and allows a court to force action without imposing on agency discretion.²⁴⁴ Although these deadlines do not mean that

234. See, e.g., Biber & Brosi, *supra* note 12, at 324 (looking at petitioning under the ESA to analyze how petitions and citizen suits affect environmental decision making).

235. 5 U.S.C. § 553(e) (2012); see also *supra* Part I.A.

236. See 16 U.S.C. § 1533(b)(3)(A) (2012). The FWS and the NMFS administer the ESA.

237. *Id.* § 1533(b)(3)(A)–(B).

238. See Biber & Brosi, *supra* note 12, at 327 n.19 (explaining that multiple provisions in the APA, read together, have been read by courts to require a timely response from agencies).

239. 21 C.F.R. § 10.30 (2014).

240. See *supra* Part I.A.

241. 21 C.F.R. § 10.30(e)(2) ("Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition.").

242. *Id.* § 10.30(e)(2)(iii).

243. See *supra* Part II.A–D.

244. See, e.g., *Ctr. for Biological Diversity v. Kempthorne*, No. C 06-04186 WHA, 2007 WL 163244 (N.D. Cal. Jan. 19, 2007) (plaintiffs sued the FWS for not responding to their

a petitioner will receive the result sought, they do mean that the agency can be compelled to seriously consider the request. I do not mean to overstate the usefulness of the petition deadlines. Emily Hammond shows in her article on serial litigation that suits beginning as “straightforward deadline suit[s]” can last for decades with no discernible change in the status of the species at issue.²⁴⁵ Nevertheless, response deadlines are tools available for citizens seeking to compel agency action.

IV. HOW THE INEFFECTIVENESS OF PRIVATE ENFORCEMENT DETRIMENTALLY AFFECTS PUBLIC HEALTH AND THE ADMINISTRATIVE STATE

The previous Part identified several episodes of FDA inaction that citizen participation could not effectively address. These episodes have effects that reverberate beyond their specific substantive impact. Although other institutions have influence over administrative agencies, the oversight of private parties is a crucial part of the administrative state, and its significance cannot be overstated. Indeed, one commentator has noted that the APA itself “is essentially a one-trick pony. All of its basic provisions rely on a single method for controlling the actions of administrative agencies, namely, participation by private parties.”²⁴⁶

When private enforcement is ineffective, the transparency of agency decision making is diminished, the interaction between deliberative bodies is reduced, and the opportunity for public participation is lessened. In addition, any benefits of judicial review to the administrative process are tempered by the dysfunction of the private enforcement process. This Part discusses these harms, starting with the most direct effects of agency inaction.

A. The Immediate Harm to Public Health

When an agency fails to act, it adversely affects the intended beneficiaries of the relevant legislation.²⁴⁷ These adverse effects can implicate the structure of the administrative state, and thus can be relatively abstract, or can be tangible and immediate. With regard to FDA, the Agency’s failures can be enormously consequential, although they may be difficult to quantify. For example, FDA did not hold the hearings on the withdrawal of approval for the subtherapeutic use of certain antibiotics in animal feed that it called for in 1977.²⁴⁸ We are left with two questions: (1) Has new evidence shown “that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved” pursuant to the statutory provision outlining the procedure for withdrawing approval of an

petition that the Siskiyou Mountains salamander be listed as threatened or endangered under the ESA).

245. Meazell, *supra* note 10, at 1747–53 (discussing the flat-tailed horned lizard cases).

246. Rubin, *supra* note 2, at 101.

247. See Michael D. Sant’Ambrogio, *Agency Delays: How a Principal-Agent Approach Can Inform Judicial and Executive Branch Review of Agency Foot-Dragging*, 79 GEO. WASH. L. REV. 1381, 1400 (2011) (discussing costs of agency delay).

248. See *supra* Part II.A.

animal drug?²⁴⁹ (2) If the answer to (1) is yes, and FDA had this information since the early 1970s (which seems to be the case) what is the effect on public health?

Although the answer to (1) appears to be yes, and the court in *Natural Resources Defense Council* based its opinion on this finding,²⁵⁰ FDA disagreed and asserted that it had not made any such findings and that its consideration of the matter was ongoing.²⁵¹ But even if the answer was clear, the effect of the continued use of these drugs is still uncertain. Numerous studies have shown some connection between the subtherapeutic use of antibiotics in animal feed and the growth of antibiotic-resistant germs with the potential to harm humans, but these conclusions are contested.²⁵²

Difficult as it is to assess whether the public health has been harmed by FDA's failure to regulate antibiotics in animal feed, it is even more difficult to quantify the effect of the Agency's inaction with regard to switching emergency contraception from prescription to OTC status. Indeed, this calculation melds science, policy, and morals so completely that any such assessment is truly impossible. However, in *Tummino v. Hamburg*, the court extensively detailed the burdens on women seeking emergency contraception when such medicine could be obtained by prescription only.²⁵³ These burdens, coupled with FDA's acknowledgement that the medicine "should be approved for all females of child-bearing potential," led the court to the conclusion that the "FDA has engaged in intolerable delays in processing the petition."²⁵⁴

Although quantification of harm may be difficult, it goes without question that the effect of agency inaction can be far reaching. In fact, the repercussions of delay extend to the very structure of the administrative state.

B. The Reduced Visibility of Agency Decision Making

The APA's procedural requirements are designed, in part, to ensure the transparency of agency decision making.²⁵⁵ The "administrative law values of

249. 21 U.S.C. § 360b(e)(1)(B) (2012).

250. 884 F. Supp. 2d 127, 141, 149–50 (S.D.N.Y. 2012).

251. *Id.*

252. See, e.g., *Antibiotic Debate Overview*, PBS, <http://www.pbs.org/wgbh/pages/frontline/shows/meat/safe/overview.html> (discussing controversy regarding feeding subtherapeutic doses of antibiotics to animals and possible risk to human health); Richard Knox, *How Using Antibiotics in Animal Feed Creates Superbugs*, NPR (Feb. 21, 2012, 11:10 AM), <http://www.npr.org/blogs/thesalt/2012/02/21/147190101/how-using-antibiotics-in-animal-feed-creates-superbugs> ("A study in the journal *mBio*, published by the American Society for Microbiology, shows how an antibiotic-susceptible staph germ passed from humans into pigs, where it became resistant to the antibiotics tetracycline and methicillin. And then the antibiotic-resistant staph learned to jump back into humans."); cf. Richard Raymond, *Antibiotics Used in Food-Producing Animals*, MEATINGPLACE (Jan. 7, 2013), <http://www.meatingplace.com/Industry/Blogs/Details/38770> (stating that most antibiotics used in food-producing animals are not used for human medicine).

253. 936 F. Supp. 2d 162, 168–69 (E.D.N.Y. 2013).

254. *Id.* at 167, 198.

255. See, e.g., *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979) ("In enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment.").

participation, deliberation, and transparency . . . guard against arbitrariness and foster accountability.”²⁵⁶ Notice-and-comment rulemaking, the citizen petition provision, and the mechanisms for judicial review provide ways to allow regulated entities and beneficiaries access to the deliberative process and a means to challenge agency determinations.

Transparency bolsters the legitimacy of agency decisions by, among other things, reducing the appearance that the agency has been “captured” by special interests. Administrative capture is a term for the phenomenon where regulated interests exert such an influence over their regulators that they essentially control the agencies, at the expense of the intended beneficiaries of the regulatory system.²⁵⁷ This relationship can be explicit, where there is an actual flow of individuals between industry and decision-making regulatory positions, or implicit, which involves more attenuated but no less real connections between decision makers and industry.²⁵⁸ And although regulatory beneficiaries may fear the synergy of agencies and their regulated objects, the term “capture” also encompasses the possibility that a regulator is so intertwined with the regulatory beneficiaries that it is no longer an effective regulating body.²⁵⁹ To address capture, judicial review can provide a degree of oversight that can root out and address unreasonable decision making affected by political considerations.²⁶⁰

256. Emily Hammond & David L. Markell, *Administrative Proxies for Judicial Review: Building Legitimacy from the Inside-Out*, 37 HARV. ENVTL. L. REV. 313, 316 & n.18 (2013) (collecting sources on administrative law values).

257. See, e.g., Nicholas Bagley, *Agency Hygiene*, 89 TEX. L. REV. 1, 2, 8 n.32 (2010); William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1590–91 (2007) (“Agencies may be able to secure expanded budgets or even engage in outright favoritism to affected industry in exchange for the usual rewards of regulatory capture—electoral support for the administration in power, revolving doors from agencies to industry, and a reduced risk of embarrassment that might result from more adversarial modes of regulatory exchange.”).

258. See Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1285 (2006). The question of whether agency capture is actually a problem, or more a perceived problem, and the effects thereof, has been amply discussed in legal scholarship. See, e.g., Thomas W. Merrill, *Capture Theory and the Courts: 1967–1983*, 72 CHI.-KENT L. REV. 1039 (1997); Cass R. Sunstein, *What’s Standing After Lujan? Of Citizen Suits, “Injuries,” and Article III*, 91 MICH. L. REV. 163, 183–84 (1992); see also Bagley & Revesz, *supra*, at 1284–92 (arguing that the theory of regulatory capture does not adequately explain the reality of governmental agency processes).

259. Bagley & Revesz, *supra* note 258, at 1286 (“[V]illains of this story are environmental groups like the Sierra Club, labor unions like the Teamsters, and consumer advocacy groups like Public Citizen, all of whom are driven by their narrow ideologies and heedless of any costs to American industries. Through their superior organizational mettle, these ostensibly ‘public-serving’ groups prey on the sensibilities of warm-hearted but fuzzy-headed bureaucrats and congressmen to drive through regulations that are unnecessary, unwise, or simply too costly.”); Stewart & Sunstein, *supra* note 16, at 1279 (“[O]ld fears of factional domination are now widely perceived to have been realized; broad legislative delegations have left agencies vulnerable to the sustained and organized political pressure of regulated firms, unions, and other powerful interest groups.”).

260. See Hammond & Markell, *supra* note 256, at 314 (“[T]he rigors of judicial scrutiny can further democratic accountability and otherwise incentivize legitimizing behaviors.”).

When the procedural mechanisms stop working smoothly, whether that happens because the agency refuses to respond to a petition,²⁶¹ abuses the “tentative response” tool,²⁶² or does not comply with a court order,²⁶³ public access to agency decision making is truncated, and the opportunities for review are lessened. For example, after calling for hearings on the withdrawal of approval for certain uses of certain antibiotics in animal feed in 1977, FDA continued to hold meetings on the issue through 1987.²⁶⁴ Between 1987 and 2003, however, when FDA proposed to withdraw the notice for a hearing, it appears that no open meetings on the issue were held although FDA was continuing to approve new subtherapeutic uses of antibiotics in animal feed during those years.

C. The Lessened Value of Judicial Review

The benefits of the judicial review of agency action are manifold.²⁶⁵ As Hammond and Markell note in their discussion of administrative legitimacy, “[a]t their core, the various principles of judicial review reinforce administrative law values of participation, deliberation, and transparency, which guard against arbitrariness and foster accountability.”²⁶⁶ The courts can increase the legality of administrative decision making by “ensur[ing] that regulatory agencies comply with congressional commands” and can foster the legitimacy of outcomes by protecting against arbitrary decisions and the excessive influence of interest groups.²⁶⁷ The judicial process itself is focused and accessible.²⁶⁸ And even divorced from its effect on outcomes, the participatory nature of judicial review is seen by some as “inherently valuable; citizen involvement in community self-determination is desirable without regard to notions of efficiency or private rights.”²⁶⁹

Ineffective private enforcement, however, diminishes these benefits in two ways. First, if an agency can delay its response to a citizen petition, the issue does not reach the courts for years, if at all. This is what happened in *Natural Resources Defense Council*, the animal antibiotics case. Second, the lack of statutory tools that leads to

261. See, e.g., *Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127, 137 n.6 (S.D.N.Y. 2012) (antibiotics in animal feed).

262. See, e.g., *In re Natural Res. Def. Council*, 645 F.3d 400 (D.C. Cir. 2011) (suit to compel response to petition calling for removal of BPA from food packaging).

263. See *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 166 (E.D.N.Y. 2013) (FDA did not rule on citizen petition calling for switch of emergency contraception to OTC status for almost three years after court order to do so).

264. See *Open Meeting Notice*, 52 Fed. Reg. 13,760 (Apr. 24, 1987) (calling for open meeting for consumer participation to discuss antibiotics in animal feed); *Open Meeting Notice*, 50 Fed. Reg. 15,980 (Apr. 23, 1985) (calling for open meeting for consumer participation to discuss antibiotics in animal feed).

265. Critics of judicial review have also noted its potential detriments. See *supra* note 13.

266. Hammond & Markell, *supra* note 256, at 316.

267. Cass R. Sunstein, *On the Costs and Benefits of Aggressive Judicial Review of Agency Action*, 1989 DUKE L.J. 522, 522–25.

268. Jonathan R. Siegel, *The Institutional Case for Judicial Review*, 97 IOWA L. REV. 1147, 1150–51 (2012).

269. Stewart & Sunstein, *supra* note 16, at 1279.

ineffective private enforcement also contributes to increased judicial deference to the agency, which can weaken some of the benefits of judicial review.

There are multiple reasons why a case of agency inaction may not reach the courts for years, if at all. To begin with, there are high barriers to filing suit against an agency, including the need for expertise in the subject matter covered by the agency, knowledge of the regulatory process, and the resources to support prolonged litigation.²⁷⁰ Even groups skilled at bringing agency-forcing suits have priorities and agendas of their own, as well as a need to satisfy the diverse constituencies that make up their membership and financial support structure.²⁷¹

Once a party files a petition against an agency, it can bring a suit to challenge the agency's determination or the agency's failure to respond.²⁷² However, the question of when a failure-to-respond suit is appropriate can be complicated by the filing of a tentative response, which provides no substantive consideration of the issue and no timeframe for disposition of the issue.²⁷³ For example, in the antibiotics in animal feed case, petitioners filed citizen petitions in 1999 and 2005 and did not sue for a response until 2011.²⁷⁴ In the emergency contraception case, petitioners filed their first petition in 2001 and did not receive a denial until 2006.²⁷⁵ Petitioners in the raw milk case first filed a petition in 1984, although the Agency had been delaying on the issue of an interstate ban since 1973.²⁷⁶

When a case does come before a court, judicial deference may weaken the value of judicial review by reducing the intensity with which the court scrutinizes agency action.²⁷⁷ There is a tradition of strong judicial deference to FDA decisions,²⁷⁸ for

270. See William W. Buzbee, *The Story of Laidlaw: Standing and Citizen Enforcement*, in ENVIRONMENTAL LAW STORIES 231–34 (Richard J. Lazarus & Oliver A. Houck eds., 2005).

271. For example, in the 1980s, Public Citizen brought several suits against FDA regarding food safety issues, but the organization no longer focuses on this type of litigation. See Winters, *supra* note 203, at 908 n.16. The Center for Science in the Public Interest's litigation docket is currently focused on deceptive labeling litigation. See *Litigation Project—Current Docket*, CENTER FOR SCI. PUB. INT., <http://www.cspinet.org/litigation/current.html>.

272. See *supra* Part I.A.

273. See, e.g., *Public Citizen v. Heckler*, 602 F. Supp. 611, 612 (D.D.C. 1985) (raw milk case).

274. *Natural Res. Def. Council, Inc. v. FDA*, 884 F. Supp. 2d 127, 137 n.6 (S.D.N.Y. 2012).

275. *Tummino v. Torti*, 603 F. Supp. 2d 519, 526 (E.D.N.Y. 2009).

276. *Public Citizen*, 602 F. Supp. at 611–12. Even more recently than any of the above listed examples, the Center for Science in the Public Interest submitted a petition to FDA in February 2013 calling for the agency to further regulate the use of certain added sugars in foods and beverages. Petition To Ensure the Safe Use of “Added Sugars,” Ctr. for Sci. in the Pub. Interest (Feb. 13, 2013), available at http://cspinet.org/new/pdf/sugar_petition_2-12-13_final.pdf. In the petition, the Center for Science in the Public Interest indicates that it submitted a petition to FDA in 1999 calling for regulations on added sugars and a petition to FDA in 2005 requesting warning notices on nondiet soft drinks regarding added sugars, and received a response to neither. See *id.* at 3 n.4.

277. See, e.g., Emily Hammond Meazell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 737–38 (2011) (“[S]uper deference . . . inhibits transparency; undermines deliberation; fails to accord with political accountability; and generally abdicates the courts’ role in the constitutional scheme by encouraging outcome-oriented review.”).

278. See CARPENTER, *supra* note 162, at 361; Laurie J. Beyranevand, *Milking It:*

two reasons. First, because of the technical and scientific complexity of many FDA determinations, courts tend to defer to FDA's expertise in its regulatory space.²⁷⁹ Second, the FDCA itself, written at the turn of the twentieth century, lacks, in certain areas, the clearly articulated congressional goals and statutory deadlines found in the more modern environmental statutes.²⁸⁰ Courts are therefore left with few guideposts by which to judge agency action.

V. SUPPLEMENTING THE TOOLS AVAILABLE TO PRIVATE LITIGANTS SEEKING TO COMPEL AGENCY ACTION

The previous Parts have shown that private enforcement has failed under certain circumstances to ameliorate the problem of arbitrary decision making by FDA, resulting in Agency inaction. In this Part, I propose several incremental changes that will address this problem. First, Congress should amend the Act to include more specific petition provisions, including mandatory response deadlines and informational requirements to support judicial review. Second, the FDCA's general citizen petition provision should be strengthened. And third, I reiterate and supplement the call made by Richard L. Revesz and Michael A. Livermore that private parties be able to petition the Office of Information and Regulatory Affairs (OIRA) for review of denials of petitions for rulemaking.²⁸¹

A. Specific Petition Provisions

The inclusion of specific petition provisions in the FDCA would help prevent Agency delay and give courts a basis on which to review Agency decision making, or lack thereof. For example, public awareness of the connection between animal drugs and human health has increased.²⁸² If 21 U.S.C. § 360b, the provision of the FDCA dealing with new animal drugs, contained a specific petition provision regarding the withdrawal of an approved animal drug, it would be easier for private parties to force movement on these issues. Section 360b creates a precise system for applications for uses of new animal drugs, which include exact response deadlines

Reconsidering the FDA's Refusal To Require Labeling of Dairy Products Produced from RBST Treated Cows in Light of International Dairy Foods Association v. Boggs, 23 FORDHAM ENVTL. L. REV. 102, 134 (2011) ("Commentators suggest that the age of deference to the FDA is coming to an end . . ."); James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 940 (2008) (discussing evolution of judicial deference to FDA).

279. See, e.g., Jessica Elizabeth Palmer, *Genetic Gatekeepers: Regulating Direct-to-Consumer Genomic Services in an Era of Participatory Medicine*, 67 FOOD & DRUG L.J. 475, 509–10 (2012) (discussing judicial deference to FDA's definition of "device").

280. See *supra* Part II.E; see also Bressman, *supra* note 9, at 1688 ("Congress often writes broad delegating statutes to create opportunities for narrow interests to dominate agency decisionmaking. Congress similarly grants power without meaningful administrative limits so that its members will have space to push agencies toward preferential outcomes.").

281. RICHARD L. REVESZ & MICHAEL A. LIVERMORE, *RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH* 174 (2008).

282. See, e.g., Ruth Reichl, Op-Ed., *The F.D.A.'s Blatant Failure on Food*, N.Y. TIMES, July 31, 2014, at A23.

by FDA.²⁸³ It also discusses the withdrawal of approval, including on what such withdrawal shall be based and how the Agency will go about withdrawing approval.²⁸⁴ The statute does not, however, contain timeframes within which this process must occur, nor a specific petition provision providing judicial review to a petitioner. For this reason, a party moving to withdraw the approval of a new animal drug will move through the mechanisms of the FDCA's general citizen petition provision and be subject to the weaknesses therein.

Congress could also incorporate a "statutory hammer" to make such a provision more effective. Statutory hammers add a layer of consequence to a statutory deadline. For example, some statutes provide a deadline before which an agency must act and prescribe substantive standards that will go into effect if the deadline is not met.²⁸⁵ The Nutrition Labeling and Education Act contained a different kind of hammer—it required the Agency to establish proposed regulations within twelve months, which became final if final regulations were not promulgated in the next twelve months.²⁸⁶

It is relatively easy to imagine how the increased use of statutory deadlines coupled with hammers could improve the regulatory process where agency inaction is caused by political pressure. Congress could amend the Animal Drug Amendments to prescribe that if a use of an approved animal drug was shown to be a harmful contaminant,²⁸⁷ hearings on its withdrawal would need to be held within twelve months or the drug would be automatically banned from animal feed. Congress could direct that once a group such as the Center for Drug Evaluation and Research finds that the OTC sale of a drug would be safe and effective, a proposed regulation switching the drug to OTC status must be written within twelve months, and a final regulation issued within twenty-four months, unless new information is discovered during the notice-and-comment period.

It is true that even when statutes are prescriptive, agency discretion remains. For example, if FDA was directed to hold hearings if an animal drug were found to be harmful to human health, the meaning of "harmful" would be contested. These determinations involve policy as well as scientific judgment.²⁸⁸ Deadlines can also improve timing at the expense of process.²⁸⁹ Nevertheless, the increased use of goal

283. 21 U.S.C. § 360b(b) (2012).

284. *Id.* § 360b(e).

285. M. Elizabeth Magill, *Congressional Control over Agency Rulemaking: The Nutrition Labeling and Education Act's Hammer Provisions*, 50 FOOD & DRUG L.J. 149, 154 (1995). Magill notes that the 1984 amendments to the Resource Conservation and Recovery Act contain several of these devices. *Id.* at 154 n.19.

286. *Id.* at 150.

287. The showing necessary to trigger a hearing would have to be precisely articulated so as to lessen the possibility of frivolous claims. For example, FDA only authorizes health claims made if "there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims"; this could be a model. 21 C.F.R. § 101.14(c) (2014).

288. *Cf.* Alon Rosenthal, George M. Gray & John D. Graham, *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269, 287 (1992) (explaining how scientists must make many policy judgments in performing quantitative risk assessment analysis on potential carcinogens).

289. *See* Jacob E. Gersen & Anne Joseph O'Connell, *Deadlines in Administrative Law*, 156 U. PA. L. REV. 923, 926 (2008).

statements and statutory deadlines would increase the incidence and effectiveness of private party oversight over agency inaction.

B. Strengthening the Petition Provision of the FDCA

Under 21 C.F.R. § 10.30(e), the FDA Commissioner has 180 days to approve, deny, or furnish a “tentative response” to a citizen petition filed with the Agency.²⁹⁰ The tentative response must “indicat[e] why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information,” and “may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.”²⁹¹

The tentative response provision should be eliminated, or altered to include a deadline for the Agency to submit an approval or denial. The Agency should also be required to inform the petitioning party when it plans to submit a final response. Under the petition provision to bring a species within the purview of the ESA, the relevant agency (either FWS or NMFS) has ninety days after a petition is submitted to determine whether the petition contained such information as to suggest that further review was warranted.²⁹² If the agency does move forward with review, it then has one year to decide whether to deny the petition, approve the petition, or decide that the petition is warranted but that a regulation implementing the final regulation cannot be promulgated immediately because of other pending proposals to add species to the endangered or threatened lists.²⁹³ Significantly, the provision states that if the agency finds that the petition should be granted but that a regulation cannot be promulgated immediately, the petition “shall be treated as a petition that is resubmitted to the Secretary . . . and that presents substantial scientific or commercial information that the petitioned action may be warranted.”²⁹⁴ This means that the twelve-month clock begins again, and a new deadline is placed on the agency to take action. These deadlines are a useful tool and should be expanded within the FDCA.²⁹⁵

There are counterarguments to the increased use of statutory deadlines. In their discussion of administrative deadlines, Jacob E. Gersen and Anne Joseph O’Connell note the importance of such deadlines, explaining that because Congress is often reluctant to impose substantive guidelines on agencies for reasons of agency discretion and expertise, “the most obvious way of controlling agency behavior is to regulate either the method or the timing of agency decision making.”²⁹⁶ However, Gersen and O’Connell find that while deadlines “do quicken agency action, at least to some degree,” they also “produce policy resulting from systematically different

290. 21 C.F.R. § 10.30(e)(2) (2014).

291. *Id.* § 10.30(e)(2)(iii).

292. 16 U.S.C. § 1533(b)(3)(A) (2012).

293. *Id.* § 1533(b)(3)(B).

294. *Id.* § 1533(b)(3)(C)(i).

295. It is important to note that the FDCA’s petition provision is in the form of a regulation, which is promulgated by the Agency. The ESA’s provision is statutory. To hold the Agency to a stricter response time, Congress may need to act.

296. Gersen & O’Connell, *supra* note 289, at 926.

decision-making processes that are less intensive than the norm. Deadlines seem to trade timing against process, and possibly even quality.”²⁹⁷

However, deadlines placed on the agency would provide private parties an important tool for compelling agency action. Parties are more likely to bring suit if a deadline is breached, and courts are better able to adjudicate such suits than those based on the merits.²⁹⁸ Because one of our concerns is that FDA has been able to escape any judicial scrutiny of its inaction, stricter deadlines would at least assist in bringing these issues before courts, which could then oversee the process.

C. Permitting Petitions to OIRA for the Review of the Denial of Rulemaking

In their book on the usefulness of cost-benefit analysis for the increased regulatory protection of health, safety, and the environment, Revesz and Livermore call for OIRA to take on an increased role in setting agency agendas.²⁹⁹ Revesz and Livermore believe that a petitioner should be able to appeal to OIRA if her petition for rulemaking is denied.³⁰⁰ If the petition is supported by credible cost-benefit analyses, “OIRA could then examine the cost-benefit analysis, and if there is a strong enough case for regulation, either mediate between the agency and the groups, or issue a finding of fact that the regulation is justified.”³⁰¹ This suggestion has merit, and could be strengthened by permitting an appeal if the agency has issued a place-holding response, like FDA’s “tentative response,” pursuant to 21 C.F.R. § 10.30(e).

OIRA was created in 1980 by the Paperwork Reduction Act,³⁰² and the office was initially occupied with reviewing agencies’ information collection requests.³⁰³ Under President Reagan, however, the Office became, and remains, charged with the centralized review of regulation. President Reagan issued Executive Order 12,291, which required agencies to prepare cost-benefit analyses for major rules and to send a copy of each proposed or final rule to OIRA before publication.³⁰⁴ The goals of centralized review during the Reagan era were twofold: (1) to coordinate the regulatory state and promote efficiency and cost effectiveness, and (2) to cut down on unnecessary (and overzealous) regulation.³⁰⁵ Critics have shown, however, that

297. *Id.* at 978. It is worth noting that in their empirical analysis, Gersen and O’Connell note that the agencies that faced the most deadlines in their period of study (1987–2003) were EPA, the Department of Commerce, the Department of the Interior, the Department of Transportation, USDA, and HHS. *Id.* at 939.

298. *See, e.g.*, Wendy Wagner, *Revisiting the Impact of Judicial Review on Agency Rulemakings: An Empirical Investigation*, 53 WM. & MARY L. REV. 1717, 1748–49 (2012).

299. REVEZ & LIVERMORE, *supra* note 281, at 173–74.

300. *Id.* at 174.

301. *Id.*

302. Paperwork Reduction Act of 1980, Pub. L. No. 96-511, 94 Stat. 2812 (codified as amended at 44 U.S.C. §§ 3501–3521 (2012)).

303. Curtis W. Copeland, *The Role of the Office of Information and Regulatory Affairs in Federal Rulemaking*, 33 FORDHAM URB. L.J. 1257, 1259 (2006).

304. *See id.* at 1261.

305. Bagley & Revesz, *supra* note 258, at 1264.

OIRA's main focus during the Reagan years was deregulation, and that the coordinating role of OIRA was deprioritized.³⁰⁶

President Clinton replaced Executive Order 12,291 with Executive Order 12,866, which maintained the framework of executive review of regulatory decision making, but increased transparency and introduced certain considerations in rulemaking review that arguably reduced the body's antiregulatory bias.³⁰⁷ President Obama reinstated Clinton's Executive Order 12,866, after changes made to the Office during the administration of George W. Bush.³⁰⁸

President Clinton's innovations notwithstanding, critics argue that OIRA review is structured to be antiregulation.³⁰⁹ The Office is also criticized for its lack of neutrality—"the available evidence supports the view that the mix of participants active in the OIRA review process heavily favors industry"³¹⁰—and for its political motives.³¹¹ It may seem counterintuitive to utilize OIRA to goad agency action, as it has often been viewed as antiregulatory by commentators. Indeed, as Sidney A. Shapiro has noted, "we do know that OIRA often intervenes to weaken proposed rules, and there is evidence that it almost always does so when it makes changes, at least when the changes involve significant rules."³¹²

Nevertheless, OIRA is still situated in a unique position to coordinate and rationalize agency action.³¹³ Revesz and Livermore suggest certain reforms that would improve OIRA's ability to assist in calibrating agency action, and coordinating interagency activity. These include increasing the transparency of OIRA deliberation, shifting OIRA's focus from curbing regulation to helping agencies prioritize agenda items, and emphasizing OIRA as a harmonizing body.³¹⁴ But even with no formal reform, reviewing denials of rulemaking petitions would serve OIRA's current goals, in that the costs of agency inaction can easily outweigh the benefits and the goals of the agencies charged with protecting the health and safety of the public.

306. See, e.g., *id.* at 1265.

307. See *id.* at 1266–67; Copeland, *supra* note 303, at 1271–72.

308. Office of Mgmt. & Budget, *Office of Information and Regulatory Affairs (OIRA) Q&A's*, WHITE HOUSE (Nov. 2009), http://www.whitehouse.gov/omb/OIRA_QsandAs.

309. E.g., Bagley & Revesz, *supra* note 258, at 1267–68. Bagley and Revesz argue that OIRA only reviews regulations to see if they are too stringent as opposed to too relaxed, that OIRA rarely if ever reviews decisions to deregulate, and that agency inaction is not scrutinized. These three factors bias the Office against regulation.

310. *Id.* at 1306.

311. Sidney A. Shapiro, *OMB and the Politicization of Risk Assessment*, 37 ENVTL. L. 1083, 1095 (2007) (arguing that the Office tried to impose additional scientific procedures on agencies for the purpose of slowing down regulation, and that it tried "to bend the risk assessment process away from the protective stance that Congress has required").

312. Sidney A. Shapiro, *The Complexity of Regulatory Capture: Diagnosis, Causality, and Remediation*, 17 ROGER WILLIAMS U. L. REV. 221, 240–41 (2012).

313. REVESZ & LIVERMORE, *supra* note 281, at 183 (stating OIRA is well placed to harmonize and coordinate agency functions given its original mission and present authority).

314. *Id.* at 171–83.

CONCLUSION

Two recent, high-profile incidents have demonstrated the importance of—but flaws in—the use of private party oversight to combat arbitrary inaction by FDA. Private enforcement has proven to be a weak counter to agency inertia in these and other circumstances, and it has been unable to avert the harm to the public health caused by this inaction. The failure of private party oversight reduces the transparency of agency decision making and diminishes the benefits of judicial review on the administrative process.

By comparing private enforcement under the FDCA to more successful private party activity under various environmental statutes, this Article shows that there are several steps that Congress can take to address agency inaction by FDA. These steps could help to restore the vitality of private party oversight, which is an integral part of the administrative enforcement scheme and benefits the public health along with the regulatory state.