

UNDUE PROCESS AT THE FDA: ANTIBIOTICS, ANIMAL FEED, AND AGENCY INTRANSIGENCE

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I. INTRODUCTION

Students of administrative law have, sadly, grown accustomed to agency proceedings that seem to last forever. Even in the ossified world of agency decision making, however, the pace of the Food and Drug Administration (FDA) in addressing the routine administration of antibiotics to animals destined for the food supply stands apart. For over forty years, the FDA has collected evidence that this agricultural practice contributes to the development of antibiotic-resistant infections in the human population.¹ Based on such evidence, the agency officially proposed to withdraw prior approvals for two antibiotics used in animal feed and offered to hold hearings on its proposal.² That was over thirty-five years ago, yet no hearings have commenced.

In a mark of dubious progress, the FDA has now officially announced that it does not intend to pursue the long-promised hearings.³ In late 2011, the agency denied two citizen petitions asking it to withdraw approvals for certain antibiotics used in animal feed⁴ and also formally withdrew the decades-old notices announcing public hearings.⁵ In both contexts, the FDA explained—without a trace of irony—that the process for withdrawing these approvals would *simply take too long* and that the agency was instead

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1. Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,266 (Oct. 21, 1977). *See also, e.g.*, U.K., Report of the Joint Committee on the Use of Antibiotics in Animal Husbandry and Veterinary Medicine (1969) (known as the “Swann Report,” after the head of the committee, Dr. M. M. Swann).

2. Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. at 56,265.

3. Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79,697 (Dec. 22, 2011) [hereinafter *FDA Withdrawal of Notices*].

4. Letter from Lesley Kux, Acting Assistant Comm’r for Policy, Food & Drug Admin., to Sarah Klein, Food Safety Program, Center for Science in the Public Interest, Original Docket No. 99G-0485/CP, New Docket No. FDA-1999-P-1286 (Nov. 7, 2011), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-1999-P-1286-0014> [hereinafter *CSPI Denial Letter*] (denying the Center for Science in the Public Interest’s petition to rescind FDA-approved uses of antibiotics in livestock feed); Letter from Lesley Kux, Acting Assistant Comm’r for Policy, Food & Drug Admin., to Andrew Maguire, Vice President of Env’t Health, Env’tl. Defense Fund, Original Docket No. 05P-0139/CP, New Docket No. FDA-2005-P-0007 (Nov. 7, 2011), *available at* <http://www.regulations.gov/#!documentDetail;D=FDA-2005-P-0007-0007> [hereinafter *EDF Denial Letter*] (denying the Environmental Defense Fund’s petition to withdraw FDA’s approval of use of antibiotics in livestock feed).

5. *FDA Withdrawal of Notices*, *supra* note 3, at 79,697, 79,698–70.

encouraging the animal feed industry to take voluntary measures to address the overuse of antibiotics.⁶ The FDA believed the process for withdrawing approvals would take too long because the agency thought itself legally bound to offer formal, trial-type, procedurally maximalist hearings on whether the relevant antibiotics were “safe” within the meaning of the Food, Drug, and Cosmetic Act (FDCA).⁷

A district court has rejected both of the FDA’s decisions. In complex but compelling rulings, a magistrate judge held that the FDA had to move forward with hearings on the safety of the routine administration of antibiotics to animals destined for the human food supply.⁸ The magistrate judge concluded that the FDA had already—in 1977 and beyond—found that routinely administering penicillin and tetracycline to animals for the purposes of promoting growth and preventing infection was not safe.⁹ The judge also concluded that the agency must initiate withdrawal proceedings for other antibiotics covered by the citizen petitions because its reasons for refusing to do so were arbitrary and capricious.¹⁰ These rulings are now on appeal in the Second Circuit.

Perhaps surprisingly, the core legal premise of the FDA’s decisions—its belief that it was legally obligated to hold formal hearings in the circumstances presented—has not been addressed, or even challenged, in the current legal proceedings.¹¹ In this article, I explain that this core legal premise is mistaken. The FDA is not required to hold formal evidentiary hearings on whether approvals for certain antibiotics should be withdrawn because the drugs are not “safe” within the meaning of the FDCA. Without this premise, the FDA’s decision to leave this problem to the industry that created it cannot stand.

Beyond its mistaken legal judgment, the FDA’s inertness on the problem of antibiotics in animal feed also reflects several pervasive

6. *CSPI Denial Letter*, *supra* note 4, at 3–4; *EDF Denial Letter*, *supra* note 4, at 3–4; *FDA Withdrawal of Notices*, *supra* note 3, at 79, 700 n.8.

7. *CSPI Denial Letter*, *supra* note 4, at 2; *EDF Denial Letter*, *supra* note 4, at 2; *FDA Withdrawal of Notices*, *supra* note 3, at 79, 700 n.8.

8. *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 872 F. Supp. 2d 318, 341–42 (S.D.N.Y. 2012); *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, No. 11 Civ. 3562 (THK), 2012 WL 983544, at *13 (S.D.N.Y. Mar. 22, 2012). *See also* *Natural Res. Def. Council v. U.S. Food & Drug Admin.*, No. 11 Civ. 3562 (JCF), 2012 WL 3229296, at *9 (S.D.N.Y. Aug. 8, 2012) (setting schedule for FDA compliance with previous orders).

9. *Natural Res. Def. Council, Inc.*, 2012 WL 983544, at *17.

10. *Natural Res. Def. Council, Inc.*, 872 F. Supp. 2d at 342.

11. The magistrate judge assumed, without discussion, that a “public evidentiary hearing” was required, if requested, before the FDA could withdraw approvals for animal drugs. *Natural Res. Def. Council, Inc.*, 2012 WL 983544, at *20; *see also* *Natural Res. Def. Council, Inc.*, 872 F. Supp. 2d at 341–42 (citing need for “formal withdrawal proceedings”).

problems in the modern administrative state. While not discussed in detail here, these problems include: institutional memory that does not adjust to changed circumstances; system-wide acceptance of indefinite delay in agency decision making; and statutory grants of epistemic authority to specific individuals within large regulatory institutions. Together, these problems conspire against what I think of as “moments of truth” in administrative law—moments when an administrative agency must confront evidence concerning a social problem it is charged with addressing, and speak the truth, as best it can, about it.

Before turning to the legal error underlying the FDA’s immobility on antibiotics in animal feed and to broader issues in administrative law reflected in the FDA’s inaction, I first review the regulatory history of the use of antibiotics in animal feed.

II. ANTIBIOTICS, ANIMAL FEED, AND THE FDA

During World War II, the United States government worked collaboratively with drug companies to develop, test, and make commercially available the antibiotics that were to become the wonder drugs of twentieth-century medicine. Following Congress’s then-recent instruction to the FDA¹² to evaluate the safety of drugs before allowing them on the market,¹³ the agency processed numerous approvals for penicillin-based drugs, used for both humans and animals, during the 1940s. In 1945, concerned that the manufacturing process for penicillin and drugs derived from penicillin did not produce drugs of consistent strength, quality, and purity, Congress passed a law requiring the FDA to issue regulations ensuring the safety and efficacy of these drugs, and to certify that batches of penicillin destined for the market met the agency’s requirements.¹⁴ At the same time, Congress also gave the FDA the authority to waive these requirements if it found that doing so would be safe.¹⁵

This waiver authority is how the FDA came to approve antibiotics used for purposes other than treating active infections in animals destined for the human food supply. Soon after farmers began to administer antibiotics to food animals for the purpose of treating infections, they discovered that the antibiotics inexplicably promoted growth in these animals.¹⁶ In 1951, the

12. The FDA’s responsibilities were at that time lodged in the Federal Security Administration.

13. Food, Drug & Cosmetic Act of 1938, ch. 675, 52 Stat. 1040.

14. Penicillin Amendment of 1945, ch. 281, § 3, 59 Stat. 463.

15. *Id.*

16. Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,265 (Oct. 21, 1977).

FDA waived the requirements of batch certification for certain antibiotics used for the purpose of promoting growth in food animals.¹⁷ Then, in 1953, the agency waived these requirements for antibiotics used for the purpose of preventing—rather than treating—certain infections in these animals.¹⁸ In both contexts, the waivers required that the supplement or feed used to deliver the antibiotics contain a denaturant making it unfit for human use.¹⁹ The head of the agency issued both waivers without any public process, explaining: “Notice and public procedure are not necessary prerequisites to the promulgation of this order, and I so find, since it was drawn in collaboration with interested members of the affected industries and since it would be against public interest to delay”²⁰

In this understated and industry-friendly fashion, the FDA approved what was to become the largest use of antibiotics in this country. Today, some 80% of the antibiotics used in the United States are given not to humans, but to animals destined for the human food supply.²¹ The great majority of these antibiotics given to animals are not meant to treat active infections, but are instead used to promote animal growth and to prevent infections in the microbe-rich environment of the factory farm.²²

The FDCA requires the FDA to withdraw approvals for animal drugs when new evidence emerges indicating that the drugs are not safe.²³ A few years after the FDA approved using antibiotics to promote growth and prevent infection in food animals, the agency began accumulating evidence that this practice contributed to the creation of antibiotic-resistant microbes and the development of antibiotic-resistant infections in the human

17. 16 Fed. Reg. 3647 (Apr. 28, 1951).

18. 18 Fed. Reg. 2335 (Apr. 22, 1953).

19. 16 Fed. Reg. 3647 (Apr. 28, 1951); 18 Fed. Reg. 2335 (Apr. 22, 1953).

20. 16 Fed. Reg. at 3648; *see also* 18 Fed. Reg. at 2336.

21. *See* Ralph Loglisci, *New FDA Numbers Reveal Food Animals Consume Lion's Share of Antibiotics*, CENTER FOR A LIVABLE FUTURE, <http://www.livablefutureblog.com/2010/12/new-fda-numbers-reveal-food-animals-consume-lion's-share-of-antibiotics> (citing FDA, SUMMARY REPORT ON ANTIMICROBIALS SOLD OR DISTRIBUTED FOR USE IN FOOD-PRODUCING ANIMALS (2009), <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM231851.pdf>) (last visited May 2, 2013).

22. Precise numbers are hard to come by, as information available from the FDA does not provide separate estimates for the amount of antibiotics used to promote growth and prevent infection. But informed estimates suggest that a sizeable majority of the total amount of antibiotics given to farm animals is for these purposes, and not to treat active infection. *See, e.g.*, Margaret Mellon, et al., Union of Concerned Scientists, *Hogging It!: Estimates of Antimicrobial Abuse in Livestock* (2001), http://www.ucsusa.org/assets/documents/food_and_agriculture/hog_front.pdf.

23. 21 U.S.C. § 360b(e)(1)(B) (2006).

population.²⁴ In 1973, armed with the emerging evidence on the link between antibiotics used in animal feed and antibiotic resistance in humans, the agency published a rule in the Code of Federal Regulations. This rule directed drug companies to come forward with evidence that their use of antibiotics in food animals for “subtherapeutic” purposes was safe within the meaning of the FDCA, and served notice that the companies’ approvals would be withdrawn if they did not present such evidence.²⁵ The agency defined “subtherapeutic” uses to include the promotion of growth and the prevention of infection.²⁶ In 1977, on the basis of evidence linking these uses to the development of antibiotic-resistant infections in humans, the FDA announced that it was proposing to withdraw its approval for the use of penicillin and tetracycline in food animals for purposes other than treating active infections. It also stated that it would hold a public hearing on the proposed withdrawals.²⁷ However, the FDA withdrew this hearing notice in 2011, explaining that the formal hearings it thought the FDCA required would take too long and that, therefore, voluntary measures by the animal feed industry were a better idea.

It bears emphasizing that the FDA approved using antibiotics for subtherapeutic purposes without holding a hearing, but has refused to consider withdrawing these approvals because it would need to hold a hearing.

In the decades between the FDA’s 1977 notices of hearing and its 2011 withdrawal of those notices, the agency continued to accumulate evidence of the link between administering subtherapeutic doses of antibiotics to food animals and the development of antibiotic-resistant infections in the human population.²⁸ Indeed, the FDA itself repeatedly acknowledged the

24. Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,266 (Oct. 21, 1977). *See, e.g.*, U.K., Report of the Joint Committee on the Use of Antibiotics in Animal Husbandry and Veterinary Medicine (1969).

25. Antibiotics and Sulfanamid Drugs in the Feed of Animals, 38 Fed. Reg. 9,811, 9,813 (Apr. 20, 1973) (codified at former 21 C.F.R. § 135.109; renumbered at 21 C.F.R. § 558.15).

26. *Id.* *See also* Tetracycline, 42 Fed. Reg. at 56,265 (“subtherapeutic” means “lower levels than therapeutic levels needed to cure disease”) (emphasis added).

27. Penicillin-Containing Premixes, 42 Fed. Reg. 43,772, 43,792 (Aug. 30, 1977); Tetracycline, 42 Fed. Reg. at 56,288.

28. For discussion of the physical mechanisms by which use of antibiotics in animal feed can cause the development of antibiotic-resistant disease in humans and the scientific evidence that such mechanisms are indeed producing antibiotic-resistant strains of microbes in the human population, *see, e.g.*, Meghan F. Davis & Lainie Rutkow, *Regulatory Strategies To Combat Antimicrobial Resistance of Animal Origin: Recommendations for a Science-Based U.S. Approach*, 25 TUL. ENVTL. L.J. 327, 334 (2011) (describing the processes that lead to antimicrobial resistance in humans); Vanessa K.S. Briceno, *Superbug Me: The FDA’s Role in the Fight Against Antibiotic Resistance*, 9 NYU J. LEGIS. & PUB. POL’Y 521, 521 (2005) (chronicling the FDA’s decision to withdraw approval for a livestock antibiotic based on concerns about antibiotic resistance in humans); Arielle Lessing, *Killing Us Softly: How Subtherapeutic Dosing of Livestock Causes Drug-Resistant Bacteria in Humans*, 37 B.C. ENVTL. AFF. L.

link between herd- and flock-wide administration of antibiotics to food animals and the development of antibiotic-resistant disease in humans.²⁹ Nevertheless, even before its official withdrawal of the 1977 hearing notices and embrace of voluntary measures, the agency had mostly relied on voluntary efforts by the animal feed industry to address the problem of overuse of antibiotics for food animals. The agency did engage in more direct action in one instance by withdrawing approval for the use of enrofloxacin in poultry.³⁰ In that case, the proceedings for withdrawing the approval stretched on for five years—a fact emphasized by the FDA in 2011 in declining to take on that procedural burden again.³¹ But, as I next explain, the FDA is mistaken in believing that it must offer an opportunity for formal evidentiary hearings before withdrawing approvals for animal drugs.

III. THE LEGAL CASE AGAINST FORMAL HEARINGS

In refusing to initiate regulatory action on antibiotics in animal feed, the FDA stated that formal evidentiary hearings would be required before

REV. 463, 464 (2010) (linking the rise of antibiotic-resistant strains of bacteria in humans to the practice of administering subtherapeutic doses of antibiotics to livestock on industrial farms); Robyn L. Goforth & Carol R. Goforth, *Appropriate Regulation of Antibiotics in Livestock Feed*, 28 B.C. ENVTL. AFF. L. REV. 39, 41 (2000) (citing a growing body of research linking the dwindling effectiveness of antibiotics in treating human borne disease and the increased levels of antibiotics added to animal feed).

29. See, e.g., *Preservation of Antibiotics for Medical Treatment Act of 2009: Hearing on H.R. 1549 Before the Comm. on Rules*, 111th Cong. 11 (2009) (statement of Joshua Sharfstein, M.D) available at http://democrats.rules.house.gov/111/ohhearings/111_hr1549_oj.pdf; (“Antimicrobial use in animals has been shown to contribute to the emergence of resistant microorganisms that can infect people. The inappropriate nontherapeutic use of antimicrobial drugs of human importance in food-producing animals is of particular concern.”); FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY #209, THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS, at 17 (Apr. 13, 2012) <http://www.fda.gov/downloads/animalveterinary/guidancecompliancencforcement/guidanceforindustry/ucm216936.pdf> (“FDA has considered all available information [on] the public health concerns associated with the use of medically important antimicrobial drugs in food-producing animals” and believes that the weight of scientific evidence supports the recommendations outlined in this guidance document,” which were to achieve the judicious use of such drugs); *CSPI Denial Letter*, *supra* note 4, at 1 (“we share your concern about the use of medically important antimicrobial drugs in food-producing animals for growth promotion and feed efficiency. . . .”); *Id.* at 3 (embracing goal of “judicious use of medically-important antimicrobials”); *EDF Denial Letter*, *supra* note 4, at 1, 4 (supporting the “judicious use of medically-important antimicrobials”).

30. FOOD & DRUG ADMIN. COMM’R, DOCKET NO. 2000N-1571, FINAL DECISION ON THE WITHDRAWAL OF APPROVAL OF THE NEW ANIMAL DRUG APPLICATION FOR ENROFLOXACIN IN POULTRY 3 (2000), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2000-N-0109-0137>[hereinafter FINAL DECISION ON ENROFLOXACIN].

31. *CSPI Denial Letter*, *supra* note 4, at 3; *EDF Denial Letter*, *supra* note 4, at 3.

the agency could withdraw any approvals for these antibiotics.³² The agency explained in some detail how such procedurally intensive hearings would drain time and resources, which the agency thought would be better spent pursuing voluntary efforts by the animal feed industry.³³ The agency did not, however, explain why it thought itself legally required to hold such formal hearings in the first place. Strikingly, the agency simply asserted the point, without citation to any source—legal or otherwise.³⁴ In a previous decision on the same subject, the agency explained that it was “required by statute” to hold a formal evidentiary hearing before withdrawing an approval for a new drug, and cited section 512(e)(1) of the FDCA—which merely requires “notice and opportunity for hearing” on such withdrawals³⁵—in support of the proposition that a “formal administrative hearing” was required.³⁶

As I argue here, however, developments in administrative law over the past several decades have dramatically relaxed legal requirements for formal agency proceedings.³⁷ Moreover, nothing in the FDCA requires the FDA to ignore these developments and cling to formal processes. The FDA’s own regulations give it the discretion to decline formal hearings when they are not statutorily required. Finally, the FDA could not non-arbitrarily claim that it is better to use more formal processes when informal ones would suffice.

A. Administrative Law After the 1950s

Anyone with even a passing familiarity with developments in administrative law in the past several decades will find the FDA’s legal stance at least curious. One of the standard—and also true—accounts of the profound changes in the administrative state during the last half of the

32. *CSPI Denial Letter*, *supra* note 4, at 2; *EDF Denial Letter*, *supra* note 4, at 2; *FDA Withdrawal of Notices*, *supra* note 3, at 79,699, 79,700 n.8.

33. *CSPI Denial Letter*, *supra* note 4, at 2; *EDF Denial Letter*, *supra* note 4, at 2; *FDA Withdrawal of Notices*, *supra* note 3, at 79,700 n.8.

34. *CSPI Denial Letter*, *supra* note 4, at 2; *EDF Denial Letter*, *supra* note 4, at 2; *FDA Withdrawal of Notices*, *supra* note 3, at 79,700 n.8.

35. 21 U.S.C. 362b(e)(1).

36. Letter from Stephen F. Sundlof, Dir., Center for Veterinary Med., Food & Drug Admin. to Margaret Mellon, Dir., Food and Env’t Program, Union of Concerned Scientists, Docket No. 99 - 0485/CP, at 2 (Feb. 28, 2001), <http://www.fda.gov/ohrms/dockets/dailys/01/Mar01/030201/let0006.pdf> [hereinafter *FDA Tentative Response to CSPI Petition*] (providing a tentative response to CSPI’s citizen petition to withdrawal approvals for subtherapeutic use of antibiotics in livestock).

37. See Alan Morrison, *The Administrative Procedure Act: A Living and Responsive Law*, 72 VA. L. REV. 253, 254–58 (1986) (detailing the shift from adjudication to rulemaking among federal agencies).

twentieth century holds that, during this period, many, if not most, agencies moved toward rulemaking and away from adjudication,³⁸ and toward informal processes and away from formal ones.³⁹ These shifts made the agency that chooses to set general policy through adjudication rather than rulemaking an odd bird, and the agency that chooses formal over informal processes the administrative equivalent of the dodo—exotic, ungainly, of a different era.

We will return to the FDA in a moment. But first, it will be useful to trace the foundations of the developments in administrative law just described.

As far back as the 1950s, administrative agencies—faced with regulatory responsibilities of daunting complexity and numerosity—began to simplify their work by deciding central issues in advance through informal rulemaking. In an important early case, *United States v. Storer Broadcasting Co.*, the Supreme Court upheld the Federal Communications Commission's decision to reduce, by rule, the number of television outlets a single licensee could control. This holding preordained the outcome of an adjudicatory proceeding in which a licensee exceeding the new limits was seeking yet another broadcast license.⁴⁰ Likewise, in *FPC v. Texaco*, the Court affirmed a Federal Power Commission rule that set new conditions for granting certificates for gas pipelines—again, obviating the need for individual, trial-type adjudications.⁴¹ The Supreme Court eventually upheld rules reducing the ability of applicants for government licenses and other benefits to argue for exceptions to generally applicable administrative rules in adjudicatory proceedings.⁴² The Court's endorsement of agencies' growing shift from adjudication to rulemaking was echoed and extended by Congress in dozens of statutes passed in the 1960s and 1970s, giving agencies broad-ranging authority to act through rules.⁴³

38. See, e.g., Antonin Scalia, *Vermont Yankee: the APA, the D.C. Circuit, and the Supreme Court*, 1978 SUP. CT. REV. 345, 376 (1978) (noting the “accelerating flight away from” adjudicatory proceedings to rulemaking among federal agencies); Morrison, *supra* note 37, at 254–58 (detailing the shift from adjudication to rulemaking among federal agencies).

39. See, e.g., Robert W. Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 CALIF. L. REV. 1276, 1314–15 (1972) (arguing that notice-and-comment rulemaking is flexible and allows for more agency input, but is lacking in legislative acceptance).

40. *United States v. Storer Broad. Co.*, 351 U.S. 192, 202–03 (1956).

41. *Fed. Power Comm'n v. Texaco, Inc.*, 377 U.S. 33, 39 (1964).

42. *Fed. Comm'n Comm'n v. WNCN Listeners Guild*, 450 U.S. 582, 584–86 (1981); *Heckler v. Campbell*, 461 U.S. 458, 467 (1983).

43. See, e.g., Clean Air Act, 42 U.S.C. §§ 7401–7642 (2006) (authorizing the Administrator to promulgate procedural and administrative rules); Occupational Safety and Health Act, 29 U.S.C. §§ 651–678 (2006); Consumer Product Safety Act, 15 U.S.C. §§ 2051–2089 (2006) (authorizing the Commission to establish safety standard rules); National Traffic and Motor Vehicle Safety Act, 15

The Supreme Court also spurred the shift from formal to informal procedures in agency decision making through decisions in the 1970s easing and even undoing requirements for formal procedures. A huge turn came in *United States v. Florida East Coast Railway*,⁴⁴ in which the Court held that an agency was not required to undertake formal rulemaking—complete with trial-type hearings⁴⁵—under the Administrative Procedure Act (APA) if its enabling statute merely required a “hearing” of an unspecified nature.⁴⁶ Because the statute at issue in that case, the Interstate Commerce Act, required only a “hearing,” the Court concluded that the Interstate Commerce Commission was within its rights in proceeding via informal rulemaking, and not via the formal rulemaking processes of the APA.⁴⁷ Although the Court insisted that the words of the APA—“on the record” and “after . . . hearing”—were not “words of art” and that “statutory language having the same meaning” could trigger the APA’s formal rulemaking requirements,⁴⁸ the fact remains that no statute lacking the words “on the record” has been held to require formal rulemaking under the APA since *Florida East Coast Railway*.⁴⁹

The Court likewise held that the bare requirement of a “hearing” in the Interstate Commerce Act did not, by itself, obligate the Interstate Commerce Commission (ICC) to offer a more elaborate process than it had in that case—a process that included only notice of the Commission’s tentative conclusions and an opportunity to make written objections.⁵⁰ The Court thought it significant that the ICC’s decision in that case was “applicable across the board” and that “[n]o effort was made to single out any particular railroad for special consideration based on its own peculiar circumstances.”⁵¹ The “factual inferences” the ICC relied on, the Court

U.S.C. §§ 1381–1426 (1970) (authorizing the Secretary to promulgate appropriate rules and regulations).

44. *United States v. Fla. E. Coast Ry.*, 410 U.S. 224 (1973). The Court’s decision in *Florida East Coast Railway* was presaged—by the Court’s lights, even controlled—by its decision the preceding term in *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 758 (1972).

45. *Fla. E. Coast Ry.*, 410 U.S. at 227, nn. 3–4 (quoting procedural requirements for formal rulemaking and adjudication under APA).

46. *Id.* at 227–28.

47. *Id.* at 235.

48. *Id.* at 238.

49. GARY LAWSON, *FEDERAL ADMINISTRATIVE LAW* 229 (5th ed. 2009). For an instructive example of the courts’ ease, after *Florida East Coast Railway*, in denying trial-type procedures under the APA in the rulemaking context, see *AT&T v. FCC*, 572 F.2d 17, 22 (2d Cir. 1978) (noting that the Communications Act required only that rules be made “after full opportunity for hearing,” and not “on the record,” and concluding “[t]herefore,” that the APA does not require trial-type procedures)(quoting 47 U.S.C. § 205(a)).

50. *Fla. E. Coast Ry.*, 410 U.S. at 235.

51. *Id.* at 246.

explained, “were used in the formulation of a basically legislative-type judgment, for prospective application only, rather than in adjudicating a particular set of disputed facts.”⁵² In due process terms, the Court placed the ICC’s decision on the side of *Bi-Metallic Investment Co.*⁵³—requiring “no hearing at all”⁵⁴ for generalized policy judgments—rather than on the side of *Londoner v. Denver*, which requires an “argument however brief,” supported, “if need be, by proof, however informal”⁵⁵ in “proceedings designed to adjudicate disputed facts in particular cases . . .”⁵⁶ Therefore, the Commission was not required to hold formal, trial-type hearings before coming to a decision on the matters at hand under the APA or the Interstate Commerce Act.

A similar story, tracing the move from formality to informality, holds for adjudication. Although the Supreme Court, in *Florida East Coast Railway*, distinguished rulemaking from adjudication and suggested that the procedural requirements for the latter could be greater than those for the former,⁵⁷ the Court has—quite remarkably—never taken up the question whether the holding of *Florida East Coast Railway* applies to adjudication as well as rulemaking. The lower courts have, however, embraced the implications of *Florida East Coast Railway* in the adjudicatory context. One early decision, holding that statutes requiring “hearings” for adjudicatory decisions must be presumed to require formal hearings,⁵⁸ has been overruled.⁵⁹ Another case has held that *Florida East Coast Railway* requires the opposite presumption—that, unless Congress clearly indicates otherwise, the bare requirement of a “hearing” in the adjudicatory context means that only informal, not formal, proceedings are required.⁶⁰ Several courts, bowing to the dominance of *Chevron* in modern administrative law, have held that an agency’s views on whether formal procedures are required for adjudication are entitled to deference so long as they are reasonable.⁶¹

52. *Id.*

53. *Bi-Metallic Inv. Co. v. State Bd. of Equalization*, 239 U.S. 441, 445 (1915).

54. *Fla. E. Coast Ry.*, 410 U.S. at 245.

55. *Londoner v. City and Cnty. of Denver*, 210 U.S. 373, 386 (1908).

56. *Florida E. Coast Ry.*, 410 U.S. at 245.

57. *Id.* at 244–45.

58. *Seacoast Anti-Pollution League v. Costle*, 572 F.2d 872, 877–78 (1st Cir. 1978).

59. *Dominion Energy Brayton Point v. Johnson*, 443 F.3d 12, 18–19 (1st Cir. 2006).

60. *City of W. Chicago, Ill. v. Nuclear Regulatory Comm’n.*, 701 F.2d 632, 641 (7th Cir. 1983).

61. *Dominion Energy Brayton Point*, 443 F.3d at 18–19; *Chemical Waste Mgmt. v. Env’tl. Prot. Agency*, 873 F.2d 1477, 1485 (D.C. Cir. 1989) (applying *Chevron* deference to rules promulgated by the EPA); *Sibley v. U.S. Dep’t of Educ.*, 913 F. Supp. 1181, 1187 (N.D. Ill. 1995) (deferring to the Department of Education’s reasonable interpretation of its own regulations); *Shell Oil v. U.S. Dep’t. of Labor*, 106 F. Supp. 2d 15, 20 (D.D.C. 2000) (applying *Chevron* deference to OSHA’s reading of OSHA Act) (quoting *Davis v. Latschar*, 202 F.3d 359, 364 (D.C.C. 2000)).

Every case applying this framework has upheld the agency's choice to use informal processes rather than formal ones.

The move toward informal process gained additional, and considerable, momentum from the Supreme Court's 1978 decision in *Vermont Yankee v. Natural Resource Defense Council*.⁶² There, the Court famously shut down the D.C. Circuit's efforts to bring more formal procedures—such as depositions and cross-examination—to informal rulemaking.⁶³ In the absence of a constitutional constraint, “extremely compelling circumstances,” or a statute expressly requiring more formal procedures, the agency—not the judiciary—was the master of its own procedures; so long as it offered the statutory minima, its procedural obligations were satisfied.⁶⁴ No longer would agencies undertaking “informal” rulemaking proceedings need to import trial-type features. Of course, even after *Vermont Yankee*, courts piled burdensome requirements of disclosure and explanation on top of the bare-bones requirements of the APA.⁶⁵ But *Vermont Yankee* did put a stop to the courts' efforts to turn informal rulemaking into the trial-like endeavor eschewed in *Florida East Coast Railway*.

Vermont Yankee also effectively embraced the practice of using rulemaking proceedings to determine generic factual issues relevant to individual adjudicatory proceedings. There, the Nuclear Regulatory Commission had issued a rule that provided numerical values for the environmental impacts of the uranium fuel cycle, including the long-term disposal of high-level radioactive waste.⁶⁶ The Commission intended to use these values in the cost-benefit analysis for individual licensing proceedings.⁶⁷ Thus, even where formal evidentiary hearings were thought to be required in individual proceedings, an agency could narrow the range of factual issues to be determined in those proceedings by conducting a generic rulemaking in advance of the individual proceedings.⁶⁸

62. *Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 544 (1978).

63. See, e.g., Gillian E. Metzger, *The Story of Vermont Yankee: A Cautionary Tale of Judicial Review and Nuclear Waste*, in *ADMINISTRATIVE LAW STORIES* 125, 153–54 (Peter L. Strauss ed., 2006) (discussing the Supreme Court's support of agency discretion to use information rulemaking procedures).

64. *Vermont Yankee Nuclear Power Corp.*, 435 U.S. at 543, 549 n.21.

65. See, e.g., Jack M. Beermann & Gary Lawson, *Reprocessing Vermont Yankee*, 75 *GEO. WASH. L. REV.* 856, 860, 876, 901 (2007) (noting that despite the decision in *Vermont Yankee*, courts continue to import adjudicative processes into administrative proceedings).

66. *Vermont Yankee Nuclear Power Corp.*, 435 U.S. at 528, 530.

67. *Id.* at 528.

68. The Nuclear Regulatory Commission eventually concluded that its enabling statute did not, in fact, require formal hearings on various nuclear licensing matters, and issued a rule streamlining its

During this period, agencies also found ways to make even their formal proceedings more streamlined. Indeed, the FDA itself was a pioneer in importing the procedural innovations of the Federal Rules of Civil Procedure—including the avoidance of trial-type proceedings through mechanisms like summary judgment—into the agency’s internal decision making framework.⁶⁹ Faced with thousands of applications for approval of new drugs, the agency found that it simply could not expeditiously perform its job of review while simultaneously holding formal hearings on drug applications.⁷⁰ Thus, the agency turned to administrative summary judgment as a way out of this predicament—a solution affirmed by the Supreme Court in 1973.⁷¹

In the same period, the FDA—bruised by its superintending of absurdly prolonged formal hearings, including, most infamously, an eleven-year administrative odyssey exploring the foundational question of the percentage of peanuts that peanut butter must contain⁷²—was encouraged to introduce legal adjustments aimed in part at avoiding the procedural quagmires created by formal hearings.⁷³

Through it all, however, the FDA has steadfastly maintained that it may not withdraw approval for a drug given to animals unless it first holds a formal evidentiary hearing.⁷⁴ The large-scale shifts in administrative law, from adjudication to rulemaking and from formal to informal decision-making frameworks, have left the agency unmoved on this matter. Even the FDA’s own procedural innovations, undertaken in the spirit of expedition and experimentation, have not found their way into this corner of the agency’s work. The agency’s unyielding legal position—that formal

procedures. Nuclear Regulatory Comm’n, Changes to Adjudicatory Process, 69 Fed. Reg. 2,182 (Jan. 14, 2004). The First Circuit upheld this rule without deciding whether the formal hearing requirements of the APA were mandatory. Regardless, the court decided the Commission’s new procedures satisfied APA requirements for formal hearings. *Citizens Awareness Network v. United States*, 391 F.3d 338, 355 (1st Cir. 2004).

69. Charles C. Ames & Steven C. McCracken, *Framing Regulatory Standards to Avoid Formal Adjudication: The FDA As a Case Study*, 64 CALIF. L. REV. 14 (1976).

70. Robert W. Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 TEX. L. REV. 1132, 1135 (1972).

71. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 622 (1973). For a thoughtful treatment of another procedural innovation offered by the FDA during this period, a hearing before a Public Board of Inquiry comprised of scientists, see Sidney A. Shapiro, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA’s Public Board of Inquiry*, 1986 DUKE L.J. 288, 289 (1986).

72. Hamilton, *supra* note 70, at 1142–45.

73. Richard A. Merrill & Earl M. Collier, Jr., “*Like Mother Used to Make*”: *An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 584 (1974).

74. See, e.g., *EDF Denial Letter*, *supra* note 4, at 2 (stating that the withdrawal process requires a statutorily mandated hearing but does not specifically cite the statute).

hearings must precede the withdrawal of approval for animal drugs⁷⁵—is like an administrative-law time capsule, filled decades ago and untouched ever since.

B. The FDCA and the Meaning of a “Hearing”

Nothing in the FDCA requires the FDA to cling so tenaciously to formal procedures. First of all, it has been clear for decades that whatever procedural requirements the FDCA sets for individual proceedings, the FDA may undertake generic rulemaking in order to limit the issues to be resolved in individual proceedings. The FDA has general authority to issue rules,⁷⁶ and those rules may be issued after informal, notice-and-comment processes. Nothing prevents the FDA from initiating a rulemaking proceeding on the risks posed by the administration of antibiotics to food animals for the purposes of promoting growth and preventing infections. The FDA may later apply the findings of that proceeding to any decision whether to withdraw approval of a specific antibiotic—or even apply those findings to decline an individual hearing altogether. Years ago, the D.C. Circuit suggested just this solution to the FDA’s difficulties in acting promptly on initial drug approvals: “The [FDA] could alleviate its own inefficiencies, perhaps through generic rulemaking”⁷⁷ This advice applies just as well to decisions about antibiotics in animal feed, where generic issues of safety predominate. As the magistrate judge in *NRDC v. FDA* noted, “[t]here is no evidence that the scientific studies undertaken by various groups and government bodies draw different conclusions for different antibiotics. Indeed, the FDA appears to accept that all of the classes of antibiotics at issue pose a similar threat, as its proposed voluntary approach makes no distinction.”⁷⁸

Even so, unaccountably, the FDA has failed to recognize the availability of generic rulemaking to address the risks posed by antibiotics in animal feed. Moreover, it has doubled down on its 1950s-era understanding of American administrative law by asserting that it must hold formal hearings, not even on whole classes of antibiotics at once, but on a

75. See e.g., *CSPI Denial Letter*, *supra* note 4, at 2 (stating that the FDA must conduct a formal evidentiary process before withdrawing animal drug approvals).

76. 21 U.S.C. §371(a) (2006).

77. *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (citing *Heckler v. Campbell*, 461 U.S. 458, 468 (1983)).

78. *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 872 F. Supp. 2d 318, 339 n.24 (S.D.N.Y. 2012).

“drug by drug” basis.⁷⁹ The FDA’s antiquated view of its procedural obligations has blinded it to the regulatory possibilities posed by generic rulemaking on common scientific issues. These possibilities are open to the agency regardless of whether the FDCA requires formal hearings in individual proceedings to withdraw approvals for animal drugs.

In any event, the FDCA does not require formal hearings in this context. The FDA’s authority to withdraw approvals for animal drugs comes from section 512(e)(1) of the Food, Drug and Cosmetic Act.⁸⁰ This provision states that the “Secretary” (of the Department of Health and Human Services, who has in turn delegated this authority to the FDA Commissioner⁸¹) shall withdraw approval for animal drugs in several circumstances. The language pertinent to the problem of antibiotics used in animal feed is as follows:⁸²

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds . . . (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved⁸³

Notice what this provision does not say. It does not specify any particular format for the required “hearing.” It does not say that the agency’s ultimate decision is to be “on the record.” In short, it does not contain anything close to the “magic words” that courts since *Florida East Coast Railway* have

79. FDA Tentative Response to 2005 Petition (Oct. 4, 2005) (“For legal, scientific and resource reasons, withdrawal actions for the petitioned drugs need to be considered on a drug by drug basis.”). The magistrate judge in *NRDC v. FDA* expressed some mystification at the FDA’s assertion on this point. *Natural Res. Def. Council, Inc.*, 872 F. Supp. 2d at 339 n.24.

80. *Id.*

81. FOOD & DRUG ADMIN., FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY, REGULATORY DELEGATIONS OF AUTHORITY TO THE COMMISSIONER FOOD AND DRUGS, § 1410.10(1)(A)(1) (May 18, 2005), available at <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm> (delegating HHS Secretary’s authority over functions under the FDCA to the FDA Commissioner).

82. *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, No. 11 Civ. 3562 (THK), 2012 WL 983544, at *9 (S.D.N.Y. Mar. 22, 2012).

83. 21 U.S.C. § 355(e)(2006).

looked for before requiring formal hearings.⁸⁴ Moreover, the provision stands in contrast to another section of the FDCA, which does contain the special language. Section 701(e)(3)⁸⁵—specifically cited in *Florida East Coast Railway* for the proposition that some statutes did indeed use the words the Court was looking for⁸⁶—states that certain FDA decisions must be accompanied by a “public hearing” if one is requested and must be made “only on substantial evidence of record at such hearing.”⁸⁷

In section 701(e)(1), Congress identified the FDA decisions to be made “on substantial evidence of record” under section 701(e)(3).⁸⁸ The extreme specificity with which Congress identified these decisions indicates that Congress acted with precision and care.⁸⁹ The specific decisions to be accompanied by a hearing on the evidence of record concern the labeling of food offered for special dietary uses,⁹⁰ emergency permit control of classes of food contaminated with micro-organisms,⁹¹ tolerances for poisonous ingredients in food,⁹² drugs adulterated on account of their departures from specifications in official compendia,⁹³ drugs misbranded on account of their propensity to deteriorate,⁹⁴ definitions and standards of identity for dairy products,⁹⁵ and definitions and standards of identity for “maple sirup.”⁹⁶ Out of all of the hundreds of regulatory decisions contemplated by the FDCA, Congress plucked these—and these alone—out of the mass and specified that they would be preceded by hearings on the evidence of record. Tellingly for present purposes, decisions to withdraw approval for animal drugs do not appear in section 701(e)(1)’s selective list.

84. *Mobil Oil Corp. v. Fed. Power Comm’n*, 483 F.2d 1238, 1250 (D.C. Cir. 1973). An excellent treatment of the implications of *Florida East Coast Railway* for the FDA’s refusal to act on antibiotics in animal feed is offered by Marc Levitt, *FDA and Antibiotics in Livestock: Decades in Violation of the Law* (Apr. 30, 2012) (unpublished manuscript on file with the author).

85. 21 U.S.C. § 371(e)(3) (2006).

86. *Fla. E. Coast Ry.*, 410 U.S. at 237–38 (citing 21 U.S.C. § 371(e)(3)).

87. 21 U.S.C. § 371(e)(3).

88. *See* 21 U.S.C. § 371(e)(1) (specifying the agency actions subject to certain procedural requirements); 21 U.S.C. § 371(e)(2) (offering opportunity to those adversely affected by decisions identified in section 701(e)(1) to request “public hearing”); 21 U.S.C. § 371(e)(3) (specifying hearing requirements that take hold “after such request for a public hearing”).

89. Congress identified the relevant decisions in section 701(e)(1) by referring to the FDCA provisions governing these decisions. *See* 21 U.S.C. § 371(e)(1).

90. 21 U.S.C. § 371(e)(1) (citing 21 U.S.C. 343(j) (2006)).

91. *Id.* (citing 21 U.S.C. 344(a) (2006)).

92. *Id.* (citing 21 U.S.C. 346 (2006)).

93. *Id.* (citing 21 U.S.C. 351(b) (2006)).

94. *Id.* (citing 21 U.S.C. 352(h) (2006)).

95. *Id.* (citing 21 U.S.C. 341 (2006)).

96. *Id.* (citing 21 U.S.C. 341); *see also* 21 C.F.R. §168.140 (2012) (defining “maple sirup”).

Also probative is the fact that another provision of the FDCA explicitly imports the requirements of section 701(e). The provision on color additives for foods, drugs, and cosmetics expressly states that section 701(e) applies to the issuance, amendment, or repeal of regulations under that provision.⁹⁷ This provision also expressly adopts the APA's requirements on burdens of proof and other matters in formal hearings.⁹⁸ Section 512(e)(1), on withdrawing approvals for new animal drugs, does not adopt section 701(e) and its reference to "evidence of record."⁹⁹

Nothing else in the FDCA suggests that formal hearings are required when the FDA withdraws approvals for animal drugs. Section 512(e)(3) does direct that an order to withdraw an approval "state the findings upon which it is based."¹⁰⁰ But section 701(e)(1) does so as well—in the same sentence in which it requires that the decisions it covers be made on "evidence of record."¹⁰¹ Congress's failure to include the requirement of on-the-record findings in section 512(e)(3), when it did include it in section 701(e)(1), warrants the conclusion that the simple requirement of "findings" does not smuggle into section 512(e) a requirement for formal, trial-type hearings.¹⁰² Nor does section 701(c)'s requirement that "[h]earings authorized or required" by the FDCA be "conducted by the Secretary or such officer or employee as he may designate for the purpose"¹⁰³ create such a requirement. Although the Center for Veterinary Medicine has listed this provision as "authority" for its policies on the management of formal evidentiary hearings,¹⁰⁴ the statutory instruction that "hearings" be conducted by the Secretary or someone designated by the Secretary says nothing about the formality or informality of such hearings.¹⁰⁵ Indeed, in *Florida East Coast Railway*, the relevant provision of the Interstate Commerce Act directed the ICC itself to make the decision under review.¹⁰⁶ The Supreme Court did not so much as mention the possibility that the designation of the Commission as the relevant decision maker meant that formal, not informal, rulemaking procedures were required for this decision.

97. *Id.* § 379e(d) (2006).

98. *Id.* § 379e(d)(2) (citing 5 U.S.C. 556(d)).

99. Food, Drug, & Cosmetic Act § 512(e)(1), 21 U.S.C. 360(b) (2006).

100. 21 U.S.C. § 360b(e)(3) (2006).

101. *Id.* § 371(e)(3).

102. *Id.* § 360b(e).

103. *Id.* § 371(c).

104. FDA, CENTER FOR VETERINARY MEDICINE, PROGRAM POLICY AND PROCEDURES MANUAL, 1240.3670, section 2(a)(5) (Nov. 5, 2009), <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/ucm046893.pdf>.

105. 21 U.S.C. § 371(e)(3).

106. *Fla. E. Coast. Ry.*, 410 U.S. at 234–35, 241–42 (citing 49 U.S.C. 1(14)(a) (1966)); 24 Stat. 379, 385 (1887).

Although the FDCA does not define the term “hearing” in section 512(e), the statute does define the term “informal hearing” and it states certain requirements for this kind of hearing.¹⁰⁷ According to the statutory definition, an “informal hearing” is one “not subject to section 554, 556, or 557 of title 5” of the United States Code—the APA provisions on formal administrative proceedings.¹⁰⁸ Some provisions of the FDCA specifically require an “informal hearing” before certain decisions can be made.¹⁰⁹ Section 512(e) requires only a “hearing,” pure and simple—not a hearing on “evidence of record,” and not an “informal hearing” as specified elsewhere.¹¹⁰

The absence of the words “on the record” or words of equivalent clarity dooms any argument that the APA requires the FDA to hold formal evidentiary hearings before it withdraws its approval of an animal drug.¹¹¹ With the APA out of the picture, the only question is whether the FDCA’s requirement of a “hearing,” standing alone, requires formal, trial-type processes and, if so, which ones. The latter question becomes important once the APA is out of the picture because the APA brings with it a long list of off-the-shelf procedural requirements for formal agency proceedings. These requirements include prohibitions on ex parte contacts, an impartial decision maker, formal findings, and more.¹¹² In contrast, apart from requiring a “hearing” and “findings,” the FDCA simply does not identify any specific procedures that must attend withdrawals of approvals for animal drugs.¹¹³ This alone should give us pause before concluding that the FDCA itself creates a requirement for formal hearings. But more fundamentally, as already discussed, there is simply nothing in the FDCA that suggests formal hearings of any kind are required before the FDA may withdraw approvals for animal drugs.

Furthermore, as in *Florida East Coast Railway* itself,¹¹⁴ the kinds of decisions important for present purposes—decisions whether antibiotics given to animals for purposes of promoting growth and preventing infection are “safe”—are broad ones, based on scientific facts that cut across the manufacturers and users of these drugs. To use Kenneth Culp Davis’s

107. 21 U.S.C. § 321(x) (2006).

108. *Id.*

109. *See, e.g.*, 21 U.S.C. §§ 360h; 360j; 360ccc (2006).

110. *Id.* § 360h(e) (2006).

111. *See supra* text accompanying note 50.

112. 5 U.S.C. §§ 556–557 (2006).

113. *See* Food, Drug, & Cosmetic Act § 512, 21 U.S.C. 360(b) (2006).

114. *Fla. E. Coast. Ry.*, 410 U.S. at 245–46.

influential formulation, they are “legislative,” not “adjudicative,” facts.¹¹⁵ They are exactly the kinds of facts that warrant departure from the trial-type framework that the FDA has clung to.¹¹⁶

So far, I have elided the question whether proceedings to withdraw approvals for animal drugs should be characterized as “rulemaking” or as “adjudication.” This characterization might matter because the cases following *Florida East Coast Railway* seem to make something of this distinction. As I have said, no case has found that formal rulemaking is required in the absence of special words. Yet the contemporary trend of cases in the adjudicatory context has been to defer to the agency’s views on whether formal or informal proceedings are required. Therefore, if decisions to withdraw approvals for animal drugs are adjudicatory, then perhaps the FDA’s view that formal proceedings are required can be saved as a permissible interpretation of the statute that the FDA is charged with implementing.

Characterizing these decisions is not easy. The FDA itself has sometimes characterized them as “adjudication” without explanation.¹¹⁷ One of the end products of these decisions is an “order,” which is often but not always a sign that the proceeding is an adjudication. Yet decisions to withdraw approvals for animal drugs also produce rules—rules that revoke other rules setting forth requirements for the administration of the animal drugs in question.¹¹⁸ Moreover, as noted, the generalized nature of the facts relevant to the decisions suggests that the proceedings are more properly characterized as rulemaking rather than adjudication. The withdrawal of an approval also acts prospectively, another hallmark of rulemaking.¹¹⁹

Happily, however, for present purposes it does not really matter whether a proceeding to withdraw approval of animal drugs is rulemaking or adjudication. This distinction does not matter here because the FDA has never offered an explanation of its interpretation of the FDCA that would qualify for *Chevron* deference. To the extent it has spoken at all of the reasons for its conclusion that formal evidentiary proceedings must precede withdrawals of approvals for animal drugs, it has spoken the language of *Chevron* step 1 rather than step 2, stating that formal proceedings are

115. Kenneth Culp Davis, *An Approach to Problems of Evidence in the Administrative Process*, 55 HARV. L. REV. 364, 402 (1942).

116. The numerous cases embracing this point include such administrative-law classics as *Am. Airlines, Inc. v. Civil Aeronautics Bd.*, 359 F.2d 624, 633 (D.C. Cir. 1966) (en banc); *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 757 (1972); *Fla. E. Coast Ry.*, 410 U.S. at 245–46.

117. FINAL DECISION ON ENROFLOXACIN, *supra* note 30, at 11, 12, 13, 72.

118. *Id.* at 121.

119. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 214–215 (1988).

“required by statute.”¹²⁰ That is, the agency has proceeded under the assumption that formal proceedings are required under the FDCA no matter what the agency thinks. The agency believes the statute is, in the parlance of *Chevron*, unambiguous on this question. But the FDA is wrong on this point, as explained above. An agency does not receive *Chevron* deference when it has mistakenly concluded that its interpretation is compelled by Congress.¹²¹ In order to prevail in this situation, the agency must explain why—despite the fact that it has discretion to interpret the statute differently—it has chosen to interpret the statute in the way that it has.¹²²

Moreover, it is hard to imagine how the agency could justify an interpretation of the FDCA that would require it to hold evidentiary hearings when it has the freedom, under the statute, to proceed more informally. The agency has, for decades, explained its immobility on the subject of antibiotics in animal feed by saying the law requires this slow and sorry state of affairs.¹²³ The agency has never stated that formal proceedings are better than informal ones, that the resources required by formal proceedings are well spent, or that the public health consequences of antibiotic resistance due to the widespread administration of antibiotics to food animals are unimportant compared to the desirability of trial-type proceedings. The agency has never, in other words, justified formal evidentiary hearings on the merits. It is hard to imagine that it could do so, given the checkered history of such proceedings in the agency, the agency’s longstanding attempts in other domains to move away from such proceedings, and the agency’s “we-are-constrained-to-conclude” attitude toward such proceedings in the specific matter of antibiotics in animal feed.¹²⁴

If the agency’s interpretation of section 512(e) were challenged, the agency would be required to explain why it exercised its interpretive

120. *FDA Tentative Response to CSPI Petition*, *supra* note 36, at 2.

121. *See, e.g.*, *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1352, 1354 (D.C. Cir. 2006) (remanding the Federal Motor Carrier Safety Administration’s statutory interpretation and withholding *Chevron* deference); *Sec’y of Labor, Mine Safety & Health Admin. v. Nat’l Cement Co. of Cal., Inc.*, 494 F.3d 1066, 107 (D.C. Cir. 2007) (refusing to afford the Secretary of Labor’s interpretation of the Mine Act *Chevron* deference because Congress’s intent was unclear as a matter of law); *Int’l Swaps & Derivatives Ass’n v. U.S. Commodity Futures Trading Comm’n*, No. 11-cv-2146, 2012 WL 4466311, at *13 (D.D.C. Sept. 28, 2012).

122. *PDK Labs, Inc. v. U.S. Drug Enforcement Agency*, 362 F.3d 786, 798 (D.C. Cir. 2004) (explaining that remand to an agency for explanation of interpretive choice is necessary when an agency has mistakenly asserted that the statute is unambiguous on the issue in question).

123. *See, e.g.*, *CSPI Denial Letter*, *supra* note 4, at 2; *EDF Denial Letter*, *supra* note 4, at 2; *FDA Withdrawal of Notices*, *supra* note 3, at 79,700 n.8.

124. *See, e.g.*, *EDF Denial Letter*, *supra* note 4, at 2–3 (describing the history of contested withdrawal hearings); Shapiro, *supra* note 71, at 289 (describing the evolution of the Agency’s hearing process).

discretion to require formal rather than informal proceedings in this context. Given that the litigation pending in the Second Circuit does not raise this precise question, I suppose that the FDA is free, for now, to continue to pretend that it is statutorily constrained to hold formal hearings—and to continue to refrain from explaining why. But this would not be a very public-spirited way to proceed, especially in an administration committed to protecting public health and promoting government transparency.

In this section, I have explained that the FDCA does not require formal hearings on the withdrawal of approvals for animal drugs and that the FDA has not justified its decision to require such hearings. Next, I turn to the FDA's regulations and explain that they, too, leave discretion to the agency on this matter—and that it is hard to imagine a non-arbitrary reason for the agency to exercise this discretion in favor of procedural maximalism.

C. Discretionary Procedural Maximalism

The FDA's own regulation on formal hearings appears to contemplate the kind of quandary just described, and to give the agency the freedom to depart from formal proceedings in circumstances in which the FDCA does not require them. This regulation, codified at 21 C.F.R. § 10.50, states the circumstances under which formal proceedings are required:

(a) The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing under part 12 whenever all of the following apply:

(1) The subject matter of the regulation or order is subject by statute to an opportunity for a formal evidentiary public hearing.

(2) The person requesting the hearing has a right to an opportunity for a hearing and submits adequate justification for the hearing as required by §§ 12.20 through 12.22 and other applicable provisions in this chapter, e.g., §§314.200, 514.200, and 601.7(a).¹²⁵

The natural reading of this regulation is that the FDA will provide formal evidentiary public hearings only where the FDCA explicitly requires them. The FDCA does not, as I have discussed, require formal evidentiary public hearings on the matter of withdrawals of approval of animal drugs. Thus, the regulation, so far, suggests a result no different from the one we have

125. 21 C.F.R. § 10.50 (2012).

already reached: The FDA is not required to offer formal hearings in this context.

But things get a little trickier in another part of the rule on formal hearings. The rule goes on to list “provisions of the act, and other laws, that afford a person who would be adversely affected by administrative action an opportunity for a formal evidentiary public hearing,”¹²⁶ and includes section 512(e) on this list.¹²⁷ Yet the rule also expressly states that its list of statutory provisions does not mean that hearings are required when the statute does not specifically require them, providing: “The list imparts no right to a hearing where the statutory section provides no opportunity for a hearing.”¹²⁸ By switching from the phrase “formal evidentiary public hearing” to “hearing,” it is possible, I suppose, that the FDA meant to signal that it would require *formal* hearings even where the listed statutory provisions required only “hearings.”¹²⁹

This reading would be quite a strange way to interpret the rule. For one thing, it would undo the opening proviso of the rule, instructing the Commissioner to hold formal hearings only when “*all of*” certain, specified conditions apply. These conditions include being “[t]he *subject matter of the regulation or order*” being “*subject by statute* to an opportunity for a *formal evidentiary public hearing*.”¹³⁰ This part of the rule unambiguously requires the FDA to ask not whether the FDCA requires a hearing of some kind, but whether the statute requires the hearing to be formal. Moreover, section 10.50(c) does not even purport to address this part of the opening proviso; it addresses only the second part, namely, statutorily afforded rights to aggrieved persons to an opportunity for a formal evidentiary public hearing.

Equally important, the FDA has not said that it requires formal hearings under 512(e) because its *regulation* requires them; it has said it requires such hearings because the *statute* requires them.¹³¹ At the very least, the FDA owes the public an explanation of why it has chosen to interpret its regulation in this way. Although agencies are given a large amount of deference when they are interpreting their own rules,¹³² they

126. *Id.* at § 10.50(c).

127. *Id.* at § 10.50(c)(17).

128. *Id.* at § 10.50 (c).

129. *Id.* at § 10.50 (c)(1).

130. *Id.* at § 10.50(a)(1) (emphasis added).

131. *See, e.g. EDF Denial Letter, supra* note 4, at 2 (stating that the withdrawal process requires a statutorily mandated hearing but does not specifically cite the statute).

132. *See Auer v. Robbins*, 519 U.S. 452, 457 (1997) (granting broad discretion to agencies to interpret their rules when Congress has not spoken directly on the question at issue.) (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council Inc.*, 467 U.S. 837, 842–43 (1984)).

must at least acknowledge that they are exercising interpretive discretion and not pretend their hands are tied. Here, the FDA's regulation does not appear to require formal hearings when the FDCA does not require them. But the regulation is at most ambiguous on this point; it certainly does not unambiguously require formal hearings when the statute does not. If the FDA wants deference for an interpretation of an ambiguous rule, it must first rely on that rule and then acknowledge the ambiguity.

Of course, an agency is free to grant more procedures than its enabling statute requires. This is one of the lessons of *Vermont Yankee*.¹³³ This discretion is also recognized explicitly in the FDA's rule on formal hearings, which allows the Commission to order a formal hearing "whenever it would be in the public interest to do so."¹³⁴ But here, too, it is hard to imagine the FDA being able to defend a decision to spend years on formal, trial-type, procedurally maximalist hearings covering legislative-type facts. Like any other agency decision, the FDA's decision to hold formal evidentiary hearings despite having the discretion to proceed informally would be subject to review for arbitrariness.¹³⁵ Given the factors cited above in discussing *Chevron* deference—the agency's unhappy history with respect to formal proceedings, its embrace of less formal proceedings in other settings, and its expressions of regret at the perceived need to conduct formal proceedings in the context of antibiotics in animal feed—the agency would have a difficult time explaining in a sensible way why it chose the longer rather than shorter path to protecting the public health.

IV. INSTITUTIONALIZED INACTION

The FDA's inaction on antibiotics in animal feed is a sad enough story in and of itself, but sadder still are the more general institutional pathologies that this episode reflects. The first is the FDA's paralyzing institutional memory. In declining to act on antibiotics in animal feed, the FDA unreflectively repeated its decades-long insistence that it must hold formal evidentiary hearings before withdrawing approvals for animal drugs. The agency did not look afresh at the procedural possibilities, short of formal hearings, for undertaking such withdrawals. It did not even seem aware of, much less alive to, the developments in administrative law that made its insistence on formal hearings seem so woefully out of touch. Yet, at the

133. *Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978).

134. 21 C.F.R. § 10.50(b).

135. 5 U.S.C. § 706(2)(A) (2006).

same time, the agency seemed to recall with painful clarity the experience of actually holding formal hearings on the use of one antibiotic—enrofloxacin—in poultry. The combination of a reflexive “we’ve always done it this way” posture as to the legal premise that formal hearings were required, and a searing “we tried doing that once” experience with such hearings, all but guaranteed the agency’s immobility on antibiotics in animal feed.

The agency’s discomfort with moving out of its usual procedural channels was attended, unfortunately, by a serene comfort with absurdly long timeframes for decision making. The thirty-five year space between the FDA’s initial notices of hearings on its proposed withdrawals of approval of certain antibiotics used in animal feed and its withdrawal of those hearing notices speaks volumes about the agency’s ease with a slow pace. But equally telling is the agency’s insistence, even after the district court had chastised it for its slowness and intransigence, that it would take almost five years to complete the process of withdrawing approvals of penicillin and tetracyclines used in animal feed.¹³⁶ The agency reported to the court that merely searching its own files on the topic would take the agency at least two months.¹³⁷ Perhaps just as stunningly, the court accepted this timeline.¹³⁸

The FDA’s simultaneous insistence on offering, and aversion to actually undertaking, formal hearings, coupled with its extreme insouciance about delay, make for a paralyzing brew. Add a final institutional factor—the grant of authority to a particular person to make initial findings on the continued safety of approved animal drugs—and inaction is virtually assured.

As noted above, the FDCA requires the Secretary of HHS to withdraw approvals for an animal drug if she finds that new evidence indicates that the drug is not safe within the meaning of the FDCA. The Secretary has delegated this authority to the Commissioner of the Food and Drug Administration,¹³⁹ who has in turn delegated authority to the Center for Veterinary Medicine to issue notices of hearings on withdrawals of

136. *Natural Res. Def. Council v. U.S. Food & Drug Admin.*, No. 11 Civ. 3562 (JCF), 2012 WL 3229296, at *9 (S.D.N.Y. Aug. 8, 2012).

137. Declaration of William T. Flynn, D.V.M., M.S., at 5, *Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 872 F. Supp. 2d 318 (S.D.N.Y. 2012).

138. *Natural Res. Def. Council*, 2012 WL 3229296, at *9.

139. FOOD & DRUG ADMIN., FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY, REGULATORY DELEGATIONS OF AUTHORITY TO THE COMMISSIONER FOOD AND DRUGS, § 1410.10(1)(A)(1), (May 18, 2005) available at <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm>.

approval.¹⁴⁰ These re-delegations of epistemic authority themselves raise questions about what it means when Congress grants authority to make particular factual determinations to particular individuals. But even without the re-delegation of authority, particularized delegation means that the agency can insist the relevant factual determinations be made only by the holder of the delegated authority in order to have legal effect. Indeed, the FDA has resisted the litigation over antibiotics in animal feed partly by asserting that the relevant factual determinations have not been made by the right person within the agency.¹⁴¹ This structure makes room for a situation in which the agency, with its many experts, can continue indefinitely to study and even to pronounce upon a factual matter—such as the link between feeding antibiotics to food animals and promoting antibiotic resistance in the human population—without ever facing a moment of truth in which it must, in a consequential way, say what it believes.

Ironically, it is possible that some of the features of the very decision making structure I have criticized here—formal administrative proceedings—could, if deployed appropriately, produce such a moment of truth. The requirement of an impartial decision maker, the ban on ex parte contacts, the power to exclude from consideration irrelevant or repetitive material, the authority to take testimony under oath and to issue subpoenas – these are the hallmarks of the formal administrative proceeding. Their clear ambition is to create space for an honest declaration of what the agency has found on a matter under its jurisdiction. Perhaps this is what the FDA fears most: That an honest declaration of the facts concerning antibiotics and animal feed would force it, finally, to act.

V. CONCLUSION

The FDA has, for decades, put off acting with any force on the health risks posed by administering antibiotics to food animals for the purposes of promoting growth and preventing infection. The agency's explanation has been that the FDCA requires it to hold time- and resource-intensive formal hearings before it can withdraw approvals for antibiotics used for these purposes. In so arguing, the FDA has ignored decades of developments in administrative law and has misread the FDCA itself. The FDA has the discretion under the law to act on antibiotics in animal feed without going through the years-long process of formal hearings. At the least, the agency

140. 21 C.F.R. § 5.84 (2000).

141. Brief for Defendants-Appellants at 29–33, *Natural Res. Def. Council v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 108 (2d Cir. 2012).

owes the public an explanation of why it has refused to pursue an easier path to protecting public health.

The FDA's legal error is, in principle, simple enough to correct. Far less remediable are the habits of mind that entrench agency inaction, including institutional memory that privileges stasis over change, and systematic acceptance of absurdly long timelines for addressing social problems. Equally immobilizing are statutory grants of epistemic authority to particular individuals within large bureaucratic institutions, which allow these institutions officially to deny certain facts about the world, even while they report them as the truth.