



2013

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Georgetown Public Law and Legal Theory Research Paper No. 13-016

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Vt. L. Rev. (forthcoming)

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Undue Process at the FDA

Lisa Heinzerling*

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 40 years, the FDA has been collecting evidence that this agricultural practice contributes to the development of antibiotic-resistant infections in the human population.¹ Based on such evidence, in fact, 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 35 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. In late 2011, the agency denied two citizen petitions asking it to withdraw approvals for certain antibiotics

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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. 56,264, 56,265 (Oct. 21, 1977).

used in animal feed³ and also formally withdrew the decades-old notices announcing public hearings.⁴ 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 thus instead encouraging the animal feed industry to take voluntary measures to address the overuse of antibiotics.⁵ The reason why the FDA believed the process for withdrawing approvals would take too long is that the agency thought itself legally bound to offer formal, trial-type, procedurally maximalist hearings on the question whether the relevant antibiotics were "safe" within the meaning of the relevant statute, the Food, Drug and Cosmetic Act (FDCA).⁶

A district court has rejected both of the FDA's decisions. In complex but compelling rulings, a magistrate judge held that the FDA was obliged to move forward with hearings on the safety of the routine administration of antibiotics to animals destined for the human food supply.⁷ The magistrate judge concluded that,

³ Letter from Lesley Kux, FDA, to Sarah Klein, 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-1286-0009> ("CSPI Denial Letter"); Letter from Lesley Kux, FDA, to Andrew Maguire, Environmental 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> ("EDF Denial Letter").

⁴ Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 246 (Dec. 22, 2011) ("FDA Withdrawal of Notices").

⁵ CSPI Denial Letter at 3-4; EDF Denial Letter at 3-4; FDA Withdrawal of Notices at 79700 & n. 8.

⁶ CSPI Denial Letter at 2; EDF Denial Letter at 2; FDA Withdrawal of Notices, 76 Fed. Reg. at 79700 n. 8.

⁷ NRDC v. FDA, 2012 US Dist. LEXIS 77384 (June 11, 2012) ("NRDC II"); NRDC v. FDA, 2012 US Dist. LEXIS 39457 (Mar. 22, 2012) ("NRDC I"). See also NRDC v. FDA,

with respect to two antibiotics, penicillin and tetracycline, the FDA had already -- in 1977 and beyond -- found that routinely administering these drugs to animals for the purposes of promoting growth and preventing infection was not safe.⁸ With respect to other antibiotics covered by the citizen petitions, the judge concluded that the agency must initiate withdrawal proceedings because its reasons for refusing to do so were arbitrary and capricious.⁹ 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.¹⁰ In this article, I explain that this core legal premise is mistaken. The FDA is not required to hold formal evidentiary hearings on the question 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.

More broadly, beyond its mistaken legal judgment, the FDA's inertness on the problem of antibiotics in animal feed also reflects several pervasive problems in the modern administrative state. I do not discuss these problems in detail in this paper, but, I will suggest, they include institutional memory that does not adjust to changed

2012 US Dist. LEXIS 12486 (Aug. 8, 2012) (setting schedule for FDA compliance with previous orders).

⁸ NRDC v. FDA, 2012 US Dist. LEXIS 39457 (Mar. 22, 2012).

⁹ NRDC v. FDA, 2012 US Dist. LEXIS 77384 (June 11, 2012).

¹⁰ The magistrate judge assumed, without discussion, that a "public evidentiary hearing" was required, if requested, before the FDA could withdraw approvals for animal drugs. NRDC I, at 23 (slip opinion); see also NRDC II, at 33 (citing need for "formal proceeding").

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 the evidence it holds 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, briefly, 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 FDA¹¹ to evaluate the safety of drugs before allowing them on the market,¹² 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

¹¹ The FDA's responsibilities were at that time lodged in the Federal Security Administration.

¹² Food, Drug and Cosmetic Act of 1938, c. 675, 52 Stat. 1040.

for the market met the agency's requirements.¹³ At the same time, Congress also gave the FDA the authority to waive these requirements if it found that doing so would be safe.¹⁴

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 they began to administer antibiotics to food animals for the purpose of treating infections, farmers discovered that – for reasons unknown – the antibiotics promoted growth in these animals.¹⁵ In 1951, the FDA waived the requirements of batch certification for certain antibiotics used for the purpose of promoting growth in food animals.¹⁶ Then, in 1953, the agency waived these requirements for antibiotics used for the purpose of preventing -- rather than treating – certain infections in these animals.¹⁷ The waivers in both contexts were conditioned on the supplement or feed, used to deliver the antibiotics, containing a denaturant making it unfit for human use.¹⁸ 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 ...”¹⁹

¹³ Penicillin Amendment of 1945, ch. 281, § 3, 59 Stat. 463.

¹⁴ *Id.*

¹⁵ Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,265 (Oct. 21, 1977).

¹⁶ 16 Fed. Reg. 3647 (Apr. 28, 1951).

¹⁷ 18 Fed. Reg. 2335 (Apr. 22, 1953).

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

¹⁹ 16 Fed. Reg. at 3618; see also 18 Fed. Reg. at 2336 (same).

In this understated fashion, the FDA approved what was to become the largest use of antibiotics in this country. Today, some 80 percent of the antibiotics used in the United States are given, not to humans, but to animals destined for the human food supply.²⁰ The great majority of these antibiotics are given to the animals, not to treat active infections, but to promote animal growth and to prevent infections in the microbe-rich environment of the factory farm.²¹

The FDCA requires the FDA to withdraw approvals for animal drugs when new evidence emerges, indicating that the drugs are not safe.²² Only a few years after the FDA had approved using antibiotics for purposes of promoting growth and preventing infection in food animals, the agency began accumulating evidence that this practice contributed to the creation of antibiotic-resistant microbes and to the development of antibiotic-resistant infections in the human population.²³ In 1973,

²⁰ See Ralph Loglisci, *New Numbers Reveal Food Animals Consume Lion's Share of Antibiotics* (Dec. 23, 2010), available at <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), available at <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM231851.pdf>).

²¹ 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., Union of Concerned Scientists, *Hogging It!: Estimates of Antimicrobial Abuse in Livestock* (2001), available at http://www.ucsusa.org/assets/documents/food_and_agriculture/hog_front.pdf.

²² 21 U.S.C. 360b(e)(1)(B).

²³ 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).

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, directing 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 serving notice that their approvals would be withdrawn if they did not present such evidence.²⁴ The agency defined "subtherapeutic" uses to include the promotion of growth and the prevention of infection.²⁵ 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 and stated that it would hold a public hearing on the proposed withdrawals.²⁶ This hearing notice was withdrawn in 2011, when the FDA explained that the formal hearings it thought required by the FDCA would take too long and that the agency therefore thought voluntary measures by the animal feed industry were a better idea.

It bears emphasizing that FDA, thus, 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.

²⁴ Antibiotics and Sulfanamid Drugs in the Feed of Animals, 38 Fed. Reg. 9,811, 9,813 (codified at former 21 C.F.R. § 135.109; renumbered at 21 C.F.R. § 558.15).

²⁵ *Id.* at 9,813. See also Tetracycline, 42 Fed. Reg. at 56,255 ("subtherapeutic" means "lower levels than therapeutic levels needed to *cure* disease") (emphasis added).

²⁶ Penicillin-Containing Premixes, 42 Fed. Reg. 43,772, 43,792 (Aug. 30, 1977); Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,288 (Oct. 21, 1977).

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.²⁷ Indeed, the FDA itself repeatedly acknowledged the link between herd- and flock-wide administration of antibiotics to food animals and the development of antibiotic-resistant disease in humans.²⁸ 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

²⁷ 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 (2012); Vanessa K.S. Briceno, *Superbug Me: The FDA's Role in the Fight Against Antibiotic Resistance*, 9 *NYU J. Legis. & Pub. Pol'y* 521 (2005/06); Ariele Lessing, *Killing Us Softly: How Sub-therapeutic Dosing of Livestock Causes Drug-Resistant Bacteria in Humans*, 37 *B.C. Envtl. Aff. L. Rev.* 463 (2010); Robyn L. Goforth & Carol R. Goforth, *Appropriate Regulation of Antibiotics in Livestock Feed*, 28 *B.C. Envtl. Aff. L. Rev.* 39 (2000).

²⁸ See, e.g., Testimony of Joshua M. Sharfstein, Principal Deputy Commissioner of Food and Drugs, Hearing on Preservation of Antibiotics for Medical Treatment Act of 2009, Before the House Committee on Rules (July 13, 2009); ("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."); FDA, *Guidance for Industry #209, The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*, at 17 (April 13, 2012) ("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 at 1 ("we share your concern about the use of medically important antimicrobial drugs in food-producing animals for growth promotion and feed efficiency"), 4 (embracing goal of "judicious use of medically-important antimicrobials"); EDF Denial Letter at 1,4 (same).

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.²⁹ 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.³⁰ But, as I next explain, the FDA is mistaken in believing that it must offer 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 the agency could withdraw any approvals for these antibiotics.³¹ The agency explained in some detail how such procedurally intensive hearings would drain time and resources from the agency, and why the agency thought its time and resources would be better spent pursuing voluntary efforts by the animal feed industry.³² 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.³³ In a previous decision on the same subject, however, the agency had explained that it was “required by statute” to hold a formal

²⁹ FDA Commissioner, Final Decision on Enrofloxacin, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2000-N-0109-0137>.

³⁰ CSPI Denial Letter, at 3; EDF Denial Letter, at 3.

³¹ CSPI Denial Letter at 2; EDF Denial Letter at 2; FDA Withdrawal of Notices, 76 Fed. Reg. at 79699, 79700 n 8.

³² CSPI Denial Letter at 2; EDF Denial Letter at 2; FDA Withdrawal of Notices, 76 Fed. Reg. at 79699, 79700 & n.8.

³³ CSPI Denial Letter at 2; EDF Denial Letter at 2; FDA Withdrawal of Notices, 76 Fed. Reg. at 79700 n. 8.

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 withdrawals³⁴ -- in support of the proposition that a "formal administrative hearing" was required.³⁵ As I argue here, however, developments in administrative law over the past several decades have dramatically relaxed legal requirements for formal agency proceedings. Moreover, nothing in the FDCA requires FDA to ignore these developments and cling to formal processes, and the FDA's own regulations give it the discretion to decline formal hearings when they are not statutorily required. Nor could the FDA non-arbitrarily claim that it is better to use more formal processes when informal ones would serve.

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 twentieth century holds that, during this period, many if not most agencies moved toward rulemaking and away from adjudication,³⁶ and toward informal processes and away from formal ones.³⁷ These shifts made the agency that chooses to set general policy through adjudication

³⁴ 21 U.S.C. 362b(e)(1).

³⁵ FDA Tentative Response to CSPI Petition, at 2 (Feb. 28, 2001), available at <http://www.fda.gov/ohrms/dockets/dailys/01/Mar01/030201/let0006.pdf>.

³⁶ See, e.g., Antonin Scalia, Vermont Yankee: the APA, the D.C. Circuit, and the Supreme Court, 1978 Sup. Ct. Rev. 345, 376; Alan Morrison, The Administrative Procedure Act: A Living and Responsive Law, 72 Va. L. Rev. 253, 256-58 (1986).

³⁷ 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 (1972).

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.

Faced with regulatory responsibilities of daunting complexity and numerosity, administrative agencies obligated to resolve individual matters through time- and resource-intensive formal adjudicatory hearings began, as far back as the 1950s, 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, thus preordaining the outcome of an adjudicatory proceeding in which a licensee exceeding the new limits was seeking yet another broadcast license.³⁸ Likewise, in *FPC v. Texaco*, the Court affirmed a Federal Power Commission rule that set new conditions for granting certificates for gas pipelines – thus, again, obviating the need for individual, trial-type adjudications.³⁹ The Supreme Court eventually even upheld rules that provided individual applicants for government licenses and other benefits little or no opportunity, in adjudicatory proceedings, to argue for an exception to the principles set out in the generally applicable rules.⁴⁰ The Court's endorsement of agencies' growing shift from adjudication to rulemaking was echoed

³⁸ 351 U.S. 192 (1956).

³⁹ 377 U.S. 33 (1964).

⁴⁰ *FCC v. WNCN Listeners Guild*, 450 U.S. 582 (1981); *Heckler v. Campbell*, 461 U.S. 458 (1983).

and extended by Congress in dozens of statutes passed in the 1960s and 1970s, giving agencies broad-ranging authority to act through rules.⁴¹

The shift from formal to informal procedures in agency decision making was also spurred by the Supreme Court, 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*,⁴² in which the Court held that an agency was not required to undertake formal rulemaking -- complete with trial-type hearings⁴³ -- under the Administrative Procedure Act (APA) if its enabling statute merely required a "hearing" of an unspecified nature.⁴⁴ 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.⁴⁵ 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,⁴⁶ the fact is that

⁴¹ See, e.g., Clean Air Act, 42 U.S.C. §§ 7401-7642; Occupational Safety and Health Act, 29 U.S.C. §§ 651-678; Consumer Product Safety Act, 15 U.S.C. §§ 2051-2083; National Traffic and Motor Vehicle Safety Act, 15 U.S.C. §§ 1381-1426.

⁴² 410 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 (1972).

⁴³ *Id.* at 238, nn. 3 and 4 (quoting procedural requirements for formal rulemaking and adjudication under APA).

⁴⁴ *Id.* at 238.

⁴⁵ *Id.* at 238.

⁴⁶ *Id.* at 238.

no statute not using the words "on the record" has been held to require formal rulemaking under the APA since *Florida East Coast Railway*.⁴⁷

The Court likewise held that the bare requirement of a "hearing" in the Interstate Commerce Act did not, standing alone and apart from the APA, obligate the 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.⁴⁸ 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 particular circumstances."⁴⁹ The "factual inferences" the ICC relied on, the Court 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."⁵⁰ In due process terms, the Court thus placed the ICC's decision on the side of *Bi-Metallic Investment Co.*⁵¹ – requiring "no hearing at all"⁵² for generalized policy judgments – rather than on the side of *Londoner v. Denver*, requiring "argument however brief" and "if need be, ... proof, however informal"⁵³ in "proceedings

⁴⁷ Gary Lawson, *Federal Administrative Law* at 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 applicable statute required only that rules be made "after full opportunity for hearing," and not "on the record," and concluding, "[t]herefore," that the APA did not require trial-type procedures).

⁴⁸ 410 U.S. at 233-34.

⁴⁹ *Id.* at 246.

⁵⁰ *Id.* at 246.

⁵¹ *Bi-Metallic Investment Co. v. State Board of Equalization*, 239 U.S. 441 (1915).

⁵² *Florida East Coast Railway*, 410 U.S. at 245.

⁵³ *Londoner v. Denver*, 210 U.S. 373, 386 (1908).

designed to adjudicate disputed facts in particular cases.”⁵⁴ Under neither the APA nor the Interstate Commerce Act, therefore, was the Commission required to hold formal, trial-type hearings before coming to a decision on the matters at hand.

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,⁵⁵ 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,⁵⁶ has been overruled.⁵⁷ 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.⁵⁸ 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

⁵⁴ *Id.* at 244-45.

⁵⁵ 410 U.S. at 244-45.

⁵⁶ *Seacoast Anti-Pollution League v. Costle*, 572 F.2d 872 (1st Cir. 1978).

⁵⁷ *Dominion Energy Brayton Point v. Johnson*, 443 F.3d 12 (1st Cir. 2006).

⁵⁸ *City of West Chicago v. NRC*, 701 F.2d 632, 641 (7th Cir. 1983).

deference so long as they are reasonable.⁵⁹ 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*.⁶⁰ 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.⁶¹ 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, and so long as it offered the statutory minima, its procedural obligations were satisfied.⁶² 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.⁶³ 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

⁵⁹ *Dominion Energy Brayton Point*, 443 F.3d at 16-18; *Chemical Waste Mgmt. v. EPA*, 873 F.2d 1477 (D.C. Cir. 1989); *Sibley v. US Dept. of Education*, 913 F. Supp. 1181 (N.D. Ill. 1995); *Shell Oil v. US Dept. of Labor*, 106 F. Supp. 2d 15 (D.D.C. 2000).

⁶⁰ 435 U.S. 519 (1978).

⁶¹ 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, 143-48 (Peter L. Strauss ed., 2006).

⁶² 435 U.S. at 543-48, 549 n. 21.

⁶³ See, e.g., Jack M. Beermann & Gary Lawson, *Reprocessing Vermont Yankee*, 75 *Geo. Wash. L. Rev.* 856 (2007).

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.⁶⁴ The Commission intended to use these values in the cost-benefit analysis for individual licensing proceedings.⁶⁵ 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.⁶⁶

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.⁶⁷ 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 at the same time holding formal hearings on drug applications. Thus, the agency turned to administrative summary

⁶⁴ 435 U.S. at 528-30.

⁶⁵ 435 U.S. at 528.

⁶⁶ 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 procedures. NRC, *Changes to Adjudicatory Process*, 69 Fed. Reg. 2,182. The First Circuit upheld this rule without deciding whether the formal hearing requirements of the APA were required, since the court decided that in any event the Commission's new procedures satisfied APA requirements for formal hearings. *Citizens Awareness Network v. United States*, 391 F.3d 338 (1st Cir. 2004).

⁶⁷ 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).

judgment as a way out of this predicament -- a solution affirmed by the Supreme Court in 1973.⁶⁸

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 contain⁶⁹ -- was encouraged to introduce legal adjustments aimed in part at avoiding the procedural quagmires created by formal hearings.⁷⁰

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

⁶⁸ Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 620 (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.

⁶⁹ Robert W. Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 Texas L. Rev. 1132, 1142-45 (1972).

⁷⁰ 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 (1974).

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,⁷¹ 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, and then applying the findings of that proceeding to any decision whether to withdraw approval of a specific antibiotic – or even applying those findings in declining 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...”⁷² 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

⁷¹ 21 U.S.C. 371(a).

⁷² *In re Barr Laboratories v. National Association of Pharmaceutical Manufacturers*, 930 F.2d 72, 76 (D.C. Cir. 1991) (citing *Heckler v. Campbell*, 461 U.S. 458 (1983)).

approach makes no distinction.”⁷³ Even so, unaccountably, the FDA has failed to recognize the availability of generic rulemaking to address the risks posed by antibiotics in animal feed. And, more than that, 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 “drug-by-drug” basis.⁷⁴ 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 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. This provision states that the “Secretary” (of the Department of Health and Human Services, who has in turn delegated this authority to the FDA Commissioner⁷⁵) “shall” withdraw approval for

⁷³ NRDC II, at 46 n. 24 (slip opinion).

⁷⁴ 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. NRDC II, at 46 n. 24 (slip opinion).

⁷⁵ FDA Staff Manual Guides, Volume II – Delegations of Authority, Regulatory Delegations of Authority to the Commissioner Food and Drugs § 1410.10(1)(A)(1). 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).

animal drugs in several circumstances. The language pertinent to the problem of antibiotics used in animal feed is as follows:⁷⁶

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 approved ...⁷⁷

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." It does not, in short, contain anything close to the "magic words" that courts, since *Florida East Coast Railway*, have looked for before requiring formal hearings.⁷⁸ Moreover, the provision stands in contrast to another section of the FDCA, which does contain the special language. Section 701(e)(3),⁷⁹ specifically cited in *Florida East Coast Railway* for the proposition that some statutes did indeed use the words the Court was looking for,⁸⁰ 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."⁸¹

⁷⁶ NRDC I, at 23 n. 9 (slip opinion).

⁷⁷ 21 U.S.C. 360b(e)(1).

⁷⁸ *Mobil Oil Corp. v. Federal Power Commission*, 483 F.2d 1238, 1250 (D.C. Cir. 1973).

⁷⁹ 21 U.S.C. 371(e)(3).

⁸⁰ 410 U.S. at 238 (citing 21 U.S.C. 371(e)(3)).

⁸¹ 21 U.S.C. 371(e)(3).

In section 701(e)(1), Congress identified the FDA decisions to be made “on substantial evidence of record” under section 701(e)(3).⁸² The extreme specificity with which Congress identified these decisions indicates that Congress acted with precision and care.⁸³ The specific decisions to be accompanied by a hearing on the evidence of record concern the labeling of food offered for special dietary uses,⁸⁴ emergency permit control of classes of food contaminated with micro-organisms,⁸⁵ tolerances for poisonous ingredients in food,⁸⁶ drugs adulterated on account of their departures from specifications in official compendia,⁸⁷ drugs misbranded on account of their propensity to deteriorate,⁸⁸ definitions and standards of identity for dairy products,⁸⁹ and definitions and standards of identity for “maple sirup.”⁹⁰ 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 our purposes, decisions to withdraw approval for animal drugs do not appear in section 701(e)(1)'s selective list.

⁸² 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”).

⁸³ 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).

⁸⁴ 21 U.S.C. 371(e)(1) (citing FDCA 403(j), 21 U.S.C. 343(j)).

⁸⁵ 21 U.S.C. 371(e)(1) (citing FDCA 404(a), 21 U.S.C. 344(a)).

⁸⁶ 21 U.S.C. 371(e)(1) (citing FDCA 406, 21 U.S.C. 346).

⁸⁷ 21 U.S.C. 371(e)(1) (citing FDCA 501(b), 21 U.S.C. 351(b)).

⁸⁸ 21 U.S.C. 371(e)(1) (citing FDCA 502(h), 21 U.S.C. 352(h)).

⁸⁹ 21 U.S.C. 371(e)(1) (citing DCA 401, 21 U.S.C. 341).

⁹⁰ 21 U.S.C. 371(e)(1) (citing FDCA 401, 21 U.S.C. 341).

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.⁹¹ This provision also expressly adopts the APA's requirements on burdens of proof and other matters in formal hearings.⁹² Section 512(e)(1), on withdrawing approvals for new animal drugs, does not adopt section 701(e) and its reference to "evidence of record."

Nothing else in the FDCA suggests that formal hearings are required when FDA withdraws approvals for animal drugs. Section 512(e)(3) does direct that an order to withdrawal an approval "state the findings upon which it is based."⁹³ 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."⁹⁴ 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. 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"⁹⁵ create such a requirement. Although the Center for Veterinary Medicine has listed this provision as "authority" for its policies

⁹¹ 21 U.S.C. 379e(d).

⁹² 21 U.S.C. 379e(d)(2) (incorporating 5 U.S.C. 1006(c), now 5 U.S.C. 556(d)).

⁹³ 21 U.S.C. 360b(e)(3).

⁹⁴ 21 U.S.C. 371(e)(1).

⁹⁵ 21 U.S.C. 371(c).

on the management of formal evidentiary hearings,⁹⁶ 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. Indeed, in *Florida East Coast Railway*, the relevant provision of the Interstate Commerce Act directed the Interstate Commerce Commission itself to make the decision under review.⁹⁷ 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.

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.⁹⁸ 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. Some provisions of the FDCA specifically require an “informal hearing” before certain decisions can be made.⁹⁹ 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.

The absence of the words “on the record” or words of equivalent clarity dooms any argument that the Administrative Procedure Act requires the FDA to hold formal evidentiary hearings before it withdraws its approval of an animal

⁹⁶ FDA, Center for Veterinary Medicine, Program Policy and Procedures Manual, 1240.3670, section 2(a)(5) (revised 11/05/09).

⁹⁷ 49 U.S.C. 1(14)(a).

⁹⁸ 21 U.S.C. 321(x).

⁹⁹ See, e.g., 21 U.S.C. 360h; 360ccc; 360j; 387j.

drug.¹⁰⁰ 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.¹⁰¹ 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. 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 that formal hearings of any kind are required before the FDA may withdraw approvals for animal drugs.

Furthermore, as in *Florida East Coast Railway* itself,¹⁰² 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. They are, to use Kenneth Culp Davis's influential formulation, "legislative," not

¹⁰⁰ See text at notes 35-38, supra.

¹⁰¹ 5 U.S.C. 556, 557.

¹⁰² 410 U.S. at 245-46.

"adjudicative," facts.¹⁰³ They are exactly the kinds of facts that warrant departure from the trial-type framework the FDA has clung to.¹⁰⁴

So far, I have elided the question whether proceedings to withdraw approvals for animal drugs should be characterized as "rulemaking" or as "adjudication." The reason why this characterization might matter is that the cases following *Florida East Coast Railway* seem to make something of the distinction. As I have said, no case has found that formal rulemaking is required in the absence of special words not present here. 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. If decisions to withdraw approvals for animal drugs are adjudicatory, therefore, then perhaps the FDA's view that formal proceedings are required can be saved, after all, as a permissible interpretation of the statute the FDA is charged with implementing.

It is not so easy to figure out how to characterize these decisions. The FDA itself has sometimes (without explanation) characterized them as "adjudication."¹⁰⁵ And one of the end products of these decisions is an "order," 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 rules setting forth

¹⁰³ Kenneth Culp Davis, *An Approach to Problems of Evidence in the Administrative Process*, 55 Harv. L. Rev. 365 (1942).

¹⁰⁴ The numerous cases embracing this point include such administrative-law classics as *American Airlines, Inc. v. Civil Aeronautics Board*, 359 F.2d 624 (D.C. Cir. 1966) (en banc); *Allegheny-Ludlum*, 406 U.S. at 757; *Florida East Coast Railway*, 410 U.S. at 245-46; and more.

¹⁰⁵ FDA Commissioner, *Final Decision on Enrofloxacin*, at 11, 12, 13, 72, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2000-N-0109-0137>.

requirements for the administration of the animal drugs in question.¹⁰⁶ 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 as adjudication. The withdrawal of an approval also acts prospectively, another hallmark of rulemaking.¹⁰⁷

Happily, however, for present purposes it does not really matter whether a proceeding to withdraw approval of animal drugs is rulemaking or adjudication. For 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 “required by statute.”¹⁰⁸ 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.¹⁰⁹ In that situation, the agency must, if it

¹⁰⁶ FDA Commissioner, Final Decision on Enrofloxacin, at 121.

¹⁰⁷ *Bowen v. Georgetown University Hospital*, 488 U.S. 204 (1988).

¹⁰⁸ FDA Tentative Response to CSPI Petition, at 2 (Feb. 28, 2001), available at <http://www.fda.gov/ohrms/dockets/dailys/01/Mar01/030201/let0006.pdf>.

¹⁰⁹ See, e.g., *Peter Pan Bus Lines, Inc. v. Federal Motor Carrier Safety Administration*, 471 F.3d 1350, 1352, 1354 (D.C. Cir. 2006); *Secretary of Labor, Mine Safety and Health Administration v National Cement Co. of California, Inc.*, 494 F.3d 1066, 1074 (D.C. Cir. 2007); *International Swaps and Derivatives Ass’n v. CFTC*, 2012 WL 4466311 (D.D.C. 2012).

wants its interpretation to prevail, 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.¹¹⁰

It is hard to imagine, moreover, 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. The agency has never stated that formal proceedings are better than informal ones, that the resources required by formal proceedings are well spent, 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. And 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.

If the agency's interpretation of section 512(e) were challenged, the agency would be required to explain why it exercised its interpretive discretion to require formal rather than informal proceedings in this context. Given that the litigation

¹¹⁰ PDK Labs v. DEA, 362 F.3d 786, 798 (D.C. Cir. 2004) (explaining that remand to agency for explanation of interpretive choice is necessary when agency has mistakenly asserted that statute is unambiguous on issue in question).

pending in the Second Circuit does not raise this precise question, I suppose 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 nevertheless to require such hearings. Next, I turn to the FDA's regulations on this point 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, thus:

(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 parts 12.20 through 12.22 and other applicable provisions in this chapter, e.g., parts 314.200, 514.200, and 601.7(a).

The natural reading of this regulation is that the FDA will provide formal evidentiary public hearings only where the FDCA requires formal evidentiary public hearings. 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 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,”¹¹¹ and to include section 512(e) on this list.¹¹² Yet the rule also expressly states that its list of statutory provisions does not mean that hearings are required when the statute does not require them, providing: “The list imparts no right to a hearing where the statutory section provides no opportunity for a hearing.”¹¹³ 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.”

This 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 – which conditions include being “the *subject matter of the regulation or order*” being “*subject*

¹¹¹ 21 C.F.R. 10.50(c).

¹¹² 21 C.F.R. 10.50(c)(17).

¹¹³ 21 C.F.R. 10.50(1)(c).

by statute to an opportunity for a formal evidentiary public hearing.”¹¹⁴ 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 the 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. At the very least, therefore, 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,¹¹⁵ they must at least acknowledge that they are exercising interpretive discretion and not pretend that their hands are tied when they are not. Here, the FDA’s regulation appears not at all 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*. This discretion is

¹¹⁴ 21 C.F.R. 10.50(a), (a)(1).

¹¹⁵ *Auer v. Robbins*, 519 U.S. 452 (1997).

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."¹¹⁶ 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. 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 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

¹¹⁶ 21 C.F.R. 10.50(b).

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 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 matched by serene comfort with absurdly long timeframes for decision making. The 35-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 some five years to complete the process of withdrawing approvals of penicillin and tetracyclines used in animal feed.¹¹⁷ It would, the agency reported to the court, take the agency at least two months just to search its own files on the topic.¹¹⁸ And, perhaps just as stunningly, the court accepted the agency's timeline.¹¹⁹

The FDA's simultaneous insistence on offering, and aversion to actually undertaking, formal hearings, coupled with its extreme insouciance about delay,

¹¹⁷ NRDC v. FDA, Memorandum and Order of August 8, 2012, at 23.

¹¹⁸ NRDC v. FDA, Declaration of William T. Flynn, D.V.M., M.S., at 5.

¹¹⁹ NRDC v. FDA, Memorandum and Order of August 8, 2012.

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.

The FDCA, as noted above, 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,¹²⁰ who has in turn delegated authority to the Center for Veterinary Medicine to issue notices of hearings on withdrawals of approval.¹²¹ 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, the fact of particularized delegation means that the agency can insist that 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.¹²² 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

¹²⁰ FDA Staff Manual Guides, Volume II – Delegations of Authority, Regulatory Delegations of Authority to the Commissioner Food and Drugs § 1410.10(1)(A)(1). available at <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm080711.htm/>.

¹²¹ 21 C.F.R. § 5.84.

¹²² Brief for Defendants-Appellants, NRDC v. FDA, 2012 WL 4834272, at 29-33 (2d Cir.).

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.

V. Conclusion

The Food and Drug Administration 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 Food, Drug and Cosmetic Act 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 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.