UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2012

(Argued: February 8, 2013 Decided: July 24, 2014)

Docket Nos. 12-2106-cv(L), 12-3607-cv(CON)

NATURAL RESOURCES DEFENSE COUNCIL, INC., CENTER FOR SCIENCE IN THE PUBLIC INTEREST, FOOD ANIMAL CONCERNS TRUST, PUBLIC CITIZEN, INC., UNION OF CONCERNED SCIENTISTS, INC.,

Plaintiffs-Appellees,

— v. —

UNITED STATES FOOD AND DRUG ADMINISTRATION, MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration, CENTER FOR VETERINARY MEDICINE, BERNADETTE DUNHAM, in her official capacity as Director, Center for Veterinary Medicine, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services,

Defendants-Appellants.

B e f o r e:

KATZMANN, *Chief Judge*, LYNCH, *Circuit Judge*, and FORREST, *District Judge*.[*]

On appeal from entry of summary judgment in the United States District Court for the Southern District of New York (Theodore H. Katz and James C. Francis IV, *Magistrate Judges*), defendants challenge the district court's conclusion that the United States Food and Drug Administration ("FDA") is required by 21 U.S.C. § 360b(e)(1) to proceed with hearings to determine whether to withdraw approval for the use of penicillin and tetracyclines in animal feed and that the FDA's decision denying two citizen petitions urging it to hold such hearings was arbitrary or capricious within the meaning of 5 U.S.C. § 706(2).

REVERSED.

Chief Judge Katzmann dissents in a separate opinion.

JENNIFER A. SORENSON (Mitchell S. Bernard, Avinash Kar, *on the brief*), Natural Resources Defense Council, New York, New York, *for* Plaintiffs-Appellees.

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[*] The Honorable Katherine B. Forrest, of the United States District Court for the Southern District of New York, sitting by designation.

ELLEN LONDON (Amy A. Barcelo, Benjamin H. Torrance, Assistant United States Attorneys, David J. Horowitz, Deputy General Counsel, Elizabeth H. Dickinson, Chief Counsel, Food and Drug Division, Eric M. Blumberg, Deputy Chief Counsel, Litigation, Thomas J. Cosgrove, Associate Chief Counsel, Department of Health and Human Services, *on the brief*), *for* Preet Bharara, United States Attorney for the Southern District of New York, New York, New York, *for* Defendants-Appellants.

GERARD E. LYNCH, *Circuit Judge*:

For nearly seventy years, antibiotics have provided dramatic medical advances in the treatment of bacterial infections.[1] For nearly as long, scientists have been concerned about the problem of antibiotic resistance. Through repeated exposure to antibiotics, some strains of bacteria develop resistance or immunity to particular antibiotics. Such resistance presents a serious threat to

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[1] The first major antibiotic, penicillin, was discovered in 1928 by the Scottish scientist Alexander Fleming. Its precise chemical structure was first described in 1945 by the American scientist Dorothy Hodgkin, and a method for its mass production was developed that same year. Despite the importance of her discovery, Hodgkin was not among the scientists awarded the 1945 Nobel Prize in Chemistry for the production of therapeutic penicillin. Hodgkin later received that prize in 1964 for her discovery of the structure of vitamin B12. See Joachim Pietzsch, The Nobel Prize in Chemistry 1964: Dorothy Crowfoot Hodgkin, Nobelprize.org, *available at* http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1964/perspectives.html (last visited July 29, 2013).

human health. Infections in humans caused by antibiotic-resistant bacteria result, on average, in longer hospital stays, worse side effects of treatment, and a greater likelihood of death. In an effort to forestall the development of antibiotic-resistant strains of bacteria, doctors exercise restraint in prescribing antibiotics and are careful to direct patients to use antibiotics only as prescribed.

However, for each dose of antibiotics given to humans for medical purposes, four doses are given to livestock for non-medical reasons to encourage faster, healthier growth. In 2009, 28.8 million pounds of antibiotics were administered to animals raised for food, most of it through animal feed. Unfortunately, research shows that bacteria that develop resistance to antibiotics used in animal feed can transfer to human beings and pose a risk to human health. For that reason, various public-interest organizations have sought to force the Food and Drug Administration ("FDA") to prohibit the use of certain antibiotics in animal feed. This case arises from one such effort.[2]

In this lawsuit, the plaintiff organizations contend that the FDA is required by 21 U.S.C. § 360b(e)(1) to proceed with hearings to determine whether to

[2] For another case arising from an effort to force the FDA to limit nontherapeutic uses of antibacterial agents in a different context, see Natural Res. Def. Council v. FDA, 710 F.3d 71 (2d Cir. 2013).

withdraw approval for the use of penicillin and tetracyclines in animal feed, and that the FDA's denial of two citizen petitions demanding such hearings was arbitrary or capricious within the meaning of 5 U.S.C. § 706(2). The district court accepted plaintiffs' contention. Because we conclude that plaintiffs and the district court are incorrect, we reverse the judgment of the district court.

BACKGROUND

I. FDA Regulation of Animal Feed Antibiotics

The FDA has statutory authority to regulate new animal drugs[3] introduced into interstate commerce. See 21 U.S.C. § 360b(a)(1). New animal drugs are prohibited unless specifically approved by the FDA following a new animal drug application ("NADA") made by a sponsor, which is usually the drug manufacturer that produced the drug.[4] Because antibiotics can be used in animal feed to produce bigger animals that grow faster on less food, many drug manufacturers have sought approval to sell antibiotics for use in animal feed.

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[3] The term "new animal drug" is defined in 21 U.S.C. § 321(v); see note 11, infra, for the text of that section.

[4] Generic-drug applications receive a slightly different label, "abbreviated NADA."

In 1951, the FDA approved the first use of antibiotics as ingredients in animal feed to encourage animal growth. Two years later, it approved the first use of antibiotics as drugs in animal feed. But by the late 1960s, the FDA "became concerned about the safety to man and animals of subtherapeutic antibiotic use" both as a general matter and specifically in the context of animal feed.[5] See Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes: Opportunity for Hearing, 42 Fed. Reg. 56264, 56266 (Oct. 21, 1977) ("Tetracycline NOOH"). Thus began the decades-long investigation of the danger posed by such use, and the concern about human safety has persisted ever since.

In 1970, prompted by a report published by the United Kingdom's Joint Committee on the Use of Antibiotics in Animal Husbandry and Veterinary Medicine, the FDA instituted a Task Force to study the problem. In 1972, the Task Force published its report, concluding that: (1) the use of antibiotics in "subtherapeutic amounts" favors the selection of antibiotic-resistant bacteria; (2)

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[5] "Subtherapeutic" uses are those that seek "increased rate of [weight] gain, disease prevention[,] etc.," as opposed to uses to treat illnesses or other pathological conditions. 21 C.F.R. § 558.15(a). Other sources prefer the term "nontherapeutic," for the same meaning.

animals treated with such doses of antibiotics can serve as hosts for resistant bacteria, which can then be transferred to humans; (3) the prevalence of resistant bacteria had increased; and (4) resistant bacteria had been found in meat and meat products intended for human consumption. The Task Force's report proposed withdrawing approval for all then-approved subtherapeutic uses of antibiotics unless the manufacturers of the drugs submitted evidence regarding the safety and effectiveness of the drugs as used in animal feed.

In 1977, after receiving the requested information from the drug manufacturers and the recommendation of the Animal Feeds Subcommittee of the National Advisory Food and Drug Committee, the FDA's Bureau of Veterinary Medicine ("CVM")[6] issued notices of opportunity for hearing ("NOOHs") with respect to both penicillin and tetracyclines, another family of antibiotics. Penicillin-Containing Premixes: Opportunity for Hearing, 42 Fed. Reg. 43772 (Aug. 30, 1977) ("Penicillin NOOH"); Tetracycline NOOH, 42 Fed. Reg. 56264 (Oct. 21, 1977). The notices detailed the history of subtherapeutic

[6] The Bureau of Veterinary Medicine is now known as the Center for Veterinary Medicine. In the interest of simplicity, we use the abbreviation CVM to refer to that subdivision of the FDA regardless of its official title at any given time.

antibiotic drug use and the scientific data on the safety and effectiveness of such use, and concluded that the drug manufacturers had "failed to resolve the basic safety questions that underlie the subtherapeutic use of [antibiotics] in animal feed." The Penicillin NOOH went on to state that the Director of the CVM had

> conclude[d], on the basis of new information before him with respect to these drug products, evaluated together with the evidence available to him when they were originally approved, that the drug products are not shown to be safe under the conditions of use prescribed, recommended, or suggested in their labeling. The evidence, in fact, indicate[d] that such penicillin use may be unsafe, particularly if the higher or therapeutic levels of penicillin should be used as substitutes for the levels currently used subtherapeutically.

42 Fed. Reg. at 43792. The Tetracycline NOOH stated that the use of such drugs was safe only for a list of specific and strictly limited uses. 42 Fed. Reg. at 56287.

Less than a year after the NOOHs were issued, congressional appropriations committees set aside funds so that the National Academies of Sciences ("NAS") could conduct further research on the safety and effectiveness of antibiotics in animal feed. The report issued by the House Appropriations Committee included thinly veiled suggestions that the FDA not go forward with the hearing process until the research was completed. See H.R. Rep. No. 95-1290,

at 99 (1978). The NAS report, which was largely inconclusive but found that "subtherapeutic use of antimicrobials does increase the prevalence of resistance among the *E. coli* and *Salmonella* of treated animals," also recommended that additional studies be conducted. National Academy of Sciences, The Effects on Human Health of Subtherapeutic Use of Antimicrobials in Animal Feed xiv (1980), http://www.nap.edu/catalog.php?record_id=21.

Two years later, the House committee reiterated its desire to see further evidence before approving the hearing process. A year after that, the Senate Committee on Appropriations noted that the additional studies recommended by the NAS had not yet been conducted and concluded that the "FDA will be expected to continue to hold in abeyance any implementation of its proposal pending the final results of the above research and evidentiary hearings." S. Rep. No. 97-248, at 79 (1981).

In 1981, several industry groups petitioned the FDA to withdraw the 1977 NOOHs. They also sought approval for new uses of antibiotics. On February 1, 1983, the FDA formally denied the petitions. Penicillin and Tetracycline (Chlortetracycline and Oxytetracycline) in Animal Feeds; Denial of Petitions, 48 Fed. Reg. 4544, 4556 (Feb. 1, 1983). The published notice accompanying the

denials stated that "the Director [of the CVM] does not have any less concern at present about the safety issues that prompted adoption of [the NOOHs]. The Director has not changed his earlier conclusion that the available scientific information warrants the proposed actions." Id. at 4555. In conclusion, the FDA stated that

> [t]he notices of opportunity for hearing represent the Director's formal position that use of the drugs is not shown to be safe. Therefore, the Director has concluded that he does not wish to withdraw the notices of opportunity for hearing. Instead, the Director wishes to place the notices in abeyance pending completion of the studies mandated by Congress.
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> The Commissioner [of the FDA] has reviewed the Director's decision and concurs with it.

That notice was signed by the Commissioner of the FDA.

Meanwhile, several additional studies were either commissioned by various government agencies or conducted by independent multinational organizations. In 1984, the FDA contracted with the Seattle-King County Health Department to conduct yet another study. That study sought to determine how easily antibiotic-resistant bacteria could travel from food animals to humans. It concluded that such transmission was likely. In 1987, the FDA asked the Institute

of Medicine ("IOM") to conduct a review of the risks to human health from subtherapeutic uses of antibiotics in animal feed. IOM found "a considerable body of indirect evidence implicating both subtherapeutic and therapeutic use of antimicrobials as a potential human health hazard," although it could not establish a definitive direct link. In 1997, the World Health Organization held a meeting of experts to develop a report on the question. The WHO report recommended ceasing subtherapeutic use in animals of any antibiotic that is prescribed for use in humans to combat bacterial infections. Many other reports were also compiled and described in the FDA's draft Guidance for Industry #209, issued on June 28, 2010.

The FDA never held the hearings it proposed in the 1977 NOOHs. On March 9, 1999, a group of public-interest organizations petitioned the FDA, pursuant to § 512(e) of the Food, Drug, and Cosmetic Act ("FDCA"), to withdraw regulatory approval for the subtherapeutic use in animal feed of a specified list of antibiotics, which included penicillin and tetracyclines. On April 7, 2005, an overlapping but distinct group of public-interest organizations petitioned the FDA a second time with the same request. Both petitions received preliminary

responses, but the FDA issued no final response until after the instant lawsuit was filed.

In the meantime, the FDA issued a series of guidance documents to industry groups, in an effort to implement a voluntary program for gradually reducing the subtherapeutic use of antibiotics in animal feed. The primary mechanism for this hoped-for reduction was an agreement to limit the use of certain antibiotics to therapeutic uses authorized by veterinary prescription. The FDA's October 23, 2003 Guidance for Industry #152 detailed the FDA's conclusions about the dangers posed by subtherapeutic use of antibiotics in animal feed. Guidance 152, by its terms, applied primarily to applications for regulatory approval for *new* uses of antibiotic drugs. On June 28, 2010, FDA released draft Guidance for Industry #209, which set out its plan to avoid *all* uses of antibiotics that were not "judicious." A disclaimer on Guidance 209 specifies that "[i]t does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."

At the time this lawsuit was filed, the FDA had issued no final response to the citizen petitions and none of the Guidances discussed above had been finalized.

II. The Instant Lawsuits

Plaintiffs, a group of advocacy organizations,[7] filed this lawsuit in the United States District Court for the Southern District of New York on May 25, 2011. They pled two distinct claims. First, they claimed that 21 U.S.C. § 360b(e)(1) compelled the FDA to hold the hearing proposed by the 1977 NOOHs and, if appropriate, withdraw approval for the antibiotic uses the NOOHs listed.[8] Second, they claimed that the FDA had unreasonably delayed by failing to respond finally to the 1999 and 2005 citizen petitions, and asked the

[7] The plaintiffs are the Natural Resources Defense Council, Inc., the Center for Science in the Public Interest, the Food Animal Concerns Trust, Public Citizen, Inc., and the Union of Concerned Scientists, Inc.

[8] Plaintiffs also pled claims pursuant to § 706(1) of the Administrative Procedure Act ("APA"), which generally authorizes courts presented with challenges to agency inaction to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). Because the essence of plaintiffs' APA claim is that the FDCA requires the FDA to hold the hearings described in the 1977 NOOHs, the question posed by § 706 is identical to that posed by the text of § 360b(e) itself.

court to order prompt responses. On July 7, 2011, they filed an amended complaint, which clarified their basis for standing to sue.

On October 6, 2011, after the FDA answered the amended complaint, plaintiffs moved for summary judgment.[9] A month later, the FDA issued final responses denying the 1999 and 2005 citizen petitions, effectively mooting the plaintiffs' second claim. Essentially, the FDA took the position that an alternative strategy for combatting the ill effects of subtherapeutic use of antibiotics in animal feed would be more efficient than pursuing an effort to withdraw approval for any such uses. By way of explaining its decision, the FDA stated that proceedings to withdraw drug approvals are very costly and lengthy. The FDA also stated that any new proceedings would require a new NOOH incorporating new scientific findings on the relationship between human health and subtherapeutic uses of antibiotics in animal feed. Moreover, the FDA argued, it could not grant the petitions because the withdrawal process had to proceed on a drug-by-drug basis. Accordingly, the FDA had decided to pursue an alternative but complementary course of voluntary measures. Shortly thereafter, the FDA formally withdrew the 1977 NOOHs. Withdrawal of Notices

[9] The parties did not conduct discovery.

of Opportunity for a Hearing: Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79697 (Dec. 22, 2011).

In light of these actions, the plaintiffs withdrew their claim to compel action on their petition, which had been mooted by the FDA's denial, and, on February 1, 2012, filed a supplemental complaint alleging that the denial of their petitions was arbitrary and capricious. The parties then filed renewed cross-motions for summary judgment. The district court ruled separately on the two remaining claims. In a March 22, 2012 order, the district court (Theodore H. Katz, *Magistrate Judge*) granted plaintiffs' motion for summary judgment on the NOOH claim.[10] Natural Res. Def. Council, Inc. v. FDA ("NRDC I"), 884 F. Supp. 2d 127 (S.D.N.Y. 2012). The district court ruled that 21 U.S.C. § 360b(e) required the FDA to hold a hearing once it had made a finding that a particular drug use was not safe. It further ruled that the 1977 NOOH constituted or contained such a finding, and that withdrawal of the 1977 NOOH did not effect a withdrawal of that finding. It therefore ordered FDA to institute withdrawal proceedings for the uses discussed in the 1977 NOOH and, unless the manufacturers could rebut the finding, withdraw approval for those drug uses.

[10] The parties had consented to trial before a magistrate judge.

In a June 1, 2012 order, the district court (Theodore H. Katz, *Magistrate Judge*) granted plaintiffs' motion for summary judgment as to the claims that the denial of the citizen petitions was arbitrary and capricious. Natural Res. Def. Council, Inc. v. FDA ("NRDC II"), 872 F. Supp. 2d 318 (S.D.N.Y. 2012). According to the district court, the reasons stated in the withdrawal were insufficient to meet even the very limited review authorized by the arbitrary-and-capricious standard. As to the FDA's claim that withdrawal proceedings are costly and lengthy, the district court ruled that the statute was clear and that these concerns were not relevant. In making this point, the district court relied primarily on Massachusetts v. EPA, 549 U.S. 497 (2007). NRDC II, 872 F. Supp. at 333-34, 337-38. As to the FDA's claim that it was pursuing alternative voluntary measures to regulate the use of antibiotics, the district court again concluded that the statute was clear and that voluntary measures – effective or not – could not be substituted for the mandatory measures required by the text of the statute.

The government timely appealed both of the district court's judgments.

DISCUSSION

We review a district court's decisions on motions for summary judgment de novo. Chandok v. Klessig, 632 F.3d 803, 812 (2d Cir. 2011). Summary

judgment is appropriate if there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Here, the facts of the case are undisputed, and the questions posed are purely legal.

I. The Required Hearings Claim

A. The Statutory Text

The principal question presented by this appeal is whether 21 U.S.C. § 360b(e)(1) requires the FDA to proceed with withdrawal hearings for certain previously approved subtherapeutic uses of antibiotics in animal feed because the FDA has made a finding that those uses are not shown to be safe for humans. The text of § 360b(e)(1) clearly requires withdrawal of approval once such a finding has been made; it does not equally clearly specify when the agency makes such a finding, and in particular whether the type of finding that mandates withdrawal of approval is a conclusion based on internal agency deliberations that precedes (and then requires) the holding of a hearing, or a finding that represents the conclusion reached as the result of such a hearing.

21 U.S.C. § 360b(e)(1) addresses the FDA's power to withdraw approval for "new animal drug[s]."[11] The text of the statute states that

> (1) The Secretary[12] shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) of this section with respect to any new animal drug if the Secretary finds . . .
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> > (B) that new evidence 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 . . . ;

Id.

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[11] "New animal drug" is elsewhere defined, subject to limited exceptions, as "any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed, . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(v) (2008).

[12] Although the statute refers to the Secretary of Health and Human Services, the Secretary has delegated her duties under the FDCA to the Commissioner of the Food and Drug Administration.

The parties dispute the circumstances under which the mandatory language "shall . . . issue an order withdrawing approval" comes into play. In particular, they dispute what it means for the Secretary to make a finding, and when that finding occurs. The text makes clear that an order withdrawing approval must be issued (and so far as relevant here may *only* be issued) upon the occurrence of two conditions precedent – a finding and a hearing. The parties, in effect, dispute the required and anticipated sequence of those conditions.

The government reads the statute as requiring the sequence: hearing, finding, order. In effect, it reads the provision to say, "If, after notice and a hearing, the secretary finds that a drug is not shown to be safe for use," she is required to withdraw approval of the drug. In this interpretation, the withdrawal process begins with a notice from the FDA to a drug sponsor of its concerns about an drug, and offering the opportunity for a hearing regarding the safety of the animal drug. If, at the conclusion of the hearing, upon consideration of the evidence presented, the secretary finds that the drug is indeed not shown to be safe for use, she must then issue an order withdrawing approval of the drug. That order of events depends upon the conclusion that a finding that an

animal drug is not shown to be safe can be made only after the drug's sponsor's due process rights – notice and an opportunity to be heard – have been respected. Therefore, the mandatory "shall" applies only to the action – withdrawal of approval – that the Secretary must take if the hearing results in a finding adverse to the drug. On the government's reading, the mandatory "shall" does not apply to the holding of the hearing itself, which the government argues is a discretionary action that the agency may undertake, or not, in its discretion, based on its judgment about whether the scientific evidence and sound public policy warrant instituting proceedings to withdraw approval.

By contrast, plaintiffs favor the sequence: finding, hearing, finding, order. In effect, they read the statute to say, "If the secretary finds a drug is not shown to be safe for use, she shall provide notice to the applicant, hold a hearing, issue a second finding, and then withdraw approval." In their interpretation, the initial finding that the drug is not shown to be safe is based on the agency's internal investigations of the scientific evidence, and comes *before* any hearing is held. On plaintiffs' reading, once the agency reaches the conclusion that the drug is not shown to be safe, the mandatory language of the statute becomes applicable – the agency must issue an order of withdrawal, though it must hold a hearing first.

The mandatory "shall" thus in effect governs not only the remedy that must follow a formal conclusion after a hearing, but also the process itself; after reaching its initial conclusion that the drug is not shown to be safe, the agency is required to institute proceedings and effectuate them through a hearing, after which (if the evidence present at the hearing sustains the finding) she must issue an order of withdrawal.

As plaintiffs admit, their construction necessarily contemplates *two* findings that a drug is not shown to be safe for use: one (based on internal deliberations) that triggers the (mandatory) hearing, and another (after the sponsor has been given notice and an opportunity to be heard, and based on the evidence presented at that hearing) that supports the issuance of an order of withdrawal.[13] Plaintiffs argue that the initial finding made by the agency is subject to rebuttal by the sponsor at the mandated hearing; in the absence of such

[13] The hearing would have an Alice-in-Wonderland quality (sentence first, trial afterward) unless it were understood that the Secretary may only ultimately withdraw approval if the evidence presented at the hearing warrants a finding that the drug is not shown to be safe. There would be no purpose to a hearing if the agency's initial internal conclusion of itself mandated withdrawal, regardless of the outcome of the hearing.

rebuttal, the original finding "ripens" and requires issuance of an order of withdrawal.

The text of § 360b(e)(1) itself does not unambiguously express either of these sequences. The syntax makes at least two things clear. First, because the mandatory verb "shall" is linked to "issue an order withdrawing approval" of an NADA if the requisite finding is made, the statute is clear that the withdrawal of the approval is mandatory if the preconditions set in the statute are met. Second, the statute is clear that two such conditions must be met before the requirement that the Secretary "shall" withdraw her approval is triggered: a temporal condition (the withdrawal order may only be issued "after due notice and opportunity for hearing"), and a factual condition (withdrawal is required only "if the Secretary finds . . . that such drug is not shown to be safe for use").

The syntax is not similarly clear as to the temporal relationship between the hearing and the finding, because the phrase "after due notice and opportunity for hearing" is inserted somewhat awkwardly between "shall" and "issue." Different placement of the notice and hearing language could have decisively directed one or the other of the competing interpretations. Had Congress written, "If the Secretary finds [that the drug is not shown to be safe for

use], she shall conduct a hearing on due notice to the applicant, and shall withdraw approval if the evidence at the hearing supports the finding," the plaintiffs would clearly be correct: after making a "finding," the Secretary would be required to withdraw approval of the drug, but only after a notice and hearing process. In contrast, if Congress had written, "The Secretary shall withdraw approval [of an NADA] if she finds, after due notice and opportunity for hearing to the applicant [that the drug is not shown to be safe]," the FDA's interpretation would clearly be correct. Unfortunately, it wrote neither, adopting a syntactically awkward variation that leaves the intended sequence ambiguous.

Although the grammar of the sentence as it is actually written does not absolutely compel either reading, we believe that the government's interpretation is far more plausible, both as a matter of language and as a matter of conventional legal practice.[14] As noted above, the plaintiffs' reading requires not

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[14] In his thoughtful dissenting opinion, Judge Katzmann correctly notes that "[W]e begin . . . any exercise of statutory construction with the text of the provision in question, and move, as need be, to the structure and purpose of the Act in which it occurs." (Dissenting opinion, post, at 5, quoting N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995)). This principle guides our analysis, and confirms our respectful disagreement with Judge Katzmann's conclusion regarding the interpretation of the statute.

Insofar as the dissent's analysis refers to the purpose of the statute, it

one but two findings, in a sentence that only refers to one. Congress expressly provided that withdrawal of approval is required (indeed, such withdrawal is authorized) only after a hearing is held and a finding is made. The hearing process is thus a critical precondition of the withdrawal order, and as plaintiffs concede, the entire purpose of the hearing is to determine whether the evidence does indeed show that the drug is not shown to be safe for use. The hearing thus eventuates in withdrawal of approval only if the Secretary concludes, based on

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hinges on the unquestioned goal of Congress to protect human health. But this is largely a red herring. As Judge Katzmann acknowledges (Dissenting opinion, post, at 6-7), that goal does not require us to interpret any ambiguity in the statute in the manner that we think is most conducive to protecting the public health; the statute reflects in its language particular judgments about how that goal should be pursued and when it must yield to or be balanced with other concerns. Our views regarding how the FDA can best serve its mission of protecting human health through the use of drugs to treat animals or the analytic import of other prospectively ambiguous Congressional statutes must defer to the most reasonable reading of the text before us. Section 360b(e)(1) is most "naturally read" (Dissenting opinion, post, at 20) in the manner that makes best sense of the statutory language itself. That in turn compels us to conclude that where a statute explicitly considers only a single finding and directs that any such finding mandates the agency to take decisive action, the statute only involves a single finding by that agency.

Insofar as the dissent addresses the statutory structure, it primarily relies on a perceived parallel between the procedures for initial approval of a drug and withdrawal of that approval. But this attempted parallel ignores the fact that a withdrawal procedure occurs after a drug has already been found safe – a difference that amply justifies a different process.

the evidence of "experience and scientific data" presented at the hearing, that the drug is not shown to be safe. Yet according to the plaintiffs' reading, the statute makes no explicit reference to any such finding at the culmination of the hearing – in plaintiffs' view, the only finding that Congress expressly requires, and the one that the grammatical construction of the sentence makes prerequisite to the withdrawal of approval, is the finding that the Secretary makes *before* the hearing even takes place.[15]

Similarly, while the plaintiffs' reading would make the initial internal administrative finding of a lack of showing of safety the trigger for a mandatory hearing, the statute does not grammatically link the only "finding" referred to in the statute to a mandatory *hearing*, but rather to a mandatory *withdrawal* of

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[15] Put another way, plaintiffs' interpretation is internally inconsistent. On the one hand, it relies on the literal language of the statute to insist that upon the "finding" of lack of showing of safety – by which plaintiffs mean the preliminary internal conclusion of the agency that leads to the issuance of an NOOH – withdrawal of approval is mandatory, but on the other they acknowledge that that preliminary "finding" does not and cannot in fact mandate withdrawal of approval, because it leads only to a hearing that may or may not result in a finding that the drug is not shown to be safe. Plaintiffs insist that the "finding" or preliminary assessment of the agency mandates that the agency hold a hearing, but the finding referred to in § 360b(e)(1) requires that the Secretary *issue an order withdrawing approval* of the drug. Only a finding that is made after notice and an opportunity for a hearing can have this effect.

approval. Moreover, the statute does *not* require withdrawal of approval based solely upon an internal, pre-hearing finding – withdrawal of approval must await the conclusion of the hearing, at which further findings would have to be made. At that point, the withdrawal is no longer the mandatory consequence of the initial finding – if the hearing demonstrated the safety of the drug, withdrawal of approval would not be required, or even permitted. It is, instead, the consequence of the further finding at the end of the hearing, based on the evidence presented there. According to plaintiffs, Congress meant to mandate that upon making the "finding" referred to in § 3609(e)(1)(A), the Secretary is required to hold a hearing, and yet Congress provided that upon making such a finding the Secretary "shall issue" not a notice of opportunity for a hearing, but a withdrawal of approval of the drug. In short, it would be singularly odd for Congress to have chosen the language that it did to describe the process that even the plaintiffs concede it intended.

The government's preferred reading yields no such difficulties. While it is true that the statute would read more smoothly, and would more clearly express the government's position, if the phrase "after due notice and an opportunity for hearing" were placed after "finds," rather than between "shall" and "issue,"

nothing in the statutory language needs to be twisted to yield the government's interpretation. Although the placement of the notice and hearing provision is awkward (on either side's interpretation), even as placed, it is entirely consonant with the government's reading. There is nothing syntactically difficult or odd about providing that the Secretary shall withdraw her approval of a drug, after a notice and hearing process, if a finding is made (after such process) that the drug is not shown to be safe.

B. Context

The parties call our attention to various aspects of the larger statutory context that might cast further light on the meaning of this particular provision. The cited portions of the statute, however, do not provide much help in clarifying the meaning of the provision in question, and certainly do not provide sufficient instruction to overcome the reading derived from the language of the debated text itself.

As the parties note, different language within the same statutory subsection provides for *emergency* withdrawal of approval for animal drugs "if the Secretary . . . finds" that the drugs pose an "imminent hazard to the health of man or of the animals." 21 U.S.C. § 360b(e)(1) (last paragraph). In such a case,

the Secretary – but not any delegate – may immediately and without a hearing suspend approval for the drug in question. That provision can be used to support either side. On the one hand, plaintiffs argue that its language supports the notion that the Secretary can make "findings" by an internal administrative process, without notice or a hearing. On the other hand, the government argues that the special exception permitting emergency interim relief to prevent "imminent hazards," and the reservation of authority to make such emergency findings to the Secretary, serves to underscore the general and otherwise-applicable rule that findings that induce final agency actions adverse to applicants must be made *after* notice and hearing, and must represent the final conclusion of the agency, rather than an interim judgment delegable to lower-ranking officials. Neither of these inferences from the emergency suspension provision can be dismissed as implausible, but neither persuasively illuminates the process anticipated by the language in question in this case.

The district court also relied on a distinction between § 360b(e)(1) and the preceding subsection of the statute, § 360b(d)(1), to support its conclusion that findings could precede hearings for purposes of § 360b(e)(1). Section 360b(d)(1) – which lists the permissible grounds on which the Secretary may initially deny an

application for approval of a new animal drug – clearly states that findings of fact must occur *after* a hearing, by placing the "after due notice [and] hearing" language immediately after the verb "finds."[16] That difference in language, the district court concluded, suggests that Congress intended different schemes under the two subsections. The government challenges that reading, however, arguing that § 360b(d) is expressly connected to the language of the preceding § 360b(c)(1), which in turn explicitly contemplates that some findings may be made without a hearing.[17] In that context, it makes sense that Congress would use more sharply contrasting language to distinguish the findings made under subsection (d) from those required in subsection (c). By contrast, under § 360b(e)(1), no order withdrawing approval may issue before a hearing unless the drug represents an "imminent hazard." In the government's reading, the

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[16] 21 U.S.C. § 360b(d)(1) states: "If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that [one of nine specified conditions is satisfied,] he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that [those conditions are not met], he shall issue an order approving the application."

[17] Specifically, the Secretary is authorized to approve an application for a new animal drug if she "finds that none of the grounds for denying approval specified in [§ 360b(d)] applies." 21 U.S.C. § 360b(c)(1).

difference in language between subsections (d) and (e) reflects the differing procedures for approval of a new drug and for the withdrawal of approval of a previously approved drug, rather than any intention to limit agency discretion to institute, pursue, or abandon procedures to withdraw drug approvals.

Again, we find both parties' inferences from the language of § 360b(d) reasonable. But neither is sufficiently compelling either to strongly corroborate or to seriously undermine our reading of the text. As noted above, it is unquestionably clear from the text that the mandate to order withdrawal only applies after the agency has held a hearing. Indeed, it is clear from the text that an order withdrawing approval may *not* be entered (except in the emergency circumstances referred to in § 360b(e)(1)) without providing notice and a hearing to the drug's sponsor. It seems to us that, when a statute provides that an agency must take some action after a hearing "if it finds" something to be true, the more persuasive reading is that the finding referred to is the fruit of the required hearing.

C. The Relevant Regulations

Both parties argue that various regulations implementing the statute support their respective interpretations. For the reasons set forth below, we do not find these arguments especially helpful.

The government argues that the FDA's interpretation of the statute is entitled to deference. We generally give deference to an agency's interpretation of statutes that the agency administers. See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844-45 (1984). The Supreme Court has held that the FDA is entitled to deference when it interprets Title 21 of the United States Code, FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000), because the FDA, as designee of the Department of Health and Human Services, is the agency tasked with administering the FDCA. We will therefore defer to the FDA's interpretation if Congress has not directly spoken to the precise question at issue and the agency can point to an official interpretation that sets forth a permissible construction of the statute.

However, before we defer to an agency's interpretation of a statute, we must identify an agency document setting forth that interpretation. The level of deference to an agency's interpretation of its own statute depends on the nature of the document setting forth the interpretation. Regulations promulgated after a

period of notice and comment are typically granted the relatively strong form of deference described by Chevron. See United States v. Mead Corp., 533 U.S. 218, 228-30 (2001). We give substantially less deference to post hoc interpretations offered only for purposes of litigation, particularly when those interpretations represent a "departure from prior norms." See Am. Fed'n of State, County, & Mun. Emps. v. Am. Int'l Grp., Inc., 462 F.3d 121, 129 (2d Cir. 2006), quoting Atchison, Topeka & Santa Fe Ry. Co. v. Wichita Bd. of Trade, 412 U.S. 800, 808 (1973). The government urges us to apply Chevron deference to the FDA's interpretation of the statute as embodied in its notice and comment regulations.

The government, however, overlooks a basic predicate of administrative deference. In order to merit deference on a given issue, a particular regulation must shed light one way or the other on the issue. The government points to three regulations to support its position, but none of them help decide the question before us: whether the findings referred to in § 360b(e) precede hearings, or follow them. The government concedes that the regulations it cites do not explicitly undertake to interpret the statutory provision at issue and answer the question before us, but nevertheless argues that the regulations presuppose an answer to that question.

First, the government relies on 21 C.F.R. § 5.84, which authorizes the Director of CVM, as the Secretary's delegate, to issue NOOHs on the latter's behalf.[18] Specifically, the regulation provides that the Director may issue NOOHs or, if the sponsor has waived the right to a hearing, the Director may issue an order of withdrawal. But that regulation fails to give any indication about what, if any, conditions might *require* a hearing. The government argues that, because § 5.84 represents a partial delegation of the Secretary's duties under § 360b(e)(1) only for purposes of issuing NOOHs, it does not authorize the Director to make "findings," and that therefore the issuance of an NOOH is never preceded by a finding as defined in the statute. But the regulation merely states that "[t]he Director and Deputy Director [of the CVM] are authorized to issue [NOOHs] . . . and to issue notices of withdrawal of approval when opportunity for hearing has

[18] 21 C.F.R. § 5.84 has been formally withdrawn in an amendment of the regulations governing the FDA organizational structure, promulgated by a rule that is "editorial in nature." Revision of Organization and Conforming Changes to Regulations, 77 Fed. Reg. 15961-02 (Mar. 19, 2012) (codified at 21 C.F.R. Chapter I). The substance of the delegation from the Secretary to the CVM contained within 21 C.F.R. § 5.84 is now authorized by FDA Staff Manual Guides, Volume II – Delegation of Authority, SMG § 1410.503 (Feb. 24, 2011). As the modification to the regulations was editorial rather than substantive, the language of the delegation remains the same, and both parties implicitly agree that § 5.84 remains in effect, we address the regulation here.

been waived." 21 C.F.R. § 5.84(a)(1)-(2). It is thus equally plausible to read § 5.84 as delegating to the Director of CVM[19] the responsibility for making any findings that might trigger the mandatory issuance of NOOHs and any resulting actions.

The government next points to 21 C.F.R. § 514.200(c), which sets out the possible responses a sponsor may make to an NOOH, and describes the requisite showing a sponsor must make to secure an actual hearing as opposed to a decision on the papers. It argues that that regulation precludes plaintiffs' reading because any pre-hearing findings are necessarily preliminary. Specifically, the regulation requires a sponsor seeking a hearing to

> giv[e] the reason why the application should not be refused or should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition to the Commissioner's proposal. A request for a hearing may not rest upon

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[19] As the district court noted, the Commissioner of the FDA ratified the judgment reflected in the 1977 NOOHs by concurring – in a policy statement published in the Federal Register – with the Director's 1983 decision not to rescind those NOOHs. Penicillin and Tetracycline (Chlortetracycline and Oxytetracycline) in Animal Feeds; Denial of Petitions, 48 Fed. Reg. 4554, 4556 (Feb. 1, 1983) ("The Commissioner has reviewed the Director's decision and concurs with it. In addition, for the reasons discussed above, the Commissioner has decided that he will not withdraw the advance notice of hearing or the proposal to restrict therapeutic approvals to prescription use, but will hold them in abeyance.").

> mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires a hearing. When it clearly appears from the data in the application and from the reasons and a factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the refusal to approve the application or the withdrawal of approval of the application (for example, no adequate and well-controlled clinical investigations to support the claims of effectiveness have been identified), the Commissioner will enter an order on this data, *stating his findings* and conclusions.

21 C.F.R. § 514.200(c) (emphasis added). The government argues that, because a decision to grant a hearing represents only the Commissioner's determination that there may be a "genuine and substantial issue of fact preclud[ing] . . . the withdrawal of approval of the application," it cannot represent a conclusive finding triggering a mandatory duty. By contrast, the plaintiffs argue, and the district court agreed, that not only does § 514.200(c) fail to support the position that findings may take place only *after* a hearing, but it also explicitly contemplates findings even in the absence of a hearing. If the sponsor's written response to a NOOH is insufficient, the Commissioner is to enter an order of withdrawal based on, among other things, the data in the initial application.

The regulation, it seems to us, simply provides a mechanism for a kind of "summary judgment" proceeding that might obviate an evidentiary hearing. If

the applicant requests a hearing, the decision to withdraw approval of the drug must be based either on formal "findings" derived from the evidence adduced at a hearing or, where that the request for a hearing does not raise a genuine issue of disputed fact, on a summary judgment–like conclusion. To that extent, the regulation is consistent with the government's basic contention that "findings" normally result from an adjudicative process, and are made *after* that process is instituted. It does not, however, directly address – let alone lead us to conclusively reject – plaintiffs' contention that the entire proceeding is triggered by an agency "finding." We therefore conclude that this regulation does not embody an unambiguous interpretation of § 360b(e)(1) to which we must defer in this case.

Finally, the government urges us to take account of 21 C.F.R. § 10.55(b)(2)(i), which provides for the separation of investigative and adjudicative responsibilities within the FDA in the event of a hearing. Specifically, that regulation provides that, from the time of the announcement of a formal hearing, CVM will be "responsible for all investigative functions" and for presenting the FDA's case before the adjudicator. According to the government, this separation of functions "reflects FDA's understanding that

throughout the withdrawal process, CVM does not speak on behalf of" the FDA. Because CVM cannot speak on behalf of the Commissioner once hearing proceedings have been instituted, the government argues that any "finding" by CVM cannot trigger a mandatory duty on the part of the Commissioner. That argument has one major flaw: the finding that plaintiffs argue triggered the FDA's duty to proceed with the hearing necessarily *preceded* the period of separation of administrative functions. Because functions are separated only upon publication of an NOOH, anything that precedes or is included in the NOOH might have represented an action by the Commissioner through her delegate, the Director of CVM.

We are therefore unable to identify a regulation promulgated by FDA pursuant to its notice and comment rulemaking authority that clearly reflects a definitive interpretation of § 360b(e)(1). While the regulations relied upon by the FDA do not expressly adopt or unambiguously require any particular interpretation of the contested language to which we must accord Chevron deference, they still provide some guidance. As we discuss below, we believe that the regulations relied upon by the FDA reflect a conventional understanding of the administrative process that is consistent with the interpretation of

§ 360b(e)(1) advanced by the government. We cannot conclude, however, that any of those regulations directly speak to the specific question of statutory interpretation before us, or reflect a clear adoption by the agency of any position on that question.

Plaintiffs, for their part, also seek support in FDA regulations. They argue that the regulation most on point is 21 C.F.R. § 514.115(b)(3)(ii), which details the procedures for withdrawal of approval of an NADA. That regulation provides: "The Commissioner shall notify in writing the person holding an application approved pursuant to section 512(c) of the act and afford an opportunity for a hearing on a proposal to withdraw approval of such application *if he finds*" that one of the conditions described in § 360b is met. 21 C.F.R. § 514.115(b)(3) (emphasis added). That regulation unquestionably lends plausibility to plaintiffs' reading of the statute because it clearly contemplates that the Commissioner must make some sort of finding before the issuance of an NOOH. Indeed it was largely on the basis of § 514.115(b)(3)(ii) that the district court interpreted the statute to require the FDA to proceed with the hearing.

The government, however, argues that this regulation is inapposite because "identical words need not have identical meanings when used in

different contexts" and the FDA's use of "finds" in the regulation refers only to a preliminary finding. While the government's argument is hardly compelling, the regulation can indeed be read as it proposes. Moreover, that the FDA regulation refers to a finding made by the Commissioner before instituting a hearing does not mean that the regulation is intended to set forth the agency's definitive interpretation, or indeed any interpretation at all, of the *statutory* language whose meaning the parties here dispute. In other words, plaintiffs' reliance on § 514.114(b)(3)(ii) suffers from the same flaw as the FDA's reliance on the regulations that it cites. All of the cited regulations are drafted to define administrative procedures, and not to interpret the mandate set forth by Congress in § 360b(e)(1). The use of certain language in those regulations or the nature of the procedures that they create may lend some support to the position of one side or the other, but the regulations simply cannot be said to answer the question before us.

In short, we are not required to defer to an agency's interpretation of a statute when its regulations do not directly address the question before the Court, and when the language of one regulation appears to be in tension with the agency's interpretation of the statute advanced for purposes of litigation. We

therefore conclude that Chevron deference does not provide an answer to the question before us.

D. Background Legal Concepts

We take some comfort from the fact that our interpretation of the statutory text is consistent with ordinary understandings of administrative and judicial litigation processes. In interpreting a statute, courts generally presume that Congress acts "against the background of our traditional legal concepts." United States v. U.S. Gypsum Co., 438 U.S. 422, 437 (1978). See also United States v. Pacheco, 225 F.3d 148, 157 (2d Cir. 2000). Of course, Congress may depart from such traditions; it may use words in ways that are unconventional, or adopt innovative procedures. But when a statute does not provide clear direction, it is more likely that Congress was adopting, rather than departing from, established assumptions about how our legal or administrative system works. We will not lightly assume a less conventional meaning absent a clear indication that such a meaning was intended. In our view, the interpretation advanced by the government is more in accordance with such conventions.

First, the government's interpretation is more consistent with our usual understanding of an administrative "finding." An agency "finding" typically

represents an official determination, reflecting a final, deliberative decision issuing at the conclusion of a process, and taking a fixed form embodied in an identifiable document. Judicial or administrative findings most commonly are adopted not as a prerequisite but as a *consequence* of a hearing or other official proceeding. For example, Black's Law Dictionary defines the verb "find" as "To determine a fact in dispute *by verdict or decision*," Black's Law Dictionary 707 (9th ed. 2009) (emphasis added), and the noun "finding of fact" as "A determination by a judge, jury, or administrative agency of a fact supported by the evidence in the record, *usu. presented at the trial or hearing*," id. at 708 (emphasis added). Thus a "finding" traditionally occurs after adversarial parties are given notice of a hearing and an opportunity to be heard there, at least if hearings are contemplated as part of the administrative scheme.

Other areas of the law define "findings" to mean written conclusions issued only at the completion of an administrative process. For example, for purposes of judicial review of agency adjudication under the Social Security Act, we have held that the term "findings" refers to the agency's on-the-record determinations at a hearing, and that the agency has an affirmative duty to develop the record during the hearing to facilitate judicial review. See Pratts v.

Chater, 94 F.3d 34, 37 (2d Cir. 1996); see also 42 U.S.C. § 405(g). Similarly, albeit in a context that does not necessarily contemplate hearings, Federal Rule of Evidence 803(8)(A)(iii), which provides an exception to the hearsay rule for written public records and reports, permits admission into evidence "findings from a legally authorized investigation," and the Supreme Court has interpreted the rule as requiring a "*conclusion* . . . based on a factual investigation." Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 170 (1988) (emphasis added). In these instances, "findings" are written and issue only at the conclusion of the entire process.

We do not suggest that the term cannot be, or indeed is not, sometimes used in a different sense. As plaintiffs point out, even in this very regulatory scheme, the FDA uses the word "find" in a context that clearly refers to a *preliminary* finding that does not share the characteristics discussed above. See 21 C.F.R. § 514.115(b)(3)(ii), discussed above. Similarly, the emergency suspension proceedings in § 360b(e)(1) itself refer to findings that are made by the Secretary without a hearing, though, notably in that context, the finding is the basis for an action that has an immediate legal effect on the rights of a drug sponsor, rather than being the basis of a decision to institute a process that may eventually lead

to such an effect. Nevertheless, where the context does not clearly indicate to the contrary, typical usage suggests that an administrative finding reflects the agency's final decision issued at the conclusion of a process, rather than a preliminary assessment that contemplates further proceedings before final action is taken.[20]

Second, the function of the finding contemplated by § 360b(e)(1), and the mandate that Congress attached to the making of such a finding, is consistent with this more natural meaning. As plaintiffs themselves emphasize, a finding by the Commissioner that a drug is not shown to be safe *requires* the FDA to "issue an order withdrawing approval" of the drug. 21 U.S.C. § 360b(e)(1). The FDA is not accorded discretion to adopt a different remedy. The consequences of such a withdrawal are significant for society and for the sponsor or manufacturer

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[20] Looking beyond the specific context of the Federal Food, Drug, and Cosmetic Act, Judge Katzmann cites a number of statutes in which Congress has used language similar to that at issue here. (Dissenting opinion, post, at 19-20). Significantly, however, he cites no judicial interpretation of this language that supports plaintiffs' readings (or, for that matter, that supports ours). The fact that Congress has created similar ambiguities in other contexts tells us nothing about how to resolve the ambiguity. Similarly, we are unpersuaded by the dissent's suggestion that the Supreme Court offhandedly endorsed plaintiffs' view of § 360(b)(1)(B) in Brown & Williamson (Dissenting opinion, post, at 13). In the cited passage, 529 U.S. at 134, the Court simply repeats, in a slightly condensed form, the ambiguous language of the statute itself.

of the drug. It is logical to assume that Congress would mandate withdrawal of approval of a drug when it has been determined that the drug has not been shown to be safe by a formal decision of the agency, after a careful hearing at which evidence both for and against the safety of the drug has been presented. In contrast, it would seem peculiar for Congress (absent an emergency of the sort authorizing unilateral agency action provided for in the last paragraph of § 360b(e)(1)) to mandate such a strong remedy based not on a final decision by the agency head after a full deliberative process, but on a preliminary conclusion reached by lower-level officials before those affected have had an opportunity to be heard.

And of course, as plaintiffs in effect concede, Congress clearly has *not* done so. While the language of the statute dictates that withdrawal of approval is the necessary consequence of a finding that an animal drug is not shown to be safe, the statute requires notice to the sponsor and an opportunity for a hearing before a final order of withdrawal may issue, and plaintiffs agree that such an order may issue only if the *hearing* results in a finding by the Secretary that the drug is not shown to be safe. Under the literal words of the statute, as well as in accordance with common sense, the agency must issue an order withdrawing

approval when it finds that the drug is not shown to be safe – something that, as a matter of statutory command and due process, may only occur *after* the hearing.

Third, the administrative process contemplated by the government's interpretation of the statute accords with our traditional expectations of governmental enforcement of legal rules. The traditional model of administrative or judicial enforcement features an investigation by executive or administrative personnel, followed by the issuance of a case-initiating document that sets forth the conclusions or charges reached by the prosecuting authority, followed by a hearing. That process culminates in a final adjudication that is reached by the agency and embodied in a formal decision, and imposes whatever remedies or penalties are applicable. In civil and criminal actions, the initial conclusions of the administrative agency or executive officer that lead to the filing of a lawsuit and an adjudication by a court are not thought of as "findings" and do not mandate final action; a remedy (discretionary or mandatory) is contingent on the ultimate finding of the court.

The same is typically true of administrative processes. Commonly, an agency seeking to take action adverse to the interests of an affected party brings a

charge that leads to a hearing process; only after the hearing does the final agency action result in formal findings and a resultant order.[21] The government's interpretation of the statute – and the regulations it has issued that implement it – is essentially consistent with this model. The plaintiffs' interpretation departs from it, by insisting that a preliminary conclusion sufficient to trigger a full-dress hearing should be treated as an agency "finding" that mandates action.

Fourth, interpreting the statute to mandate action upon a "finding" that is *not* the result of the required hearing presents the problem of identifying when and how such a finding has been made. Under the plaintiffs' interpretation, the "finding" that would trigger these mandatory consequences is not, as in the normal understanding of an agency finding, a formal decision embodied in documentary form. The most plausible place to look for a formal finding that precedes and therefore could trigger a hearing under the plaintiffs' interpretation is in the NOOHs issued by the CVM in 1977 which set forth the scientific

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[21] To take only one example of this familiar process, when the Securities and Exchange Commission seeks to impose a cease-and-desist order against a corporation for violating Section 21C of the Securities Exchange Act of 1934, the Commission's staff issues a notice of a hearing prior to the issuance of such an order. It is the final decision of the Commission, not the charges contained in the notice, that constitute the "findings" of the agency, lead to the issuance of the order, and trigger judicial review.

conclusions of the Director regarding the safety issues affecting animal antibiotics and initiate the process by which the agency can withdraw approval of their subtherapeutic use.

But if the NOOHs contain or embody the findings on which plaintiffs rely, plaintiffs are confronted with the problem that those NOOHs have been withdrawn. Nothing in the statute or regulations explicitly restricts the FDA's ability to withdraw an NOOH after it has issued. Thus, at this moment, there is no operative document that contains any formal finding, final or preliminary, that any use of animal antibiotics pose health threats to humans. Accordingly, the plaintiffs must, and do, argue that the withdrawal of the NOOHs does not effectively withdraw the finding that was documented in them. They reason that "findings" need not be reflected in any one document but rather comprise the FDA's considered collective judgment about the science underlying antibiotic resistance and its effects on human safety. To withdraw the findings, plaintiffs argue, the FDA must publicly recant its earlier position on the safety of the use of antibiotics in animal feed. According to plaintiffs, the agency's continued insistence, up to and including in briefing and oral argument on this appeal, that such use of antibiotics does pose risks for humans actually "reaffirmed" the

findings first announced in the 1977 NOOHs. In short, the "finding" that subtherapeutic uses of antibiotics in animal feed is not shown to be safe resides not in any formal legal conclusion but in the scientific judgment of the relevant FDA officials, current and past, that such uses may be dangerous. By the plaintiffs' argument, once the Secretary reaches a conclusion that a drug use is not shown to be safe, she is required to act on that opinion.

The withdrawal of the NOOHs, however, simply makes more stark a problem inherent in the plaintiffs' argument. The underlying logic of the plaintiffs' position is that the finding of the Secretary that triggers a hearing must precede even the NOOH itself, for it is this finding that triggers the obligation of the FDA to hold a hearing that, assuming that it results in yet another finding adverse to the drug, is the precursor to a mandatory order withholding approval of the drug. In other words, once the Secretary reaches a certain conclusion, an NOOH must issue, and a hearing must commence.

That interpretation is problematic. Administrative findings, whether or not preceded by adversarial evidentiary hearings, are ordinarily clothed in the garb of decision, and reflect a formal determination. The fact that plaintiffs argue that the findings originated with the 1977 NOOHs underscores that conclusion,

since the NOOHs have the level of formality we typically expect findings to have. But if the NOOHs embody (or contain) the requisite findings, and revocation of the NOOHs does not suffice to withdraw them, where do the findings exist? In the thoughts and beliefs of the Secretary or Commissioner? Scattered across various agency documents reflecting such thoughts?

That is not merely a formal or metaphysical point, but an intensely practical one. By the language of the statute, once a finding is made, agency action is mandatory, and in default of that action, the courts may compel the agency to act. Under the government's interpretation of the statute, the mandate that the courts are to enforce is straightforward. If, after holding a hearing and reviewing the evidence presented, the agency formally finds that a particular use of an animal drug has not been shown to be safe for humans, but fails to withdraw approval of the use of that drug and instead adopts some other approach for dealing with the prospective danger, the courts must enforce the congressional mandate and require the Secretary to withdraw approval.[22]

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[22] Moreover, upon the issuance of findings for or against the demonstration of the safety of the drug at the conclusion of a hearing, judicial review of whether the findings are adequately supported by the record will be available.

Under the plaintiffs' interpretation, in contrast, the courts must first determine whether an entirely subjective and unexpressed finding has been made during internal agency deliberations. On the facts of this case, plaintiffs would have us seek such a finding in the now-withdrawn 1977 NOOH, and would have us conclude that the finding continues to exist based on various statements of FDA representatives in public and before the Congress, in litigation, and in the actions taken by the FDA to encourage voluntary reductions in animal antibiotic use. That is itself sufficiently problematic, but in principle plaintiffs' position would permit lawsuits contending that the Secretary or her delegates have actually made findings that remain entirely unexpressed in *any* formal document, because they have formed opinions based on internal agency deliberations or on a review of scientific studies.[23]

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[23] The dissent disavows any reliance on the subjective views of FDA officials (Dissenting opinion, post, at 24-25), but then falls back on essentially the same argument about what the agency really believes by arguing that the now-withdrawn NOOHs were merely the "medium" for the "message" they contained: the prior internal agency conclusions that penicillin and tetracycline had not after all been shown to be safe (Dissenting opinion, post, at 25-26). The dissent concludes that withdrawal of the formal document on which it relies as a basis for judicial review is insufficient unless the agency has actually changed its mind, and deduces from a variety of sources that it has not.

Fifth, the traditional model of enforcement action described above contemplates considerable discretion on the part of an agency to decide, for prudential reasons, whether to initiate action or not, and whether to desist from proceeding before a final conclusion is reached. Such discretion is a typical and often necessary feature of the administrative process. Agencies have many responsibilities, and limited resources. Deciding whether and when to deploy those resources in an arduous, contested adversarial process is an important and difficult responsibility. It is rare that agencies lack discretion to choose their own enforcement priorities. Indeed, the Supreme Court has long applied a presumption against judicial review of agency decisions declining to proceed with enforcement actions because such decisions are, for purposes of the Administrative Procedure Act ("APA"), "committed to agency discretion." Heckler v. Chaney, 470 U.S. 821, 832-33 (1985), quoting 5 U.S.C. § 701(a)(2).

Plaintiffs' interpretation of § 360b(e)(1) would deny that discretion to the FDA. Were the "finding" that requires the withdrawal of approval located not in the final decision of the Commissioner at the conclusion of a hearing at which all relevant evidence is publicly presented, but in a determination by the head of the CVM, based on an internal consideration of studies conducted by the agency or

in the academic literature, that the scientific evidence warrants initiating a hearing so that the Commissioner might eventually reach such a final decision, the agency would be required to take irrevocable action whenever the CVM forms such an opinion that a drug is not shown to be safe, regardless of whether the FDA believes that proceeding further is worth the diversion of resources from other agency priorities. Ordinarily, administrative discretion is at its zenith when an agency decides whether to initiate enforcement proceedings. The government's position is consistent with this longstanding discretion; the plaintiffs' position is not.

In canvassing these various principles and practices, we do not suggest that they are mandatory and inescapable presumptions about administrative law. Administrative procedure is flexible, and different approaches may be appropriate in different contexts. We have pointed to what we believe are the more common understandings or expectations about agency findings, orderly procedure, administrative discretion, and judicial review. We are confident that numerous exceptions and counter-examples exist. More importantly, it is beyond doubt that Congress has the power to alter these assumptions, in any particular case or in general, by adopting legislation that imposes contrary

mandates on administrative agencies.[24] Moreover, given the preeminent importance of health and safety in the usage of powerful bioactive substances such as human and animal drugs, it would hardly be surprising for Congress to impose limits on traditional agency discretion or to mandate actions protective of human safety. But the issue here is not whether Congress *can* impose the sort of mandate plaintiffs would find in the statute – of course it can – but whether Congress has done so.

E. Summary

Our survey of the text, the context, the regulations, and the background legal principles leave us firmly persuaded that Congress has not required the FDA to hold hearings whenever FDA officials have scientific concerns about the safety of animal drug usage, that the FDA retains the discretion to institute or

[24] Such was the situation in the recently decided Cook v. FDA, 733 F.3d 1 (D.C. Cir. 2013). There, the D.C. Circuit found the FDA failed to enforce a statute that included a clear Congressional mandate for the FDA to take action in particular circumstances. The FDA argued that because enforcement is a matter of agency discretion, the decision to not enforce the statute was not subject to judicial review. Id. at 5. The court found the relevant statute to be "unambiguously binding" on the FDA in mandating that particular actions be taken. Id. at 7 (citation omitted). Thus, the case addressed an instance of explicit legislative instruction stripping an agency of discretion. Such clear legislative instruction is noticeably absent here.

terminate proceedings to withdraw approval of animal drugs by issuing or withdrawing NOOHs, and that the statutory mandate contained in § 360b(e)(1) applies to limit the FDA's remedial discretion by requiring withdrawal of approval of animal drugs or particular uses of such drugs only when the FDA has made a final determination, after notice and hearing, that the drug could pose a threat to human health and safety.

That conclusion begins, as it must, with the text of the statute. Although the text is not unambiguously clear, we believe that the FDA put forth the more natural reading. The statute requires the FDA to withdraw approval of an animal drug only "after due notice and opportunity for hearing" has been afforded, and then only "if the Secretary finds" that the drug is not shown to be safe. 21 U.S.C. § 360B(e)(1). That language most naturally refers to a finding that is issued as a result of the hearing. That interpretation, moreover, avoids injecting a second, unexpressed "finding" into the sequence of events mentioned in the statute.

Although the regulations implementing the statute do not directly address the question of interpretation posed by the plaintiffs, and contain at least some language that arguably supports the plaintiffs' reading of some terms in the

statute, the overall thrust of the regulations is consistent with the government's interpretation, and with what we regard as the more natural reading of the statutory language. Moreover, the procedure set forth in those regulations, and our reading of the text, are consistent with common assumptions about agency procedure. Under that procedure, relevant experts within the agency (the staff of the CVM) first assess the scientific issues regarding the risks and benefits of the drug, and a high-ranking agency official (the Director of the CVM) exercises discretion to institute a proceeding that can lead to the revocation of approval of the drug. Then (if the sponsor of the drug requests a hearing and raises genuine issues of material fact about the preliminary conclusions set forth in the NOOH) the staff proceeds to present evidence at a hearing featuring the separation of functions between the "prosecuting" officials instituting the hearing and the objective decisionmaker who will hear the evidence. At the conclusion of that hearing, that decisionmaker issues findings that must be approved by a higher-ranking official, the Commissioner of the FDA. If the ultimate agency finding,

which is subject to judicial review, is that the drug is not shown to be safe, the statute permits only one remedy – withdrawal of approval.[25]

Our interpretation of the statute is consistent with the regulations and with conventional procedure. That alone does not make it correct; Congress undoubtedly has the power to alter those conventions. We believe, however, that if Congress intended to do so, and to mandate the commencement of the notice and hearing process whenever the agency staff formed a scientific opinion adverse to the drug, it would have stated those intentions explicitly. Far from doing so, it has utilized language that is not only consistent with the traditional administrative process, but that is more naturally read as adopting it.

II. The Citizen Petitions

Alternatively, plaintiffs argue that even if the FDA is not required to proceed with hearings, its decision denying plaintiffs' 1999 and 2005 citizen petitions and withdrawing the 1977 NOOHs represented arbitrary or capricious agency action in violation of the APA. See 5 U.S.C. § 706(2)(A). In particular,

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[25] Our reading thus emphatically recognizes the mandatory language of the statute. Where the FDA would otherwise have considerable discretion to take whatever action might be appropriate to protect the public safety in light of the results of the hearing, Congress has specifically mandated in § 360b(e)(1) that only one response is appropriate.

plaintiffs argue that the FDA's denials were based on factors not explicitly mentioned by the statute, namely cost, time, and a preference for voluntary compliance over adversary proceedings.

The FDA's notice withdrawing the 1977 NOOHs sets out the reasons for the action:

> FDA is taking this action, and closing the corresponding dockets, because: FDA is engaging in other ongoing regulatory strategies developed since the publication of the 1977 NOOHs with respect to addressing microbial food safety issues; FDA would update the NOOHs to reflect current data, information, and policies if, in the future, it decides to move forward with withdrawal of the approved uses of the new animal drugs described in the NOOHs; and FDA would need to prioritize any withdrawal proceedings (for example, take into account which withdrawal(s) would likely have the most significant impact on the public health) if, in the future, it decides to seek withdrawal of the approved uses of any new animal drug or class of drugs.

Withdrawal of Notices of Opportunity for a Hearing: Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79697, 79697 (Dec. 22, 2011). The letters in which the FDA finally denied of the citizen petitions further elaborate on the decision to withdraw the NOOHS and deny the petitions, stating "reviewing safety information for antimicrobial drugs approved before 2003, and pursuing withdrawal proceedings in some cases, would take many years and would

impose significant resource demands on the [FDA]." J. A. at 622; J. A. at 627. In the letters the FDA describes its plan to "work[] cooperatively" with the animal pharmaceutical industry to "ensur[e] the judicious use of medically important antimicrobial drugs in food-producing animals." Id.

In arguing that such denial is arbitrary or capricious, plaintiffs claim that the FDA ignored the reams of scientific data presented in the petitions and that the reasons given by the FDA are illegitimate because they are orthogonal to what plaintiffs persuaded the district court is the governing criterion described in the statute: "whether the drugs at issue pose a threat to human health." See NRDC II, 872 F. Supp. 2d at 338.

Plaintiffs argue that this case is best analogized to Massachusetts v. EPA, 549 U.S. 497 (2007), in which the Supreme Court invalidated the denial of a petition seeking to require the Environmental Protection Agency ("EPA") to regulate greenhouse gases. But Massachusetts dealt with a much different statutory provision, one which unambiguously compelled agency action. In that case, a group of states, municipalities, and non-profit organizations sought to force the EPA to regulate four greenhouse gases as air pollutants under Section 202(a)(1) of the Clear Air Act, which provides that:

> The [EPA] Administrator *shall* by regulation prescribe . . . standards applicable to the emission of *any* air pollutant from *any* class or classes of new motor vehicles or new motor vehicle engines, which in his judgment cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare.

42 U.S.C. § 7521(a)(1) (emphasis added). The Supreme Court agreed with the plaintiffs that the text of the Clean Air Act required the EPA to regulate greenhouse gases. In reaching that conclusion, the Court understood the "judgment" contemplated by the statute as limited to the scientific question whether a particular pollutant contributed to air pollution. Put differently, the Supreme Court read the Clean Air Act not to grant the EPA discretion to choose to regulate only those pollutants that it deemed feasible or wise to regulate. As the Court had it, "the use of the word 'judgment' is not a roving license to ignore the statutory text." Massachusetts, 549 U.S. at 533. Once the EPA determined that carbon dioxide contributed to air pollution, the Court concluded, the statute required it to regulate the emission of that gas.

Massachusetts v. EPA is therefore fully distinguishable from the present case. The Clean Air Act limited the EPA Administrator's "judgment" to the scientific question of whether the pollutant in question causes dangerous air

pollution; nothing in § 360b(e)(1) limits the considerations that the FDA may take into account in deciding whether to initiate the hearing process by issuing an NOOH. Moreover, unlike the Clean Air Act, which explicitly and unambiguously requires the regulation of pollutants ("The Administrator *shall* by regulation prescribe . . . standards"), as explained above, § 360b(e)(1) does not mandate that the FDA take any action until and unless certain findings are made after a hearing.[26] In short, the Clean Air Act provision at issue in Massachusetts v. EPA unambiguously required the EPA to undertake action to create emission standards (leaving it to the EPA's expertise to determine the substance of the standards) whenever it forms a scientific judgment that a particular pollutant contributes to dangerous air pollution, while the provision of the FDCA at issue in this case requires the FDA to take a specific remedial step when, after a

[26] Plaintiffs' reliance on Brown & Williamson is also misplaced. In that case, the Supreme Court held that the FDA lacked statutory authority to regulate the sale of tobacco products. 529 U.S. at 125-26. In the course of its analysis, the Court noted that if it had statutory jurisdiction to regulate tobacco products, FDA would have been required by its organic statute to remove them from the market altogether. Id. at 135-36. There was no question in that case, however, that FDA had made "findings" about the safety of tobacco before issuing a final rule governing youth access to tobacco products. The Supreme Court did not address whether, if tobacco fell within its jurisdiction, the FDA would have been required to initiate, or forbidden from abandoning, a course of hearings that might or might not have resulted in such findings.

hearing, it has made certain findings, without imposing any absolute requirement that the agency investigate the need for withdrawing approval of animal drugs under any particular circumstance.

The present case is therefore more analogous to New York Public Interest Research Group v. Whitman, 321 F.3d 316 (2d Cir. 2003), in which we interpreted section 502(i) of the Clean Air Act, 42 U.S.C. § 7661a(i)(1). That provision required the Administrator of the EPA to give notice and, if appropriate, impose the relevant sanctions, "[w]henever the Administrator makes a *determination* that a permitting authority is not adequately administering and enforcing a program . . . in accordance with the requirements of this subchapter." Id. (emphasis added) We held that the use of the word "determination" "grants discretion." Whitman, 321 F.3d at 330. Rejecting the view that the EPA was required to issue a notice of deficiency whenever it found defects in a state permitting program, we noted that "Congress could have fashioned a regime under which, for example, an interested party could initiate the process leading to a determination of whether 'a permitting authority is adequately administering and enforcing a program,'" but that by referring to a "determination" on the part of the agency, Congress left

it to the discretion of the EPA Administrator whether and when to initiate enforcement proceedings. Id. at 331, quoting 42 U.S.C. 7661a(i)(1).[27]

For the reasons set forth above, we conclude that the decision whether to institute or terminate a hearing process that may lead to a finding requiring withdrawal of approval for an animal drug is a discretionary determination left to the prudent choice of the FDA.[28]

On that basis, it is relatively easy for us to accept the FDA's determination that its preferred program of voluntary compliance offers greater prospect for immediate and significant reductions in animal antibiotic use than the pursuit of

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[27] As further evidence of the absence of a statutory mandate, we noted the lack of any time statutory time limits on the agency's action, 321 F.3d at 331 n.8, a factor also applicable here.

[28] We respectfully disagree with Judge Katzmann's assertion (Dissenting opinion, post, at 32) that because we find Whitman to offer a helpful analogy to determine whether the FDA abused its discretion, we are implicitly equating a withdrawal action to an enforcement action. Whitman provides guidance in that the relevant statutory language in that case ("Whenever the Administrator makes a determination," 321 F.3d at 330, quoting 42 U.S.C. § 7661(a)(i)(1)) left the mandatory agency action conditional upon a discretionary agency finding, much like the statutory provision at issue here (action is required only "if the Secretary finds" that certain conditions adhere). The relevant parallel in these cases is one of analogical statutory construction that leaves action dependent upon agency discretion, a construction distinguishable from the unequivocal imperative in the statute at issue in Massachusetts v. EPA. Whether a withdrawal action is an enforcement action is not relevant to our conclusion.

a potentially contentious withdrawal hearing. That is the sort of prudential judgment better suited to expert administrators than to federal judges. We are bolstered in this conclusion by the nature of the problem confronted by the FDA. Nothing in the NOOHs suggests that penicillin and tetracycline, when administered to animals, are inherently dangerous to human health; such antibiotics are widely, effectively, and beneficially used in human medical care. And while we are hesitant, for the reasons set forth above, to ascribe scientific conclusions to the FDA based on our reading of a melange of different studies, regulatory documents, and litigation positions, it appears clear that while the agency regards the *indiscriminate* and extensive use of such drugs in animal feed as threatening, it does not necessarily believe that the administration of antibiotics to animals in their feed is inherently dangerous to human health.

Under these circumstances, we cannot conclude that it is arbitrary or capricious for the FDA to pursue polices intended to reduce the use of animal feed containing antibiotics through a variety of steps short of withdrawing approval for the use of antibiotics in feed via a protracted administrative process and likely litigation. As it was neither arbitrary nor capricious for the FDA to

deny the petitions for the reasons it did, the district court's decision to the contrary was error.

In letters recently submitted to the Court by the government, the government notes that the FDA is "encouraged" by the "overwhelmingly cooperative" reaction of the animal feed industry to the guidelines for voluntary compliance that the agency has issued in lieu of proceeding with the process initiated in 1977 with the issuance of the Penicillin and Tetracycline NOOHs, Gov't Letter dated March 27, 2014, and asserts that the high level of cooperation by drug manufacturers "demonstrate[s] that the cooperative approach . . . has been effective in enabling FDA to achieve its goals of phasing out the use of medically important antimicrobial drugs for food-production purposes," Gov't Letter Dated July 1, 2014. In light of the discussion above, it should be obvious that we express no opinion on the effectiveness of the FDA's approach to what it agrees is a significant regulatory concern about the overuse of antibiotics in animal feed, and that in determining the issues in this case, we place no weight on the agency's informal assurances that its program is successful. It is not for us to determine whether the agency has been prudent or imprudent, wise or foolish, effective or ineffective in its approach to this problem. Whether the agency's long

inaction in the face of the dangers highlighted in the 1977 NOOH's represented politically-inspired foot-dragging or wise caution in developing a cost-effective approach, it was for the agency, and not the courts, to determine how best to proceed.

CONCLUSION

For the foregoing reasons, the decisions of the district court are REVERSED, and the case is remanded to the district court with instructions to deny the plaintiffs' motion for summary judgment, grant the defendants' motion for summary judgment, and dismiss the action.

KATZMANN, *Chief Judge*, dissenting:

In 1977, nearly four decades ago, the Food and Drug Administration ("FDA") formally declared that the subtherapeutic use of penicillin and tetracyclines in animal feed "ha[s] not been shown to be safe." Penicillin-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 43,772, 43,772 (Aug. 30, 1977) [hereinafter Penicillin NOOH]; Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56,264, 56,264 (Oct. 21, 1977) [hereinafter Tetracycline NOOH]. It has never abandoned that position. Indeed, the FDA has consistently reaffirmed that using low doses of antibiotics on healthy livestock to promote growth could accelerate the development of antibiotic-resistant bacteria, causing "a mounting public health problem of global significance." FDA, Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals 4 (April 13, 2012). The FDA has nevertheless refused to move forward with the statutorily-prescribed process for withdrawing approval from the subtherapeutic use of penicillin and tetracyclines. It has also refused to begin the

process of withdrawing approval from the subtherapeutic use of other medically important antibiotics on animals.

The majority begins by recognizing that antibiotic resistance presents a serious global health problem, and that the indiscriminate use of antibiotics on animals contributes to that problem. Its ruling nevertheless seems to accept the view that Congress gave the FDA discretion to do virtually nothing about that problem for over 30 years—and then, when it finally decided to act, to adopt a different regulatory strategy than Congress expressly provided. More precisely, it permits the FDA to renounce the statutory withdrawal procedure in favor of its own "voluntary compliance" strategy, which consists of asking animal drug sponsors to voluntarily relabel their products in order to prevent them from being used to promote animal growth. *See* FDA, Guidance for Industry # 213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals (December 2013).

I cannot agree with the majority's conclusions. In light of the statutory structure and its purposes, I am convinced that 21 U.S.C. § 360b(e)(1) requires the

FDA to continue the proposed withdrawal proceedings for the subtherapeutic use of penicillin and tetracyclines in animal feed. I am likewise convinced that the agency's decision to deny the citizen petitions was arbitrary and capricious under *Massachusetts v. EPA*, 549 U.S. 497 (2007), because it failed to address the statutory question of whether the animal drug uses at issue were shown to be safe.

Today's decision allows the FDA to openly declare that a particular animal drug is unsafe, but then refuse to withdraw approval of that drug. It also gives the agency discretion to effectively ignore a public petition asking it to withdraw approval from an unsafe drug. I do not believe the statutory scheme can be read to permit those results, and I must therefore respectfully dissent.

I. The Required Hearings Claim

A. Text

Like the majority, I begin with the text of the statute:

> The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . with respect to any new animal drug if the Secretary finds—
>
> . . .
>
> (B) that new evidence . . . 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 . . . .

21 U.S.C. § 360b(e)(1).

I agree with the majority that the bare text of this statute is ambiguous, and that both plaintiffs and the FDA have presented plausible readings. In plaintiffs' view, "if the Secretary finds . . . that new evidence . . . shows that [a] drug is not shown to be safe" then "[t]he Secretary shall, after due notice and opportunity for a hearing to the applicant, issue an order withdrawing approval of . . . [that] drug." *Id.* In that case, the FDA is statutorily required to institute withdrawal proceedings whenever it makes a preliminary finding that a particular animal drug has not been shown to be safe for its approved use. In the government's view, on the other hand, "if the Secretary finds," "after due notice and an opportunity for a hearing to the applicant," "that new evidence . . . shows that [any new animal] drug is not shown to be safe" then "[t]he Secretary shall . . . issue an order withdrawing approval of . . . [such] drug." *Id.* On that reading, the FDA is never statutorily required to initiate or continue withdrawal proceedings for a drug—no matter how terrifyingly unsafe that drug may be. Instead, the FDA has complete discretion to decide when (and whether) to begin the process of withdrawing approval for drugs that it has determined are not shown to be

safe; the only statutory requirement is that if the FDA chooses to hold a hearing, and finds after that hearing that a drug has not been proven safe for its approved use, then the FDA must withdraw its approval.

In an ideal world, Congress would have written a statute that clearly selects between one of these two possible readings. But as the statutory language is ambiguous, we must do our best to determine which of these two meanings Congress intended to convey. To answer that question, I turn to the purpose and structure of the statute as a whole.

B. Purpose and Structure

"[W]e begin . . . any exercise of statutory construction with the text of the provision in question, and move on, as need be, to the structure and purpose of the Act in which it occurs." *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995). The statute at issue here, 21 U.S.C. § 360b, is part of the Federal Food, Drug, and Cosmetic Act ("FDCA"), enacted in 1938 to protect American consumers from unsafe food, drugs, medical devices, and cosmetics. *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399f).

"The FDCA statutory regime is designed primarily to protect the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use. This essential purpose pervades the FDCA." (citations omitted)). The same purpose is reflected in the FDA's mission, as defined by Congress:

> The Administration shall—
> (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
> (2) with respect to such products, protect the public health by ensuring that—
> . . .
> (B) human and veterinary drugs are safe and effective . . . .

21 U.S.C. § 393(b). Of course, this broad statutory mandate to "promote the public health" and "ensur[e] that human and veterinary drugs are safe and effective" does not compel the agency to use any particular method to attain those goals. After all, "no legislation pursues its purposes at all costs . . . and it frustrates rather than effectuates legislative intent simplistically to assume that

whatever furthers the statute's primary objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987). But in construing § 360b, we must surely keep in mind that the primary purpose of the FDCA (and of the FDA itself) is to protect the public by prohibiting commerce in unsafe food and drugs.

The structure of § 360b reflects that primary purpose, ensuring that no animal drug can be sold on the national market for a particular use unless the FDA is convinced that drug has been shown to be safe for that use. Speaking in broad outlines, § 360b(a) generally prevents any person from distributing a new animal drug unless that drug has been approved by the FDA.[1] Section 360b(b) requires any person applying for approval of a new animal drug to submit (inter alia) studies showing that drug is safe and effective, and § 360b(c) then requires the FDA to determine whether there is any statutory reason not to approve the

[1] To be more precise, § 360b(a) declares that a new animal drug "shall, with respect to any particular use or intended use of such drug, be deemed unsafe" unless it has been approved by the FDA or a special exception applies. Section 351(a)(5) then declares that any new animal drug deemed unsafe under § 360b(a) shall be deemed "adulterated," and § 331(a) prohibits introducing any adulterated drug into interstate commerce. Throughout the discussion below, I omit similarly tangential details of the FDCA's intricate statutory scheme.

new drug. Among the statutory grounds for disapproval, of course, is that the drug has not been shown to be safe. 21 U.S.C. § 360b(d)(1)(B).

The statutorily-defined process for approving a new animal drug is marked by the strict limits it places on the FDA's discretion. Within 180 days after receiving an application, the FDA "shall either" enter an order of approval, if it finds no reason to disapprove the application, or else give the applicant notice of an opportunity for a hearing. *Id.* § 360b(c)(1)(A)–(B). If the applicant requests a hearing, the FDA "shall" provide one within ninety days. *Id.* § 360b(c)(1). After the hearing, the FDA "shall" issue a final order within ninety days. *Id.* If it finds that any of the statutory grounds for disapproval apply, it "shall" refuse to approve the application; otherwise, it "shall" approve the application. *Id.* § 360b(d)(1). At each step, the FDA is constrained to follow the approval process laid out by the statute; and it is strictly forbidden at each stage of the process from approving any drug that is not shown to be safe, or from disapproving any drug without first giving its sponsor the opportunity for a hearing. The initial approval provisions in § 360b(c)–(d) are thus designed to

ensure that the FDA fulfills its statutory role of keeping unsafe drugs off of the market, while also providing due process to drug sponsors.

On plaintiffs' interpretation, the withdrawal provision at § 360b(e)(1)(B) fits comfortably within that statutory scheme. It requires the FDA to commence withdrawal proceedings whenever the FDA preliminarily determines that an approved animal drug is no longer shown to be safe for its approved use. The FDA must then provide notice and an opportunity for the drug's sponsor to be heard; and if, after the hearing, it continues to find that the approved drug use is no longer shown to be safe, it must withdraw its approval of that use. In other words, plaintiffs' interpretation reads the initial approval provisions and the withdrawal provision in parallel: both require the FDA, if it thinks a drug is not shown to be safe for a particular use, to provide a hearing and then (if still unconvinced) to disapprove that drug for that use. Both parts of the statute thus work together to make sure there are no unsafe drugs on the national market. The initial approval provisions ensure that the FDA will keep new animal drugs off the market unless they are shown to be safe, while the withdrawal provision

ensures that the FDA will withdraw approval from an existing drug if it is not shown to be safe.

The FDA's position, on the other hand, sets the approval provisions and the withdrawal provision entirely at odds. The former provisions clearly indicate that the FDA has no discretion to admit a new animal drug to the market if it initially finds that drug is not shown to be safe for its proposed use; instead, the agency must begin the rejection process by providing an opportunity for a hearing. But according to the FDA, the withdrawal provision then gives the agency complete discretion to leave an approved animal drug on the market even if it later learns that drug is utterly unsafe. That interpretation cannot be reconciled with the purpose of the FDCA, and it cannot be reconciled with the mission of the FDA itself. I see no reason to believe that Congress carefully cabined the FDA's ability to admit new drugs to the market, but then *sub silentio* left the agency entirely free to leave dangerous drugs on the market once admitted. [2]

[2] The statute does contemplate certain grounds that would prevent a new drug from being initially approved, but that would not require withdrawal of an approved drug. *Compare* 21 U.S.C. § 360b(d)(1)(C) (barring approval of a new drug for which "the methods used in, and the facilities and controls used for, the manufacture, processing,

The FDA argues that the formal withdrawal process contemplated by the statute can be expensive and time-consuming, and that its voluntary compliance strategy will reach the same result more quickly and at lower cost. There is a certain irony in the FDA's argument that the formal withdrawal process is too time-consuming, given that the agency has now delayed even beginning that process for thirty-seven years. In any case, the minimum due process protections provided by the statute—notice and an opportunity to be heard—are the same for both the initial approval process and for the withdrawal process. If the FDA preliminarily determines that a new animal drug is not shown to be safe, it must provide the drug's sponsor with the opportunity to be heard, even though the resulting hearings may be long and expensive. *See id.* § 360b(c)–(d). The agency has no discretion to deny those hearings. So too here: if the FDA preliminarily determines that an approved animal drug is not shown to be safe, it must provide the drug's sponsor with the opportunity to be heard, and then (if still not

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and packing of such drug are inadequate to preserve its identity, strength, quality, and purity"), *and id.* § 360b(d)(1)(H) (barring approval where a new drug's "labeling is false or misleading in any particular"), *with id.* § 360b(e)(2)(B)–(C) (giving the Secretary discretion to decide whether to withdraw approval from drugs under those conditions). That is, where Congress wanted to give the FDA the discretion that the agency seeks here, Congress expressly granted it.

convinced the drug is safe) must withdraw its approval. *Id.* § 360b(e)(1)(B). Providing drug sponsors an opportunity to be heard may be tedious and costly, but Congress has determined that the agency must use that process—both when it finds a new animal drug is not shown to be safe, and when it finds an existing animal drug is not shown to be safe.[3] To the extent that statutory mandate prevents the FDA from pursuing other regulatory strategies, "this is the congressional design." *Massachusetts v. EPA*, 549 U.S. 497, 533 (2007).

That same congressional design appears in 21 U.S.C. § 355, the FDCA provision regulating the approval and withdrawal of approval for non-animal drugs. Sections 355 and 360b were once a single statutory section, *see* FDCA § 505, 52 Stat. at 1052–53, and the language of the latter was largely modeled on the former. *See* H.R. Rep. No. 90-875, at 5 (1967) (noting that the two sections correspond); S. Rep. No. 90-1308, at 5 (1968) (same). Both statutory sections apply much the same process for the approval of drugs, using the same language to prevent the FDA from approving new drugs unless they have been shown to be

[3] The sole exception comes in § 360b(e)(1)'s "imminent hazard" provision, which permits the Secretary of Health and Human Services to immediately suspend approval of a particular animal drug use without a hearing if he finds that use presents an imminent hazard to human or animal health.

safe. *Compare* 21 U.S.C. § 355(c)–(d) *with id.* § 360b(c)–(d). And both use the same syntax in their respective withdrawal provisions, meaning that both share the same textual ambiguity as to whether the FDA is required to hold a withdrawal hearing once it makes a preliminary finding that a particular drug is not shown to be safe.[4]

But the available evidence indicates that courts have uniformly construed § 355(e) to require the FDA to move forward with withdrawal proceedings if it makes a preliminary finding that a drug is not shown to be safe. In dicta, the Supreme Court characterized § 355(e) in language that almost exactly mirrors the plaintiffs' interpretation of § 360b(e)(1)(B): "If the FDA discovers after approval that a drug is unsafe or ineffective, it 'shall, after due notice and opportunity for hearing to the applicant, withdraw approval of' the drug." *Brown & Williamson*, 529 U.S. at 134 (quoting 21 U.S.C. § 355(e)). The precise interpretation of § 355(e) was not before the Court in that case; but its analysis assumed that once the FDA determines a product under its jurisdiction is not shown to be safe, it is

[4] For comparison, the first sentence of § 355(e) reads: "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 that [any of the listed statutory grounds apply]." 21 U.S.C. § 355(e).

statutorily required to begin withdrawal proceedings.[5] *See id.* at 135 ("[I]f tobacco products were [covered] under the FDCA, the FDA would be required to remove them from the market."); *see also American Public Health Ass'n v. Veneman*, 349 F. Supp. 1311, 1315–16 (D.D.C. 1972) (holding that the FDA must commence withdrawal proceedings after announcing in the Federal Register that certain drugs were not shown to be effective for their approved uses). Given the parallel structure of the two statutes, § 360b(e)(1)(B) should be interpreted as § 355(e) has been: to require the agency to commence withdrawal proceedings if it initially finds that a drug has not been shown to be safe for its approved use.

C. The Relevant Regulations

Like the statute, the regulations implementing § 360b(e)(1)(B) show that the agency's duty to institute withdrawal proceedings is mandatory. In particular, 21 C.F.R. § 514.115(b) states: "The Commissioner shall notify in writing the

[5] The majority indicates that *Brown & Williamson* is inapposite because the FDA had already made "findings" showing that tobacco products were unsafe. But the "findings" referred to in that case were the result of a notice-and-comment rulemaking procedure, not the formal evidentiary hearing process envisioned by § 355(e) (or § 360b(e)(1)) and its accompanying regulations. *Compare Brown & Williamson*, 529 U.S. at 126–28, 134–35, *with* 21 C.F.R. § 10.50(c)(16)–(17). In other words, *Brown & Williamson* clearly assumes that the agency can be bound in this context by a finding that does not result from any formal evidentiary hearing.

person holding [an animal drug application] and afford an opportunity for a hearing on a proposal to withdraw approval of such application if he finds . . . that such drug is not shown to be safe . . . ." 21 C.F.R. § 514.115(b)(3)(ii). Unlike the statute, the meaning of this regulation is entirely clear. If the FDA makes an initial finding that a particular drug is not shown to be safe, it "shall" then provide the drug's sponsor with an opportunity to be heard. In sum, this regulation imposes exactly the mandatory duty that plaintiffs see in the statute: once the FDA makes a preliminary finding that a particular drug is not shown to be safe, it *must* commence withdrawal proceedings.[6]

The majority asserts that § 514.115(b) does not represent an agency interpretation of the statute, and so is not entitled to the deference we afford

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[6] The regulation is plainly mandatory. *See Lopez v. Davis*, 531 U.S. 230, 241 (2001) (noting the use of the word "shall" to "impose discretionless obligations"). That alone may well be enough to resolve this case, since "[w]here the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures." *Morton v. Ruiz*, 415 U.S. 199, 235 (1974). I say "may well be enough" because some agency regulations do not create judicially enforceable obligations. *See Leslie v. Attorney General*, 611 F.3d 171, 176 (3d Cir. 2010) ("[N]ot every promulgated regulation is of such a nature that a violation should invalidate agency action."). The parties have not thoroughly briefed whether 21 C.F.R. § 514.115(b)(3)(ii) can, of its own force, require the FDA to carry out withdrawal hearings. Because I think the statute provides sufficient grounds to reach that result, I need not decide whether the regulation does as well.

under *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). I am not sure I agree. But even if so, the regulation at least counsels strongly in favor of plaintiffs' interpretation. It makes clear that the FDA expects the withdrawal procedure to begin with an initial agency finding that a particular drug is not shown to be safe, followed immediately by notice and an opportunity for a hearing.[7] With or without *Chevron* deference, I would still interpret the statute to accord with that regulatory scheme.[8]

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[7] Other agency pronouncements confirm that the FDA has interpreted the statutory finding described in § 360b(e)(1)(B) to be a preliminary finding that begins the withdrawal process. *See* Guidance for Industry # 209, at 19 ("[I]nitiating action to withdraw an approved new drug application . . . would require the agency to make the showing required under [§ 360b(e)(1)]."); *see also* 21 C.F.R. § 514.80(a)(3) ("FDA reviews the records and reports required in this section to facilitate a determination under [§ 360b(e)] as to whether there may be grounds for suspending or withdrawing approval . . . ."); Letter from Leslie Kux, Assistant Acting Commissioner for Policy, FDA, to Sarah Klein, Center for Science in the Public Interest 2 (Nov. 7, 2011) ("If the [agency] concludes that grounds exist to withdraw a new animal drug approval, . . . FDA must provide the drug's sponsor with notice and an opportunity for a formal administrative hearing ('NOOH').").

[8] By contrast, I agree with the majority that none of the other regulations cited by the FDA help our analysis, because none of them address the interpretive question before us: whether the agency is required, after making an initial finding that a drug is not shown to be safe, to commence withdrawal proceedings. I also reject the agency's bid for *Auer* deference to its argument that § 514.115(b) and the statute refer to different findings, since "*Auer* deference is warranted only when the language of the regulation is ambiguous." *Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000).

D. Counterarguments

For the reasons described above, I believe 21 U.S.C. § 360b(e)(1)(B) compels the FDA to initiate withdrawal proceedings once it makes a preliminary finding that a drug is no longer shown to be safe. I now turn to the counterarguments that the majority finds persuasive.

1. Text

The majority's primary objection is that my interpretation of this provision contravenes either basic principles of due process or else the statutory text. As I construe the statutory text, "if the Secretary finds" that a drug is not shown to be safe, "[t]he Secretary shall, after due notice and opportunity for a hearing to the applicant, issue an order withdrawing approval of" the drug. 21 U.S.C. § 360b(e)(1). That reading grammatically links the agency's pre-hearing finding to a mandatory withdrawal order. Taken literally, it would require the FDA to withdraw approval from a drug whenever it made a pre-hearing finding that drug was not shown to be safe—making the hearing a pointless exercise. That result would contravene basic principles of due process. *See Hamdi v. Rumsfeld*,

542 U.S. 507, 533 (2004) (plurality opinion) (noting that due process requires notice and a meaningful opportunity to be heard).

There is an easy solution to this due process problem, however: to read the statute "against the background of our traditional legal concepts," *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 437 (1978), as implicitly guaranteeing the drug sponsor a meaningful opportunity to rebut the agency's preliminary finding. On that reading, the statute adopts the following procedure: When the FDA makes a preliminary finding that a drug is not shown to be safe, it must offer the drug's sponsor a hearing. If after that hearing the FDA continues to find that the drug is not shown to be safe, then it must issue an order withdrawing approval of the drug. Alternatively, if after that hearing the FDA finds the drug's sponsor has presented persuasive evidence that the drug is safe, it will announce that finding and end the withdrawal process. This procedure constrains the FDA to proceed to a hearing if it makes a preliminary finding that a drug is not shown to be safe, but also preserves the right of the drug's sponsor to rebut that preliminary finding by presenting evidence at the hearing.

The majority recognizes that this interpretation would solve the due process problem, but objects that it is not true to the statutory text. It observes that the text of § 360b(e)(1) only refers to a single finding, while this interpretation implies both a pre-hearing finding and a post-hearing finding. It also observes that the statute literally requires the agency to issue a withdrawal order if it makes the finding described in the statute. The majority infers that the finding described in the statute must therefore be a post-hearing finding, since (to preserve due process) only a post-hearing finding can absolutely require a withdrawal order.

If Congress were always perfectly precise in its language, the majority's argument would have some force. In fact, however, Congress does draft statutes that refer only to a single finding but that obviously imply both a pre-hearing and post-hearing finding. To list a few:

> If . . . the Administrator [of the Environmental Protection Agency ("EPA")] determines that [a person has violated a rule governing an exemption], the Administrator shall . . . after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption . . . .

15 U.S.C. § 2603(c)(4)(B).

> If the Secretary [of Education] determines that an accrediting agency or association has failed to apply effectively the criteria in this section, or is otherwise not in compliance with the requirements of this section, the Secretary shall . . . after notice and opportunity for a hearing, limit, suspend, or terminate the recognition of the agency or association . . . .

20 U.S.C. § 1099b(*l*)(1).

> [I]f the Secretary [of the Treasury] determines that any substantial obligation under any agreement is not being fulfilled, he may, after notice and opportunity for hearing to the person maintaining the fund, treat the entire fund or any portion thereof as an amount withdrawn from the fund in a nonqualified withdrawal.

26 U.S.C. § 7518(e)(2).

> The Administrator [of the EPA] shall review approved plans from time to time and if he determines that revision or corrections are necessary . . . he shall, after notice and opportunity for public hearing, withdraw his approval of such plan.

42 U.S.C. § 6947(a)(2).

Despite their literal text, none of these statutes (as far as I know) have been interpreted to require or permit an agency to take action based solely on its pre-hearing finding. Instead, these statutes are naturally read in the same way that I read § 360b(e)(1): as implying that the agency can only take final action after both a pre-hearing and a post-hearing finding, even though the statutory text only

explicitly mentions one such finding. Given these examples, I see nothing "singularly odd," *supra*, at ___ (majority slip op. at 26), in believing that Congress used the same shorthand in this statute that it did in those statutes—especially since the agency regulations implementing this statute explicitly envision a pre-hearing finding as well as a post-hearing finding. *See* 21 C.F.R. § 514.115(b).

2. Background Legal Concepts

The majority argues next that its interpretation is more consistent with our ordinary understanding of administrative and judicial processes. In the majority's view, the normal administrative sequence runs "hearing, finding, order," and my interpretation violates that sequence by reading the statute to refer to a pre-hearing finding.

I concede that in many contexts, a "finding" is a post-hearing determination. But as the majority recognizes, *see supra*, at ___ (majority slip op. at 42), the word "finding" can equally refer to a pre-hearing determination—and here, the agency's own regulations clearly adopt that sense. Section 514.115(b) explicitly states that the agency will only issue a notice of opportunity for a hearing if it "finds" that one of the statutory grounds for withdrawal applies. 21

C.F.R. § 514.115(b); *see also Sterling Drug, Inc. v. Weinberger*, 384 F. Supp. 557, 588 (S.D.N.Y. 1974) (referring to the agency's pre-hearing determination under 21 U.S.C. § 355(e) that a drug was ineffective as a "finding").

Nearby provisions of the statute also explicitly contemplate pre-hearing findings. When the FDA receives a new animal drug application, if it "finds that none of the grounds for denying approval" in the statute apply, it must approve the drug; if it finds otherwise, it must give notice of an opportunity for a hearing. 21 U.S.C. § 360b(c)(1). The FDA's own brief describes that pre-hearing determination as a "finding." Br. for Defendants-Appellants at 25; *see also id.* (noting that a hearing is required "[o]nly if FDA preliminarily 'finds' . . . a reason for disapproval"). Likewise, under the imminent hazard provision—as the majority notes—the Secretary first "finds that there is an imminent hazard" and then "give[s] the applicant prompt notice of his action and afford[s] the applicant the opportunity for an expedited hearing. 21 U.S.C. § 360b(e)(1); *see supra*, at ___ (majority slip op. at 42–43).

These examples point to a larger problem with the majority's analysis: namely, that it takes too limited a view of the normal administrative sequence.

Agency action often begins not with a hearing, but with a preliminary agency finding that triggers notice and an opportunity for a hearing. After all, agencies do not arbitrarily decide to initiate hearings; instead, they begin the hearing process only when they find there is some reason to do so. As described above, 21 U.S.C. § 360b and 21 C.F.R. § 514.115(b) are not unique in explicitly envisioning that a formal agency determination can occur before and lead to a hearing. *See* 15 U.S.C. § 2603(c)(4)(B); 20 U.S.C. § 1099b(*l*)(1); 26 U.S.C. § 7518(e)(2); 42 U.S.C. § 6947(a)(2). And as the majority recognizes, administrative enforcement proceedings often begin with the agency's preliminary findings in the form of "a case-initiating document that sets forth the [agency's] conclusions or charges." *Supra*, at ___ (majority slip op. at 45). In other words, the normal administrative sequence in many cases is not simply "hearing, finding, order," but instead "preliminary finding, hearing, final finding, order." In many cases, the agency's preliminary findings are not attached to any mandatory consequences —especially not in the enforcement context, where agency discretion is at its height. *See Heckler v. Chaney*, 470 U.S. 821 (1985). But if Congress so chooses, it can require an agency to act on the basis of its preliminary

findings. *Cf. id.* at 834 (explaining that Congress can "withdr[a]w discretion from the agency and provide[] guidelines for exercise of its enforcement power"). That in no way contravenes our basic understanding of the administrative process.

The majority argues next that the statute cannot refer to a pre-hearing "finding" because it will be impossible to determine when the agency has made that finding. In the majority's view, if the pre-hearing finding triggers the withdrawal process, it must precede (and require) the issuance of an NOOH. Therefore, the majority concludes, that pre-hearing finding can only exist as an intangible conclusion in the mind of the Secretary (or perhaps the collective mind of the agency); and it is hard to believe that Congress would compel an agency to act based on the internal beliefs of its officers or employees. Alternatively, the majority argues that if the pre-hearing finding is embodied in an NOOH itself, then plaintiffs cannot compel the FDA to act because the FDA has withdrawn the two NOOHs it issued.

The majority's first argument attacks a straw man. No one contends that the statute can require the FDA to act based on "an entirely subjective and unexpressed finding . . . made during internal agency deliberations." *Supra*, at

___ (majority slip op. at 50). Plaintiffs contend only that if the FDA *does* issue an NOOH announcing that a drug is not shown to be safe, it must then move forward with the withdrawal process.[9] In other words, the statutory phrase "if [the FDA] finds" does not mean "if the FDA subjectively believes"; it instead means "if the FDA formally states a preliminary finding." That interpretation in no way requires courts to review the internal thoughts or beliefs of the agency—only the agency's official public statements about a particular drug. It consequently raises none of the problematic reviewability issues that the majority suggests. To the contrary, "the mandate that the courts are to enforce" under this interpretation is just as "straightforward" as under the majority's. *Supra*, at ___ (majority slip op. at 49).

Alternatively, the majority argues that the plaintiffs cannot compel agency action based on the findings expressed in the 1977 NOOHs because those NOOHs have now been withdrawn. That argument mistakes the medium for the message. The findings that the FDA made in 1977 were that the use of penicillin

[9] Because the FDA did issue two NOOHs in this case, we are not called on to decide here whether the statute might require the FDA to commence withdrawal proceedings if it used some other means to announce its position that a particular drug had not been shown to be safe.

and tetracyclines had not been shown to be safe; the NOOHs were the medium through which the FDA announced those findings. As described above, the statute does not compel the FDA to take any action until it makes some formal public announcement of its preliminary findings. But once the FDA announces its findings, it cannot avoid withdrawal proceedings just by retracting the *announcement*. Instead, it can only avoid withdrawal proceedings by retracting the *findings*—that is, by announcing that those preliminary findings were mistaken.

Here, the FDA has never retracted its preliminary findings. To the contrary, the agency "has not issued a single statement since the issuance of the 1977 NOOHs that undermines [its] original findings." *NRDC v. FDA* ("*NRDC I*"), 884 F. Supp. 2d 127, 150 (S.D.N.Y. 2012) (opinion below). And the FDA made clear in the notices withdrawing the 1977 NOOHs that its action was based on its choice to pursue a new regulatory approach, rather than on any doubt about its findings that the subtherapeutic use of these drugs in animal feed was not shown to be safe. Because the agency has never formally repudiated the preliminary

findings announced in the 1977 NOOHs, I would hold that it remains bound by those findings under the statute.[10]

3. Agency Discretion

Finally, the majority argues that its interpretation is more consonant with our tradition of agency discretion in the enforcement context. The FDA puts this position more strongly, arguing that its decision to refrain from withdrawal proceedings is entirely immune from judicial review under *Heckler v. Chaney*, 470 U.S. 821 (1985).

The Administrative Procedure Act (APA) embodies a "basic presumption of judicial review." *Lincoln v. Vigil*, 508 U.S. 182, 190 (1993) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967)); *see* 5 U.S.C. § 702 ("A person suffering legal wrong because of agency action . . . is entitled to review thereof."); *Bowen v. Mich. Academy of Family Physicians*, 476 U.S. 667, 670 (1986) (noting "the strong presumption that Congress intends judicial review of administrative action"). Under 5 U.S.C. § 701(a)(2), however, judicial review is not available for "agency action [that] is committed to agency discretion by law." *Id.* This "very narrow

[10] For the same reason, I would also hold that the withdrawal of the NOOHs did not moot plaintiffs' claim. *See NRDC I*, 884 F. Supp. 2d at 149–51.

exception" applies "in those rare instances where statutes are drawn in such broad terms that in a given case there is no law to apply." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (internal quotation marks omitted). In such circumstances, judicial review would be useless, because the reviewing court "would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler*, 470 U.S. at 830.

The Supreme Court has explained that § 701(a)(2) creates a presumption against judicial review for "certain categories of administrative decisions that courts traditionally have regarded as committed to agency discretion." *Vigil*, 508 U.S. at 191 (internal quotation marks omitted). One such category of administrative decisions are agency refusals to institute investigative or enforcement proceedings. *See Heckler*, 470 U.S. at 830–31 ("[A]n agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion."). Although an agency's decision not to take enforcement action is presumptively unreviewable, "the presumption may be rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Id.* at

832–33. If Congress specifies by statute the conditions under which an agency must bring enforcement proceedings, then a court can review whether the agency has followed Congress's directions. But if Congress merely authorizes the agency to bring enforcement proceedings, without specifying when the agency is required to do so, then the agency's decision not to bring a particular enforcement proceeding is unreviewable. *See id.* at 834–35, 838; *see also Vigil*, 508 U.S. at 193 ("Congress may always circumscribe agency discretion . . . by putting restrictions in the operative statutes . . . ."). *Heckler* therefore "requires careful examination of the statute on which the claim of agency illegality is based," to determine the extent to which Congress has placed judicially enforceable limits on the agency's discretion. *Webster*, 486 U.S. at 600.

As I discuss in more detail below, it is not clear whether the withdrawal proceedings contemplated by § 360b(e)(1)(B) should be characterized as enforcement proceedings under *Heckler*. I believe they should not. But even if withdrawal proceedings were a form of enforcement, I would still conclude that § 360b(e)(1)(B) places judicially enforceable limits on the FDA's discretion over whether to commence those proceedings. In my view, the statute precisely

specifies when the FDA is required to commence withdrawal proceedings: when the agency finds that a particular drug is not shown to be safe. Congress has thus "indicated an intent to circumscribe agency . . . discretion, and has provided meaningful standards for defining the limits of that discretion." *Heckler*, 470 U.S. at 834. Because the statute makes withdrawal proceedings mandatory under particular circumstances, we have "law to apply" in determining whether the agency has complied with the statutory command. *See Citizens to Preserve Overton Park*, 401 U.S. at 410. I would therefore hold that even if *Heckler*'s presumption against review applies, that presumption is overcome by the statutory text.

I recognize that Congress often affords great discretion to agencies in the enforcement context, and rightly so. Enforcement decisions often require "a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise," including the resources available to the agency, the seriousness of the violation, the likelihood of a successful outcome, and many others. *Heckler*, 470 U.S. at 831–32. Nevertheless, Congress also sometimes decides to constrain agency discretion in order to ensure that its statutory purposes are fully carried out. *Cf. id.* at 834–35. As the majority recognizes, there

are particularly good reasons to believe that Congress would cabin the FDA's discretion in this context: "[G]iven the preeminent importance of health and safety in the usage of powerful bioactive substances such as human and animal drugs, it would hardly be surprising for Congress to impose limits on traditional agency discretion or to mandate actions protective of human safety." *Supra*, at ___ (majority slip op. at 53). In my opinion, § 360b(e)(1)(B) does indeed constrain the FDA's discretion in order to protect the public from unsafe drugs. I would therefore affirm the district court's decision that the agency must proceed to a hearing on whether to withdraw approval from the subtherapeutic use of penicillin and tetracyclines in animal feed.

II. The Citizen Petitions

The second issue presented in this case is whether the FDA acted arbitrarily and capriciously by denying the 1999 and 2005 citizen petitions. Those petitions asked the FDA to initiate (and conclude) proceedings to withdraw approval from the subtherapeutic use of medically important antibiotics on animals. In effect, the petitions asked the FDA to make the same preliminary finding for all medically important antibiotics that it had already made for

penicillin and tetracyclines, and then to move forward on withdrawal proceedings regarding the subtherapeutic use of all of those antibiotics. The FDA denied those petitions. In so doing, it did not address the plaintiffs' scientific evidence that the subtherapeutic use of medically important antibiotics on animals was not shown to be safe; instead, the agency said only that it preferred to employ a voluntary compliance strategy rather than formal withdrawal proceedings.

The FDA argues that withdrawal proceedings are a form of enforcement action, and so its refusal to initiate those proceedings is presumptively unreviewable under *Heckler*. It further argues that nothing in the statute rebuts that presumption, because the statute places no limit on the FDA's discretion over whether to find that a particular drug is not shown to be safe.

While the majority opinion does not explicitly consider whether withdrawal proceedings should be characterized as a form of enforcement action, it implicitly accepts the FDA's view by analogizing this case to *N.Y. Public Interest Grp. v. Whitman*, 321 F.3d 316 (2d Cir. 2003), which dealt with the EPA's "discretion to determine whether to engage its formal enforcement mechanism."

Id. at 330. *Whitman* made clear that its logic was limited to the enforcement context. Indeed, it relied on *Heckler* for the proposition that "an agency's decision not to invoke an enforcement mechanism provided by statute is not typically subject to judicial review." *Id.* at 331.

I agree with the FDA that if *Heckler* and *Whitman* governed this case, then we could not disturb the agency's decision to deny the citizen petitions. But *Heckler* and *Whitman* do not govern here, because the withdrawal proceedings contemplated by § 360b(e)(1)(B) are not a form of agency enforcement action. Instead, this case falls squarely under the framework established by *Massachusetts v. EPA*, 549 U.S. 497 (2007), which forbids an agency from relying on outside factors in refusing to make a particular statutory determination.

A. Nature of Withdrawal Proceedings

The Supreme Court has never clearly defined what agency actions are "enforcement" actions within the meaning of *Heckler*. The prototypical enforcement action, of course, is an action taken by the agency to punish a past violation of the law that the agency administers, or to enjoin an ongoing violation of that law. *See Heckler*, 470 U.S. at 831 (discussing "an agency's decision not to

prosecute or enforce, whether through civil or criminal process"); *see also NRDC II*, 872 F. Supp. 2d at 333 ("[E]nforcement proceedings are traditionally undertaken upon a finding that an entity has violated an existing regulation or law."). In this area, "an agency's refusal to institute proceedings shares to some extent the characteristics of the decision of a prosecutor not to indict," *Heckler*, 470 U.S. at 832; the agency must weigh its resources and its priorities in determining whether a particular violator should be pursued. *Cf. Whitman*, 321 F.3d at 332 (noting the impracticality of requiring the EPA to challenge every violation "no matter how slight, isolated, or technical"). At the same time, *Heckler* indicates that its concept of an "enforcement action" may extend somewhat beyond the prototypical meaning of the term. In *Heckler* itself, the plaintiffs asked the FDA not only "to recommend the prosecution" of those who used certain drugs for lethal injection, but also (inter alia) "to affix warnings to the labels of [those] drugs stating that they were unapproved and unsafe for human execution" and "to send statements to the drug manufacturers and prison administrators stating that the drugs should not be so used." 470 U.S. at 824. The Court characterized all

of these requests as seeking "investigatory and enforcement actions," *id.*, even though the latter two do not directly punish or enjoin any statutory violation.

As it is unclear what qualifies as an "enforcement action," it is doubly unclear whether the withdrawal proceedings contemplated by § 360b(e)(1)(B) fall into that category. These withdrawal proceedings share some characteristics with a traditional enforcement action; for instance, they envision an adversarial process, in which the agency attacks the safety of a particular drug and its sponsor defends it. *See* 21 U.S.C. § 360b(e)(1); 21 C.F.R. §§ 12.1–.159, 514.201 (describing hearing procedures). And like traditional enforcement actions, they implicate the agency's ability to manage its resources and set administrative priorities. *See Heckler*, 470 U.S. at 834.

At the same time, withdrawal proceedings are also similar in many ways to rulemaking proceedings, which we know fall outside the *Heckler* presumption. *See Massachusetts v. EPA*, 549 U.S. at 527–28. First, the FDA "has chosen to utilize withdrawal proceedings as the primary means of formally regulating approved drugs," the function normally served by notice-and-comment rulemaking. *NRDC II*, 872 F. Supp. 2d at 333. Second, withdrawal proceedings (like approval

proceedings) establish a general standard of conduct; they apply to anyone marketing a drug, not just the drug's sponsor. *Cf. A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1487 (D.C. Cir. 1995) (characterizing the approval of a new animal drug as a "rule"). They also have only future effect; they can prevent regulated entities from marketing a previously-approved drug in the future, but they cannot punish any past violation of the law. *See* Attorney General's Manual on the Administrative Procedure Act 14 (1947) [hereinafter Attorney General's Manual] ("Rule making is agency action which regulates the future conduct of either groups of persons or a single person . . . . The object of the rule making proceeding is the implementation or prescription of law or policy for the future, rather than the evaluation of a respondent's past conduct."); *see also id.* (contrasting rulemaking with adjudication, which normally involves "a decision as to whether past conduct was unlawful, so that the proceeding is characterized by an accusatory flavor and may result in disciplinary action"); 5 U.S.C. § 551(4) (defining a "rule" under the APA in part as an "agency statement of general or particular applicability and future effect"). Because withdrawal of approval has only future effect, the FDA must invoke a completely separate set of

enforcement procedures in order to enjoin or punish any person who markets a drug from which approval has been withdrawn. *See, e.g.*, 21 U.S.C. § 335b(b)(1)(A) (establishing procedures by which the Secretary may assess a civil penalty); *see also Cutler v. Hayes*, 818 F.2d 879, 893 & n.116 (D.C. Cir. 1987) (distinguishing the "enforceable statutory directive" to withdraw approval for unsafe drugs under 21 U.S.C. § 355(e) from typical FDA enforcement actions). Finally, although I "hesitate to place too much significance on the location of a statute in the United States Code," *Jones v. R.R. Donnelley & Sons Co.*, 541 U.S. 369, 376 (2004), it is worth noting that the FDCA's traditional enforcement mechanisms fall in a different subchapter (titled "Prohibited Acts and Penalties") from the substantive regulatory section governing withdrawal proceedings. In sum, withdrawal proceedings are in many ways "essentially legislative in nature," Attorney General's Manual at 14, rather than essentially enforcement-oriented.

Though I recognize the decision is close, I would hold that withdrawal proceedings under § 360b(e)(1)(B) are not enforcement actions within the

meaning of *Heckler* and *Whitman*.[11] Given that these withdrawal proceedings resemble rulemaking at least as much as they do enforcement, I think it better to apply "the strong presumption that Congress intends judicial review of administrative action," *Bowen*, 476 U.S. at 670, rather than the "very narrow exception" applicable for actions committed to agency discretion by law, *Citizens to Preserve Overton Park*, 401 U.S. at 410. That strong presumption seems particularly appropriate here, where there is every reason to believe that Congress did not mean to give the FDA unlimited discretion to leave unsafe drugs on the market for extended periods of time. *Cf. Bowen*, 476 U.S. at 670 ("[J]udicial review of a final agency action . . . will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." (quoting *Abbott Labs.*, 387 U.S. at 140)); *A.L. Pharma*, 62 F.3d at 1487, 1490–92 (reviewing the FDA's denial of a citizen petition asking it to withdraw approval of an approved animal drug); *cf. also supra*, at ___ (majority slip op. at 53) (recognizing there is good reason to believe Congress would limit the FDA's discretion in this sphere

[11] We are not called on to decide in this case whether withdrawal proceedings initiated under the other subsections of 21 U.S.C. 360b(e) are likewise outside the scope of *Heckler* and *Whitman*.

"given the preeminent importance of health and safety in the usage of powerful bioactive substances").

B. Arbitrary and Capricious Action

Given that the denial of the citizen petitions is subject to judicial review, I think that *Massachusetts v. EPA* squarely requires us to hold that denial was arbitrary and capricious. In *Massachusetts v. EPA*, the Court addressed a statute with a discretionary determination that triggered a mandatory consequence:

> The Administrator [of the EPA] shall by regulation prescribe . . . standards applicable to the emission of any air pollutant from any . . . new motor vehicles or new motor vehicle engines, which in his judgment cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare.

42 U.S.C. § 7521(a)(1). As construed by the Court, that statute gives the Administrator discretion to determine whether any particular air pollutant causes or contributes to air pollution that might endanger public health or welfare. But if the Administrator does judge that a particular air pollutant endangers public health, then he must prescribe emission standards. *See Massachusetts v. EPA*, 549 U.S. at 532–33.

A group of concerned organizations filed a citizen petition asking the EPA to issue regulations governing greenhouse gas emissions from motor vehicles, on the ground that those emissions endangered public health by causing global warming. 549 U.S. at 510. The agency responded by refusing to decide whether greenhouse gas emissions from motor vehicles endangered public health; instead, it denied the citizen petition based on "a laundry list of reasons not to regulate," including its belief that regulating motor vehicle emissions would not be an effective means of addressing global warming. *Id.* at 533.

The Court held that the EPA's action was arbitrary and capricious, because its reasons for denying the petition were "divorced from the statutory text." *Id.* at 532. The statutory provision authorizing the agency to exercise its judgment was "not a roving license to ignore statutory text," but only "a direction to exercise discretion within defined statutory limits." *Id.* at 533. Since the discretionary "judgment" contemplated by the statute asked only whether a particular air pollutant endangered public health, the EPA could not rely on other reasons—such as the cost or inefficiency of new regulations—in deciding whether or not to regulate. Instead, the EPA could only avoid regulating

greenhouse gas emissions from motor vehicles if it found that "greenhouse gases do not contribute to climate change," or that "the scientific uncertainty is so profound that it precludes [the agency] from making a reasoned judgment" on that issue. *Id.* at 533–34. The agency's discretion was thus limited to considering the scientific question described in the statute, not any other factors the agency might deem relevant. *Cf. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (noting that an agency acts arbitrarily and capriciously if it "has relied on factors which Congress has not intended it to consider").

Like *Massachusetts v. EPA*, this case involves a statute that (as I interpret it) follows a discretionary determination with a mandatory consequence. If the FDA (in its discretion) determines that a particular drug is not shown to be safe, then it shall commence (mandatory) withdrawal proceedings. *See* 21 U.S.C. § 360b(e)(1)(B). But just as in *Massachusetts v. EPA*, the agency's discretion is limited to making the determination required by the statute; it cannot refuse to make that determination just because it would prefer a different regulatory strategy than the statute specifies.

The FDA offers reasons for inaction that are eerily similar to those rejected by the Court in *Massachusetts v. EPA*; it complains that withdrawal proceedings "would take many years and would impose significant resource demands," and claims that its voluntary compliance approach will work just as well. Letter from Leslie Kux, Assistant Acting Commissioner for Policy, FDA, to Sarah Klein, Center for Science in the Public Interest 3–4 (Nov. 7, 2011). Again, there is some irony in the FDA's protestation that withdrawal proceedings could take many years; the agency failed to respond to the citizen petitions for twelve and six years, respectively, and its own voluntary compliance strategy contemplates a three-year "phase in." *See NRDC II*, 872 F. Supp. 2d at 339; Guidance for Industry # 213, at 9. But that is beside the point. Even if the agency's reasons were indisputably sound, they are not contemplated by the statute. Because the FDA must "exercise [its] discretion within defined statutory limits," *Massachusetts v. EPA*, 549 U.S. at 533, it must respond to the citizen petition by evaluating the statutory question of whether the drug uses at issue are shown to be safe.

The majority contends that *Massachusetts v. EPA* is distinguishable because the statute in that case "unambiguously compelled agency action" and "limited

[the agency's] 'judgment' to the scientific question." *Supra*, at ___ (majority slip op. at 58, 60). I respectfully believe that the first distinction is incorrect, and that the second begs the question.

As for the first: The statute construed in *Massachusetts v. EPA* was just like the statute at issue here—part discretionary (as to the agency's "judgment"), and part mandatory (as to the ensuing regulation). Indeed, the Court recognized in its opinion that the EPA was not necessarily required to take any action beyond adequately responding to the citizen petition. *See* 549 U.S. at 534–35 ("We need not and do not reach the question whether on remand EPA must make an endangerment finding, or whether policy concerns can inform EPA's actions in the event that it makes such a finding."). I do not understand how that can be read to "unambiguously compel[]" agency action.

As for the second: Nothing in the Clean Air Act explicitly "limited the EPA's Administrator's 'judgment' to the scientific question," *supra*, at ___ (majority slip op. at 60), any more than 21 U.S.C. § 360b(e)(1)(B) explicitly limits the FDA's judgment to the scientific question. *See Massachusetts v. EPA*, 549 U.S. at 549–53 (Scalia, J., dissenting). Instead, the question presented in *Massachusetts*

v. EPA was whether the statute *implicitly* limited the agency's judgment to the scientific question, by specifying only that question for the agency's consideration. The Court held that it did: although the agency may have "significant latitude as to the manner, timing, content, and coordination of its regulations with other agencies, . . . its reasons for action or inaction must conform to the authorizing statute." *Id.* at 533 (majority opinion). Exactly the same logic applies here: the FDA's "reasons for action or inaction" must conform to the authorizing statute, meaning that they must rest on the statutory question of whether the drugs have been "shown to be safe," 21 U.S.C. § 360b(e)(1)(B). Like the EPA with air pollutants, the FDA cannot "choose to regulate only those [drugs] that it deem[s] feasible or wise to regulate." *Supra*, at ___ (majority slip op. at 59).

The majority apparently believes that the FDA's approach is permissible because although the agency regards "the *indiscriminate* and extensive use of [medically important antibiotics] in animal feed as threatening, it does not necessarily believe that the administration of antibiotics to animals in their feed is inherently dangerous to human health." *Supra*, at ___ (majority slip op. at 63). I

see no reason why that should matter to our analysis. As the majority recognizes at the opening of its opinion, antibiotic resistance "presents a serious threat to human health," and can result in "longer hospital stays, worse side effects of treatment, and a greater likelihood of death." *Supra*, at ___ (majority slip op. at 3–4). The FDA agrees. *See* J.A. 405 (reproducing statements from the FDA website). The agency likewise agrees that the overuse of antibiotic drugs on livestock can contribute to the development of antibiotic resistance. *NRDC II*, 872 F. Supp. 2d at 340. This problem, like global warming, is tied to the combined effects of many small actions. Each individual animal dose of antibiotics may not endanger human health; but that is no reason to think that Congress gave the agency discretion to ignore the larger problem.

In any case, the 2005 citizen petition specifically asks the FDA to withdraw approval from the indiscriminate "herdwide/flockwide" use of these antibiotics. J.A. 262. If indeed the FDA regards such indiscriminate uses as threatening—or more precisely, as "not shown to be safe," 21 U.S.C. § 360b(e)(1)(B)—then it should withdraw the relevant approvals. At the very least, it should be required

to squarely address the scientific issue of whether those uses have been shown to be safe, which is the sole issue that the statute makes relevant.

Today as in 1977, drug manufacturers have "failed to resolve the basic safety questions that underlie the subtherapeutic use of [antibiotics] in animal feed." *Supra*, at ___ (majority slip op. at 8) (alteration in original) (quoting Penicillin NOOH, 42 Fed. Reg. at 43,792); *see* Tetracycline NOOH, 42 Fed. Reg. at 56,288. In not addressing those safety questions, the FDA has shirked its statutory responsibilities. I would hold that action was arbitrary and capricious.

III. Conclusion

After thirty-seven years of delay, the FDA has finally come up with a strategy for confronting the dangers caused by the subtherapeutic use of medically important antibiotics on animals. That strategy is to ask pharmaceutical manufacturers to voluntarily relabel their drugs to prevent these uses. *See* Guidance for Industry # 213. Meanwhile, the FDA continues to avoid the withdrawal procedure contemplated by the statute, claiming that procedure is too slow and too expensive. "One can only wonder what conceding the

absence of an effective regulatory mechanism signals to the industry which the FDA is obliged to regulate." *NRDC II*, 872 F. Supp. 2d at 339 n.23.

I agree with the majority that it is not our duty to judge the wisdom of the FDA's approach. But it is emphatically our duty to judge whether the FDA's actions conform with the dictates of Congress. For the reasons I have given, I am convinced that they do not. As I interpret 21 U.S.C. § 360b(e)(1)(B), it requires the FDA to pursue formal withdrawal proceedings whenever it makes a preliminary finding that an animal drug is not shown to be safe for its approved use. And under *Massachusetts v. EPA*, it also requires the agency to address that preliminary question based on the scientific evidence available—not based on its preference for a different regulatory strategy. Whatever the merits of the FDA's voluntary compliance strategy, the agency may not escape its statutory responsibilities "simply by asserting that its preferred approach would be better policy." *Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1089 (D.C. Cir. 1996).

To be clear, the statute does not restrain the agency from employing other strategies in tandem with formal withdrawal proceedings. As the district court below noted, nothing prevents the agency from simultaneously initiating

withdrawal proceedings and also seeking voluntary compliance. *See NRDC II*, 872 F. Supp. 2d at 340. But while the FDA is free to take any additional steps it thinks are appropriate, it must at least carry out the minimum responsibilities placed on it by the statute. If the FDA finds those statutory responsibilities are unmanageable, then it should ask Congress—not us—to provide it with broader discretion.

Because the majority decides otherwise, I respectfully dissent.