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.