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Murky Intentions: The Decision to Allow Subtherapeutic Use of Antibiotics in Animal Feed

Kristina Youmaran

Murky Intentions: The Decision to Allow Subtherapeutic Use of Antibiotics in Animal Feed

NRDC v. FDA, 760 F.3d 151 (2d Cir. 2014)

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I. INTRODUCTION

The threat of a superbug has been heard across a variety of mediums. The medical community tells society not to use too much hand sanitizer in order to reduce the development of bacteria that is more resistant. In addition, medical personnel avoid over-prescribing antibiotics to children to treat minor illnesses that do not necessarily require medication.[1] The threat of a resistant superbug to all developed antibiotics is a real concern that many people may not have considered. One threat that has received mixed reviews from the general public, the food industry, and the drug industry is the use of antibiotics in animal feed.[2] If you go into a grocery store, you may find labels that proclaim "no antibiotics." However, this remains in the minority, as most meat sold in stores has at least some exposure to antibiotics.[3]

If humans are given antibiotics for common illnesses, why is it an issue that animals are fed antibiotics? Animals are prone to disease and become expensive to farmers if the animals die from contracting diseases, which, in turn, affects the consumer. Antibiotics have been used for decades in the United States.[4] Not only are they administered into animal feed to fight illness, but they are also used to prevent disease and promote growth.[5]

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[1] Dr. Richard Raymond, What the Center for a Livable Future, Pew Commission & Others Aren't Telling You About Food Production 1-2.
[2] Brent F. Kim et al., Industrial Food Animal Production in America: Examining the Impact of the Pew Commission's Priority Recommendations ix-xi (2013).
[3] *Id*. at 2.
[4] *Id.*
[5] News Desk, *Poultry 'Feed Tickets' Show Systematic Antibiotics Use,* http://www.foodsafetynews.com/2014/09/poultry-feed-tickets-show-systematic-

Studies have shown that antibiotic resistant bacteria can result from subtherapeutic use of these drugs in animal feed, which can easily spread to humans.[6] Society has already experienced the effects of at least one strain of antibiotic-resistant bacteria, Methicillin Resistant Staphylococcus Aureus (MRSA), which killed more Americans than HIV/AIDS or homicide.[7] As the connection between antibiotic over-usage and antibiotic-resistant bacteria becomes more evident, it is crucial that the government, food industry, and health professionals take tangible steps to ensure public safety.

The Food and Drug Administration ("FDA") allows the use of antibiotics in animal feed for disease control, disease prevention, and animal growth, but does not have a system in place to review the distribution of antibiotics.[8] The FDA can initiate withdrawal proceedings that review subtherapeutic drugs and remove them from service if deemed unsafe. However, as seen in *NRDC v. FDA,*[9] despite a proceeding filed in 1977 for the banning of certain subtherapeutic uses of drugs in animal feed, the FDA is not currently required to hold withdrawal proceedings for those drugs.[10]

II. FACTS AND HOLDING

The FDA sought an appeal after the U.S. District Court for the Southern District of New York entered summary judgment in favor of public interest advocacy organizations, including 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. (collectively, "Plaintiff").[11]

In 2011, Plaintiffs filed this lawsuit against the FDA alleging two claims: (1) under 21 U.S.C. § 360b(e)(1), the FDA must hold the 1977

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antibiotics-use/#.VGIwaVPF800 (last visited Nov. 21, 2014).

[6] Brent F. Kim et al., Industrial Food Animal Production in America: Examining the Impact of the Pew Commission's Priority Recommendations 2 (2013).

[7] Lauren Orrico, Note, *Squashing the Superbugs: A Proposed Multifaceted Approach to Combatting Antibiotic-Resistant Bacteria*, 27 J. L. & Health 259, 260-61 (2014).

[8] *Id.*

[9] 760 F.3d 151 (2d Cir. 2014).

[10] Lauren Orrico, Note, *Squashing the Superbugs: A Proposed Multifaceted Approach to Combatting Antibiotic-Resistant Bacteria*, 27 J. L. & Health 259, 262 (2014).

[11] NRDC v. FDA, 760 F.3d 151, 156 (2d Cir. 2014).

notices of opportunities for hearing ("NOOHs") hearings, and (2) the FDA delayed its response to the 1999 and 2005 petitions to withdraw some of the subtherapeutic use of antibiotics in animal feed.[12] Depending on what the hearings under the first claim revealed, the FDA would have to remove approval for the listed drugs.[13] Additionally, under the second claim, Plaintiffs asked the Court to prompt a response from the FDA.[14]

The FDA denied the petitions in the second claim, thus making the claim moot.[15] They opined that granting the requests in the petition would be too "costly and lengthy."[16] In addition, new research would have to be performed along with an individual drug analysis.[17] The plaintiff responded by filing a supplemental complaint, which alleged that "denial of their petitions was arbitrary and capricious."[18]

The district court "granted plaintiffs' motion for summary judgment on the NOOH claim," and found "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."[19] The district court also "ordered [the] 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."[20] Further, it ruled in favor of the plaintiff's claim "that the denial of the citizen petitions was arbitrary and capricious," because the FDA's claim regarding the cost and length of withdrawing the proceedings was not relevant under the provided statute.[21] Even though the FDA argued that it was trying to regulate antibiotic use in animal feed, the court found that the

[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.* at 157.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*; *See* NRDC v. FDA, 872 F.Supp.2d 318 (S.D.N.Y.2012).

statute was clear and there were still certain mandatory measures that must be taken.[22] In its decision, the court primarily relied on *Massachusetts v. EPA*.[23]

On appeal by the FDA, the appellate court reversed the district court's ruling.[24] The appellate court found that it was ultimately the FDA's decision to "institute or terminate a hearing process."[25] As such, the FDA's decision to deny the petitions was not "arbitrary nor capricious."[26]

III. LEGAL BACKGROUND

A. *The Required Hearings Claim*

1. History of the FDA's Task-Force and NOOH Hearings

Dating back to 1951, the FDA approved antibiotics as an ingredient in animal feed in order to promote animal growth, and two years later, the use of antibiotics as a drug in the feed.[27] This trend began as animal meat producers sought to yield larger animals in a shorter time span.[28] Since the FDA had authority to regulate animal drugs under 21 U.S.C. § 360b(a)(1), drug manufacturers asked the FDA to approve a number of different antibiotics for animal usage.[29] It was not until the 1960s that 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."[30] By 1972, the FDA created a task force to investigate a claim on animal antibiotic use made by the United Kingdom's Joint Committee.[31] The task force eventually recommended that antibiotic manufacturers provide

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[22] *Id.*
[23] 549 U.S. 497, 127 S.Ct. 1438, 167 L.Ed.2d 248 (2007).
[24] *NRDC,* 760 F.3d at 176 (2d Cir. 2014).
[25] *Id.* at 175.
[26] *Id.*
[27] *Id.* at 153.
[28] *Id.*
[29] *Id.; See* 21 U.S.C. § 360b(a)(1).
[30] *Id.*; *See* Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes: Opportunity for Hearing, 42 Fed.Reg. 56264, 56266 (Oct. 21, 1977) ("Tetracycline NOOH").
[31] *Id.* at 154. ("The claim included the notion that there was a fatality of 0.26% with the drug.").

evidence regarding drug safety in animal feed. Specifically, the investigation revealed that:

(1) the use of antibiotics in 'subtherapeutic amounts' favors the selection of antibiotic-resistant bacteria; (2) 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.[32]

After obtaining the requested information, NOOHs were created for two antibiotics – penicillin and tetracycline. The FDA's Bureau of Veterinary Medicine Director found the usage of these antibiotics unsafe. However, the antibiotics were ultimately allowed to be used in certain amounts.[33] In the 1980s and 1990s, studies of antibiotic use in animals and their effect on humans continued, reaching various conclusions regarding the safety of the drugs for animals and humans.[34] By 1999, public interest groups began efforts to push the FDA to withdraw any approval for the subtherapeutic use of antibiotics in animal feed.[35]

2. The Statute and Regulations

The FDA regulates drugs administered into animal feed under 21 U.S.C. § 360b(a)(1).[36] Section 360b(e)(1) lays out when it is appropriate to withdraw approval of antibiotics.[37] Specifically, it states that "[t]he Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed . . . with respect to any new animal drug if the Secretary finds." The statute also lists six different examples involving scientific data, untrue statements of material fact, or new information.[38] The statute allows the Secretary or the Commissioner of the

[32] *Id.*
[33] *Id.*
[34] *Id.* at 154-55.
[35] *Id.* at 155-56.
[36] *Id.* at 153.
[37] 21 U.S.C. § 360b(e)(1).
[38] *Id.*

FDA[39] to suspend any drug approval if he or she finds that it presents an imminent danger to animals or humans.[40] The statute does not clearly specify when the finding must take place or the process leading to the findings.[41] If the statute's meaning is disputed, courts shall explain the language of the statute along with an analysis of what is typically found in legal practice.[42]

Another important regulation in this case is § 360b(d)(1).[43] This section outlines the grounds on which an application for approval of a drug may be dismissed, which may occur only after due notice and an opportunity for a hearing.[44]

Sections 5.84, 514.200(c), 10.55(b)(2)(i), and 514.155(b)(3)(ii) are also relevant in regards to various interpretations of § 360b(d)(1).[45] Ultimately, these regulations sketch out who can issue NOOHs, when these findings are appropriate and how these decisions relate to holding hearings.[46] Under 21 C.F.R. § 5.84,[47] "[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 been waived."[48] Regulation § 514.200(c) dictates that an application for a hearing must:

> 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 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

[39] NRDC v. FDA, 760 F.3d 151, 156 n. 12 (2d Cir. 2014).
[40] 21 U.S.C. § 360b(e)(1).
[41] *NRDC*, 760 F.3d at 158.
[42] *Id.* at 160. (Dissenting opinion, post at 5, quoting N.Y. State Conference of Blue Cross & Blue Sheifl Plans v. Travelers Inc. Co., 514 U.S. 645, 655 (1995)).
[43] 21 U.S.C. § 360b(d)(1).
[44] *Id.*
[45] *NRDC*, 760 F.3d at163-66.
[46] *Id.*
[47] NRDC v. FDA, 760 F.3d 151, 156 n. 18 (2d Cir. 2014).
[48] *NRDC*, 760 F.3d at 164 (quoting 21 C.F.R. § 5.84(a)(1)-(2)).

> 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.[49]

This regulation outlines the requisites for the hearings in regards to a NOOH and relates that findings could happen after a hearing or in absence of a hearing.[50] Lastly, § 514.155(b)(3)(ii) details that 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)."[51] Under this rule, the Commissioner must make a finding to order a NOOH and withdraw approval of a NADA.[52]

B. *The Petition's Claim*

1. A Comparison to *New York Public Interest Research Group v. Whitman*[53]

In *New York Public Interest Research Group v. Whitman*, an advocacy group challenged the EPA's insufficient enforcement of environmental programs under § 502(i) of the Clean Air Act ("CAA").[54] Under section 502(i) of the CAA, notices or sanctions are to be provided when "the Administrator makes a determination that a permitting authority is not adequately administering and enforcing a program."[55] One issue in the case was an interpretation of § 502(i), specifically when the EPA is required

[49] *NRDC*, 760 F.3d at 164-65.
[50] *NRDC*, 760 F.3d at 165.
[51] *Id.* at 166. (quoting §514.155(b)(3)(ii)).
[52] *NRDC*, 760 F.3d at 166.
[53] 321 F.3d 316 (2d Cir.2003).
[54] New York Pub. Interest Research Grp. v. Whitman, 321 F.3d 316 (2d Cir. 2003).
[55] *Id.* at 330.

to hold these enforcement proceedings.[56] However, the court found that the EPA Administrator has discretion as to when an enforcement proceeding must be initiated. Furthermore, if Congress intended for the EPA to initiate enforcement proceedings whenever there was a deficiency in a program, then "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.'"[57]

IV. INSTANT DECISION

The *NRDC* begins with a review of 21 U.S.C. § 360b(e)(1) to determine if the FDA must continue withdrawal hearings for antibiotics previously approved for subtherapeutic purposes but later shown to not necessarily be "safe for humans."[58] The court focuses on the language "shall ... issue an order withdrawing approval"[59] and determines that this language is one of the major areas that the parties disagree over in interpreting when an order of withdrawal must be made.[60] The court ultimately sides with the FDA's interpretation with respect to both grammar and standard legal practice.[61] The plaintiff's interpretation requiring two findings goes beyond what is called for in the statute itself because the plaintiff's interpretation would necessitate the Secretary to make findings before the hearings would even begin.[62] The court concedes that the statute's grammar can make interpretation difficult. Nonetheless, the FDA's interpretation is correct in allowing the Secretary to withdraw a drug's approval following a notice and hearing process when a drug is determined unsafe.[63]

Next, the court examines the broader statutory context in order to better understand the intent of the statute.[64] In this section, approval of a drug can be withdrawn immediately "'if the Secretary . . . finds' that the drugs

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[56] *Id.*
[57] *NRDC*, 760 F.3d at 174-75.
[58] *NRDC*, 760 F.3d at 158.
[59] 21 U.S.C. § 360b(e)(1).
[60] *NRDC*, 760 F.3d at 158.
[61] *Id.* at 161.
[62] *Id.*
[63] *Id.* at 163.
[64] *Id.*

pose an 'imminent hazard to the health of man or of the animals.'"[65] However, this language supports neither party's arguments.[66] The language in § 360b(d) also discusses when the Secretary can refuse the approval of a new drug for animal-use, but the court found this does not occur until a hearing has concluded.[67] On this issue, the court held that "it is unquestionably clear from the text that the mandate to order withdrawal only applies after the agency has held a hearing.[68] 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."[69]

The court then looks at the regulations brought by the parties regarding the required hearings claim but reasons that the proffered regulations are not taken into consideration because they do not "directly address the question before the Court."[70] Finally, the court examines the background legal concepts concerning administrative law and finds it likely that Congress would "impose limits on traditional agency discretion or to mandate actions protective of human safety" when dealing with the safety of drugs.[71]

In responding to whether hearings are required, the court takes the text of the statute, the context of the statute, regulations surrounding the use of the statute, and the legal context that the statute was used in, and holds that the FDA is not required to hold hearings and has broad discretion when deciding whether or not a drug used on animals must be discontinued.[72]

For the second claim, regarding denial of the 1999 and 2005 petitions as being "arbitrary or capricious," the court turns to *New York Public Interest*

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[65] *Id.*; *See* 21 U.S.C. § 360b(e)(1) (last paragraph).
[66] *Id.* at 162.
[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] *Id.* at 166.
[71] *Id.*
[72] *Id.*

Research Group v. Whitman[73] and relies on the text "'[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.'"[74] The court decides that using the word "determination" allows for discretion by, in this case, the EPA Administrator.[75] The court finds this analogous to the *NRDC* case, in that the FDA, like the EPA Administrator, has discretion to decide if, and when, a hearing process will take place in response to requiring a withdrawal of approval for animal drugs.[76] The court asserts that it is reasonable for the FDA to merely reduce the amount of antibiotics used instead of withdrawing them completely.[77] Therefore, the FDA was not acting arbitrarily or capriciously when it denied the petitions.[78]

V. COMMENT

Two major results emerged from the *NRDC*[79] decision: (1) the FDA has discretion when deciding if withdrawal proceedings are necessary for drugs and (2) the FDA reasonably exercised diligence when deciding whether or not to take action on previous citizen petitions by taking some level of action.[80] Considering relevant precedent, the language of the statute leaves room for many interpretations. When these regulations are subject to multiple interpretations, the court will ultimately defer to the agency in charge.[81] This decision, in addition to raising awareness of the procedural issues regarding the use and removal of certain drugs, highlights the fundamental issues under the current system in allowing drugs to be used in animal feed, particularly when research indicates these drugs pose public health risks.[82]

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[73] 321 F.3d 316 (2d Cir. 2003).
[74] *Id.*
[75] *Id.*
[76] *NRDC*, 760 F.3d at 175.
[77] *Id.*
[78] *Id.*
[79] 760 F.3d 151 (2d Cir. 2014).
[80] *Id.*
[81] *NRDC*, 760 F.3d at 175.
[82] *Id.* at 176.

The FDA's intentions appear fair, given that their objective is to create a forum where hearings are held to determine if a drug is no longer safe for public use.[83] However, these intentions may be misguided provided that no hearings are held, despite citizen petitions and the instant case.[84] The reasoning behind the FDA's decision to not pursue these hearings remains unclear.[85] As the dissent describes, "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.'"[86] The FDA is aware of the dangers of these drugs, even in low doses.[87] Yet, no action has been taken, and courts continue to allow the FDA to abuse its discretion on this issue.[88] By allowing the FDA to use its discretion has ensured change will not occur, especially since inaction has reigned since the 1977 introduction of the withdrawal procedures.[89] Essentially, the decision in this case allowed the FDA to ignore a public petition deeming a drug unsafe, which is not in line with the original intention of the regulation 21 U.S.C. § 360.[90]

A. *The Required Hearings Claim*

Under 21 U.S.C. § 360b(e)(1),

> "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

[83] Lauren Orrico, Note, *Squashing the Superbugs: A Proposed Multifaceted Approach to Combatting Antibiotic-Resistant Bacteria*, 27 J. L. & Health 259, 277 (2014).
[84] *NRDC*, 760 F.3d at 156.
[85] *Id.*
[86] *NRDC*, 760 F.3d at 176, *citing* FDA, Guidance for Industry # 209: The Judicious Use of Medically Important Antimicrobial Drugs in Food–Producing Animals 4 (April 13, 2012).
[87] *Id.*
[88] *Id.*
[89] *Id.*
[90] *Id.*

> to be safe for use under the conditions of use upon the basis of which the application was approved...."[91]

The text reveals the ambiguity within the statute and in situations such as in the present action. It is up to the courts to look to Congress' intent when drafting the statute.[92] In one interpretation, it would be up to the Secretary after notice and a hearing to declare whether the drug needs to be withdrawn.[93] Alternatively, the statute could be interpreted so that the FDA is required to withdraw approval when evidence shows the drug is no longer safe.[94] The decision at hand sided with the former, providing the FDA with more discretion.[95]

However, as the dissent states, the purpose of the FDA, according to the Federal Food, Drug, and Cosmetic Act,[96] is to "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."[97] It is also up to the FDA to "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective."[98] This language does not specifically present how the FDA can "promote public health" or ensure that drugs are "safe and effective."[99] If the primary purpose of the FDA is to promote public health and to ensure that drugs are safe and effective, it makes sense that Congress intended that the FDA thoroughly investigate all claims that a drug may no longer be safe for public use.[100] These investigations are time-consuming and expensive; however, they align with the main purpose of the FDA and are a necessary part of the agency's role in ensuring public safety.[101]

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[91] *NRDC*, 760 F.3d at 177, *citing* 21 U.S.C. § 360b(e)(1).
[92] *NRDC*, 760 F.3d at 175, *citing* FDA, Guidance for Industry # 209: The Judicious Use of Medically Important Antimicrobial Drugs in Food–Producing Animals 4 (April 13, 2012).
[93] *NRDC*, 760 F.3d at 177.
[94] *Id.*
[95] *Id.*
[96] Pub.L. No. 75–717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399f).
[97] *NRDC*, 760 F.3d at 178, *citing* 21 U.S.C. § 393(b).
[98] *Id.*
[99] *Id.*
[100] *NRDC*, 760 F.3d at 178.
[101] *NRDC*, 760 F.3d at 180.

Additionally, courts have "construed § 355(e) to require the FDA move forward with withdrawal proceedings if it makes a preliminary finding that a drug is not shown to be safe."[102] The dissent properly brings attention to the fact that "[i]n 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.'"[103] Sections 360b(e)(1)(B) and 355(e) are similar regulations, but have been interpreted differently.[104] One requires mandatory withdrawal proceedings, while the other is up to the discretion of the FDA. Given the similarities between the statutes, if a drug is found to be no longer safe, § 360b(e)(1)(B) should be construed in similar fashion to § 355(e) and require withdrawal proceedings to commence.[105] Without this interpretation, the FDA fails to achieve its purpose.

1. The Citizen Petition

In 1999 and 2005, the FDA ignored citizen petitions asking to initiate withdrawal proceedings.[106] Instead, the FDA simply employed a voluntary program where drug companies could follow a compliance strategy in lieu of partaking in the withdrawal proceedings.[107] The question is whether the FDA did so arbitrarily and capriciously.[108]

Comparing this case to *Whitman,*[109] where the court ruled that the Administrator has authority to determine the enforcement of a program,[110] the FDA's discretion in denying the citizen petitions seems to be warranted.

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[102] *Id.*
[103] *NRDC*, 760 F.3d at 181.
[104] *NRDC*, 760 F.3d at 180-81.
[105] *Id.*
[106] *NRDC*, 760 F.3d at 187.
[107] *Id.*
[108] *NRDC*, 760 F.3d at 188.
[109] N.Y. Public Interest Grp. v. Whitman, 321 F.3d 316 (2d Cir.2003) (Holding that "the EPA's finding that in the notice of final rulemaking granting interim approval, the agency had to specify what changes the state had to make before fully approving the program."). *Id.*
[110] *Id.* at 330.

Yet, the issue in *Whitman* involved an agency enforcement action, whereas § 360b(e)(1)(B) does not.[111] As the dissent discusses, the withdrawal proceedings are similar to traditional enforcement actions in certain aspects, such as how "they envision an adversarial process, in which the agency attacks the safety of a particular drug and its sponsor defends it . . . [and] they implicate the agency's ability to manage its resources and set administrative priorities."[112] However, this case and the processes that the withdrawal proceedings follow are more analogous to the rule-making process.[113] The proceedings resemble a notice-and-comment format because they allow petitions to be heard and responded to accordingly.[114] Furthermore, they also generally apply to standard contact by applying to drug sponsors and marketers.[115]

Whether withdrawal proceedings succumb to the rulemaking process or enforcement actions is a close debate. Nevertheless, Congress likely did not intend to give the FDA "unlimited discretion to leave unsafe drugs on the market for extended periods of time," which would be the case under an enforcement action interpretation.[116] Indeed, it appears more plausible that Congress intended to allow for judicial review of the FDA's administrative actions.[117] Without allowing for judicial review, the FDA would have unlimited power to avoid withdrawal proceedings and potentially unsafe drugs would remain in use.[118]

According to the majority opinion, the FDA can continue to ignore citizen petitions because the agency believes that "the *indiscriminate* and extensive use of [medically important antibiotics] in animal feed is threatening, it does not necessarily believe that the administration of antibiotics to animals in their feed is inherently dangerous to human health."[119] However, the majority and the FDA agree that antibiotic

[111] *NRDC*, 760 F.3d at 188.
[112] *NRDC*, 760 F.3d at 188-89.
[113] *Id.*
[114] *Id.*
[115] *Id.*
[116] *NRDC*, 760 F.3d at 190.
[117] *Id.*
[118] *Id.*
[119] *NRDC*, 760 F.3d at 192.

resistance is a public health concern and there is a connection between the over-administration of drugs and the development of antibiotic resistance.[120]

Regardless, inaction remains. Subtherapeutic administration of the drugs may not immediately endanger the public, but a combination of these smaller acts will lead to an increasing threat.[121] The purpose of the citizen petitions is to bring the issues of antibiotic use before the FDA. Instead of taking the claims seriously and investigating them, the FDA has continually ignored them. This is particularly concerning given that "[i]f 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."[122] Simply ignoring the issue does not align with Congress' intent.

2. Moving forward

The *NRDC*[123] court sought a ruling on two drugs – penicillin and tetracyclines – when, in reality, there are hundreds of antibiotics being used subtherapeutically in animals.[124] There remains substantial room for progress in ensuring that antibiotic drug use in animal feed is not a serious public health concern. If the FDA does not take action, the threat of developing antibiotic resistant bacteria is of imminent concern.

A potential step forward is to have Congress enact a less ambiguous statute addressing when withdrawal proceedings need to be held and under what conditions.[125] Creating timetables and specific procedures to create actionable steps forcing the FDA to, at a minimum, investigate claims, would

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[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] 760 F.3d 151 (2d Cir. 2014).
[124] Brent F. Kim et al., Industrial Food Animal Production in America: Examining the Impact of the Pew Commission's Priority Recommendations 2 (2013).
[125] Lauren Orrico, Note, *Squashing the Superbugs: A Proposed Multifaceted Approach to Combatting Antibiotic-Resistant Bacteria*, 27 J. L. & Health 259, 289 (2014).

ensure that the claims are researched and scrutinized appropriately.[126] The FDA should be able to use its discretion, but not at the expense of the welfare of the public, which contradicts its purpose and public policy.[127]

VI. CONCLUSION

Antibiotic resistance is a growing issue. Although there are systems in place that are theoretically used to remove drugs that are not safe, Congress needs to enact clear legislation so that if challenged in court, there are effective means for drugs to be removed from the market. Not only is more well-defined statutory language necessary, but cooperation from the FDA will also be required to ensure that the safest practices are being adhered to in the food industry.[128] Change comes at a cost though. In this case, the cost may be absorbed by the general public. However, given that public health is threatened with the use of these subtherapeutic drugs, this is a necessary and justifiable cost. *NRDC v. FDA*[129] was not decided in support of efforts to prevent antibiotic-resistant bacteria through the subtherapeutic use in animal feed. However, by highlighting the inadequacies in the current language of current legislation it is an important development to more productive efforts.

[126] *Id.*
[127] *Id.*
[128] *Id.* at 262.
[129] 760 F.3d 151 (2d Cir. 2014).