Public Health Takes a Major Hit: Natural Resources Defense Council v. U.S. Food & Drug Administration

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**INTRODUCTION**

The U.S. Food and Drug Administration (FDA) became concerned about the use of subtherapeutic antibiotics in animal feed in the mid-1960s and publicly stated in 1977 that drug manufacturers had failed to show such drug use was safe.¹ Despite this finding, the FDA chose not to hold hearings on the safety and effectiveness of antibiotic use in animal feed.² As a result, a group of public interest organizations petitioned the FDA to withdraw regulatory approval of subtherapeutic drug use in animal feed, including the use of penicillin and tetracyclines.³ In July 2014, the Second Circuit adopted the FDA’s interpretation of the Food, Drug, and Cosmetic Act (FDCA) in a two-to-one decision.⁴ The court held that the FDA’s statement regarding the safety of the subtherapeutic antibiotics did not constitute a “final determination” because it did not occur after notice and hearing, and therefore did not mandate withdrawal of regulatory approval in and of itself.⁵ This decision undermines the FDA’s mission to protect public health and the FDCA’s purpose to ensure the safety and effectiveness of approved drugs by allowing the continued use of products not shown to be safe.⁶

**I. BACKGROUND**

Since the FDA first approved the use of subtherapeutic antibiotic drugs in animal feed in 1952, ranchers and farmers have used them in large quantities to expedite and increase animal growth while increasing feed efficiency.⁷ The term “subtherapeutic” refers to low dosages aimed at increasing the rate of

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3. *Id.* at 155–56.
4. NRDC III, 760 F.3d 151.
5. *Id.* at 172.
7. NRDC III, 760 F.3d at 153–54.
weight gain and disease prevention, as opposed to treating illnesses.\(^8\) It is well
established that the complete elimination of bacteria requires an appropriate
dosage of antibiotics for a sufficient period of time.\(^9\) A lower dosage, like
subtherapeutic uses, risks selecting for antibiotic-resistant bacteria.\(^10\) As
Alexander Fleming, the scientist who discovered penicillin, cautioned in 1945:
“If you use penicillin, use enough.”\(^11\)

Resistant bacteria ingested through improperly cooked meat pose a major
threat to human health because people may no longer respond to antibiotic
treatment when ill.\(^12\) This concern led the FDA to establish a task force of
scientists with consultants from the government, universities, and industry to
comprehensively review the use of antibiotics in animal feed.\(^13\) In 1972, the
task force concluded that (1) the use of subtherapeutic antibiotics favors the
selection and development of antibiotic-resistant bacteria, (2) animals treated
with antibiotics can be hosts for resistant bacteria that can be transferred to
humans, (3) antibiotic-resistant bacteria was found on meat and meat products,
and (4) the prevalence of resistant bacteria in animals and humans has
increased.\(^14\) The task force proposed withdrawing approval for all
subtherapeutic uses of antibiotics.\(^15\)

After reviewing the recommendations and comments submitted by the
drug industry, animal scientists, and other concerned parties, the Bureau of
Veterinary Medicine—an organization within the FDA—issued notices of
opportunity for hearing (NOOHs) proposing to withdraw approval for
penicillin and tetracyclines.\(^16\) The Bureau concluded that the drug
manufacturers “failed to resolve the basic safety questions that underlie . . .
widespread subtherapeutic use.”\(^17\)

However, congressional appropriations committees funded the National
Academy of Sciences to conduct further research and “expected [the FDA] to
hold in abeyance any and all implementation of their proposal” pending results

\(^8\) 21 C.F.R. § 558.15(a) (2015).
ConsumerUpDATES/ucm092810.htm (last updated Mar. 23, 2015).
\(^10\) Alexander Fleming, Penicillin Nobel Lecture, December 11, 1945, in NOBEL LECTURES,
PHYSIOLOGY OR MEDICINE 1942–1962, at 83, 93 (1964), available at
\(^11\) Id.
\(^12\) Pfizer, Inc., et al.: Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes;
\(^13\) Id.
\(^14\) Id.
\(^15\) Id.
\(^16\) Id.
\(^17\) Id. at 56,288; see also Diamond Shamrock Chemical Co., et al.: Penicillin-Containing
of the research.\textsuperscript{18} The Academy reached similar findings and recommended further research.\textsuperscript{19} Three years later, the Senate directed the FDA not to move forward with its proposal to withdraw approval until the recommended research was conducted.\textsuperscript{20} The FDA’s failure to conduct further research led industry groups to petition for withdrawal of the 1977 NOOHs. In 1983, the FDA denied the petitions, stating that the “notices of opportunity for hearing represent the Director’s formal position that use of the drugs is not shown to be safe.”\textsuperscript{21}

In 1997 the World Health Organization recommended halting the use of antibiotics for growth promotion that are also used in human medicines, and the following year the European Union banned all such uses.\textsuperscript{22} The United States did not heed that call, and the FDA never held the hearings it had proposed in 1977. In 1999, and again in 2005, public interest organizations petitioned the FDA, pursuant to section 512(e) of the FDCA, to withdraw regulatory approval for subtherapeutic antibiotic use in animal feed.\textsuperscript{23} The FDA issued no formal response.\textsuperscript{24} The FDA did, however, issue guidance documents for industry leaders in order to implement a voluntary program to avoid all “injudicious uses” of subtherapeutic antibiotics.\textsuperscript{25}

\section*{II. THE LAWSUIT}

Plaintiffs, Natural Resources Defense Council, the Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, and the Union of Concerned Scientists, filed suit against the FDA in 2011.\textsuperscript{26} They claimed first that 21 U.S.C. § 360b(e)(1) compelled the FDA to hold the hearings it proposed in 1977, and, second, that the FDA had caused unreasonable delay in failing to respond to the 1999 and 2005 citizen petitions.\textsuperscript{27} Following commencement of the suit, the FDA formally denied both petitions, stating that, because of cost and time concerns, the alternative strategy of

\begin{thebibliography}{9}
\bibitem{**} Id. at xii–xvi.
\bibitem{****} Penicillin and Tetracycline (Chlortetracycline and Oxytetracycline) in Animal Feeds; Denial of Petitions, 48 Fed. Reg. 4554-02, 4555 (Feb. 1, 1983).
\bibitem{*******} NRDC III, 760 F.3d 151, 156 (2d Cir. 2014).
\bibitem{********} Id.
\bibitem{*********} Id. at 156 & n.7.
\bibitem{**********} Id. at 156.
\end{thebibliography}
implementing a voluntary program was more efficient than a withdrawal process on a drug-by-drug basis. The FDA then withdrew the 1977 NOOHs. Because the FDA’s actions mooted the plaintiffs’ second claim, they filed a complaint stating that the denial of their petitions was arbitrary and capricious. The district court ruled that 21 U.S.C. § 360b(e) requires the FDA to hold a hearing once it makes a finding that a particular drug’s use is not safe. The court found that the 1977 NOOHs constituted such a finding, and that the withdrawal of the NOOHs did not represent a withdrawal of the finding. The court further held that the reasons stated in the denial of the citizen petitions were arbitrary and capricious, that concerns about cost and length of proceedings were irrelevant, and that a voluntary program could not substitute mandatory measures when they were required. On appeal, the Second Circuit came to entirely opposite conclusions. The Second Circuit first looked to the statutory text:

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

(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 . . .

The text makes clear that a finding and hearing are required before the FDA may issue an order withdrawing its approval. However, the crux of the debate in this case is the sequence of those conditions and the definition of a finding. These two issues determine whether the hearings are mandatory. The FDA argued that the sequence is “hearing, finding, order.” The plaintiffs

30. NRDC III, 760 F.3d at 157.
32. Id.
33. Id.
34. See NRDC III, 760 F.3d 151 (2d Cir. 2014).
36. NRDC III, 760 F.3d at 159.
37. Id. at 158–59.
argued that the sequence is “finding, hearing, finding, order”—one preliminary finding based on internal deliberations that triggers a mandatory hearing, and the other based on the evidence presented at the hearing.\textsuperscript{38} The court held that the FDA’s reading was more plausible because it conformed more easily to the syntax of the statute and conventional legal practice.\textsuperscript{39} Specifically, the court was swayed because the plaintiffs’ reading would require two findings in a sentence that refers to only one.\textsuperscript{40} The court further stated that according to the plaintiffs’ reading, the preliminary finding would trigger a mandatory hearing, but the statute grammatically links the finding to only a mandatory withdrawal.\textsuperscript{41} The court found it “singularly odd” for Congress to have chosen the language it did if it intended the process that plaintiffs described.\textsuperscript{42}

Next the court looked to traditional legal conceptions of “findings” that it believed further supported the FDA’s interpretation.\textsuperscript{43} Traditionally, a finding is an official determination issued at the end of a process and most commonly occurs as a consequence of a hearing.\textsuperscript{44} It is typical for administrative processes that may result in actions adverse to certain parties to allow the parties to defend themselves in a hearing before the agency issues a formal finding.\textsuperscript{45} Furthermore, formal findings are usually embodied in formal documents.\textsuperscript{46} The plaintiffs argued that the 1997 NOOHs constituted such a document, and that withdrawing the NOOHs would not result in a withdrawal of the finding.\textsuperscript{47} The court rejected this interpretation as problematic and asked, “where do the findings exist? In the thoughts and beliefs of the Secretary or Commissioner?”\textsuperscript{48}

Lastly, the court discussed legal traditions regarding agency discretion.\textsuperscript{49} An agency’s decision declining to take enforcement action has traditionally been left to its discretion and not been judicially reviewable.\textsuperscript{50} The plaintiffs’ interpretation would not allow such discretion.\textsuperscript{51} The court decided that the FDA’s interpretation was more consistent with these background legal concepts.\textsuperscript{52}

\begin{flushleft}
\begin{itemize}
\item \textsuperscript{38} Id.
\item \textsuperscript{39} Id. at 160.
\item \textsuperscript{40} Id.
\item \textsuperscript{41} Id. at 161.
\item \textsuperscript{42} Id.
\item \textsuperscript{43} Id. at 166-67.
\item \textsuperscript{44} Id. at 167.
\item \textsuperscript{45} Id. at 168.
\item \textsuperscript{46} Id. at 169.
\item \textsuperscript{47} Id.
\item \textsuperscript{48} Id. at 170.
\item \textsuperscript{49} Id.
\item \textsuperscript{50} See Heckler v. Chaney, 470 U.S. 821, 832–33 (1985).
\item \textsuperscript{51} NRDC \textit{III}, 760 F.3d at 171.
\item \textsuperscript{52} Id.
\end{itemize}
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Ultimately the court held that the FDA (1) is not required to hold hearings whenever officials have scientific concerns about safety, (2) retains the discretion to initiate or terminate withdrawal proceedings, and (3) is only required to withdraw approval of animal drugs when a final determination is made, after notice and hearing, that the drug poses a threat to human health and safety.\textsuperscript{53} Moreover, the court found that nothing in 21 U.S.C. § 360b(e)(1) limits the considerations that the FDA may take into account in deciding whether to initiate the hearing process by issuing a NOOH.\textsuperscript{54} Therefore, the decision to initiate or terminate the hearing process is a discretionary determination not limited to scientific considerations.\textsuperscript{55} The court further found that nothing in the NOOHs suggested that antibiotic use is inherently dangerous, and therefore it was not arbitrary or capricious for the FDA to pursue voluntary policies and deny the citizen petitions.\textsuperscript{56}

### III. DISCUSSION

The Second Circuit’s decision puts public health at the mercy of those in power at the FDA instead of requiring action when a health hazard is known. For almost forty years the FDA has been concerned about subtherapeutic antibiotic use in animal feed—a fear borne out in a number of studies.\textsuperscript{57} Indeed, the FDA has consistently reaffirmed that approved uses accelerate development of resistant bacteria, causing a public health issue of “global significance.”\textsuperscript{58} The Second Circuit’s decision permits the FDA to continue allowing subtherapeutic antibiotic use despite this widespread knowledge. The decision also gives the FDA discretion to deny citizen petitions without addressing the safety of a drug.

Contrary to the majority’s opinion, the plaintiffs’ interpretation is consistent with the purpose of the FDA and the FDCA, the structure of the Act itself, and basic legal concepts.\textsuperscript{59} As noted in the dissent, the majority takes a very narrow view of typical administrative processes.\textsuperscript{60} Chief Judge Robert Katzmann agreed with the plaintiffs’ view that the typical sequence of events is preliminary finding, hearing, final finding, and order.\textsuperscript{61} He pokes fun at the

\textsuperscript{53.} Id. at 171–72.
\textsuperscript{54.} Id. at 174.
\textsuperscript{55.} Id. at 175.
\textsuperscript{56.} Id.
\textsuperscript{58.} Id. at 4.
\textsuperscript{59.} See NRDC III, 760 F.3d at 176–93 (Katzmann, C.J., dissenting).
\textsuperscript{60.} Id. at 184.
\textsuperscript{61.} Id.
majority by stating, “[a]fter 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.”\footnote{Id.} Against the backdrop of the FDCA’s objectives, this reading seems more appropriate than that adopted by the majority.

The FDCA’s objective “is to ensure that any product approved by the FDA is ‘safe’ and ‘effective’ for its intended use.”\footnote{Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000).} The drug approval process achieves this objective by limiting FDA discretion. Once an application for approval is submitted, the FDA can either approve or give the applicant a NOOH, after which the FDA is required to issue a final order.\footnote{21 U.S.C. § 360b(c)–(d) (2012).} It is strictly forbidden at each stage of the process to approve a drug that is not shown to be safe.\footnote{Id.} The plaintiffs’ interpretation of the withdrawal process mirrors the application process by limiting FDA’s discretion in order to advance the FDCA’s goal of protecting public health. Logic suggests that Congress would not ensure that unsafe drugs are denied during the approval process only to later allow them to stay on the market once determined to be unsafe. This would undermine the purpose of the Act.\footnote{NRDC III, 760 F.3d at 179 (Katzmann, C.J., dissenting).}

The decision does not further the FDA and FDCA’s goal of protecting public health. Any argument that the cost of withdrawal proceedings or the cost to the meat industry would be high if subtherapeutic antibiotic use is banned needs to be compared to the societal cost of continuing its use. In 2009, the FDA estimated that out of the thirty-six million pounds of antibiotics sold in the United States, nearly twenty-nine million pounds were used for animal feed.\footnote{Helena Bottemiller, Most U.S. Antibiotics Go to Animal Agriculture, FOOD SAFETY NEWS (Feb. 24, 2011), http://www.foodsafetynews.com/2011/02/fda-confirms-80-percent-of-antibiotics-used-in-animal-ag/#.VRJf7ymRPzJ.} This amount constitutes 80 percent of total antibiotic use in the country.\footnote{Id.} Such a high degree of antibiotic use at low dosages creates the risk of bacteria mutating into resistant strains.\footnote{Id.} And because 60 percent of antibiotic types used for animals are also used for humans, resistant bacteria transfer through animal products has become a sizable threat to human health.\footnote{Jacob Bunge et al., Meat Companies Go Antibiotics-Free as More Consumers Demand It, WALL ST. J. (Nov. 3, 2014, 10:30 PM), http://www.wsj.com/articles/meat-companies-go-antibiotics-free-as-more-consumers-demand-it-1415071802.} According to the Centers for Disease Control and Prevention, at least two million people are infected with antibiotic-resistant bacteria annually in the
At least twenty-three thousand people die each year as a direct result of these infections. Antibiotic-resistant infections cause longer and costlier treatments, prolonged hospital stays, additional hospital visits, and increased mortality. It is estimated that the total economic cost is $20 billion in health care expenses, with lost productivity adding up to $35 billion per year. The cost to society is staggering—both economically and in terms of human suffering.

The cause of the problem is the overuse and misuse of antibiotics in both animals and humans, and preventing infections will require a multifaceted approach that addresses both sources. Although antibiotic use in animal feed is not the only cause of this problem, it nevertheless plays a major role and needs to be addressed. Countries around the world began banning subtherapeutic antibiotic use in animal feed as early as 1986. Twenty-nine years have passed and the United States still has not taken any legitimate action to combat this growing problem.

**CONCLUSION**

The Second Circuit’s decision, giving deference to the FDA to initiate or terminate withdrawal proceedings, permits the impermissible. By allowing subtherapeutic antibiotic use in animal feed to continue, the FDA is failing in its responsibility to actively prevent and reduce threats to public health.

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