Natural Resources Defense Council, Inc. et al v. United States Food and Drug Administration et al Doc. 38 Att. 1

EXHIBIT A

TO PLAINTIFFS' MOTION FOR LEAVE TO FILE A SUPPLEMENTAL COMPLAINT

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC.; CENTER FOR SCIENCE IN THE PUBLIC INTEREST; FOOD ANIMAL CONCERNS TRUST; PUBLIC CITIZEN, INC.; and UNION OF CONCERNED SCIENTISTS, INC.,	)	
Plaintiffs,	)	11 CIV 3562 (THK)
	)	ECF Case
v.	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration; CENTER FOR VETERINARY MEDICINE; BERNADETTE DUNHAM, in her official capacity as Director, Center for Veterinary Medicine; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services,	)	
Defendants.	)	

FIRST SUPPLEMENTAL COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs submit this Supplemental Complaint pursuant to Rule 15(d) of the Federal Rules of Civil Procedure to challenge the U.S. Food and Drug Administration's (FDA's) denial of two citizen petitions. Plaintiffs incorporate by reference the allegations set forth in their First Amended Complaint for Declaratory and Injunctive Relief, dated July 7, 2011.

2. The Federal Food, Drug, and Cosmetic Act (Food and Drug Act), 21 U.S.C. § 360b(e)(1), requires FDA to withdraw approval for an animal drug if the agency finds that the drug is unsafe or not shown to be safe for the uses for which it was approved. In 1999 and 2005, Plaintiffs Center for Science in the Public Interest (CSPI), Food Animal Concerns Trust (FACT), Public Citizen, and Union of Concerned Scientists (UCS) submitted citizen petitions (the Petitions) to FDA requesting that the agency withdraw approvals for nontherapeutic uses of antibiotics in livestock if those antibiotics are also important to human medicine. The Petitions asserted that such drug uses present serious human health risks because they promote the development of antibiotic-resistant bacteria that can be transferred from animals to people.

3. After delaying ruling on the Petitions for twelve and six years respectively, FDA denied both Petitions on November 7, 2011, one day before the agency's response to Plaintiffs' motion for summary judgment was due in this Court. In its final responses to the Petitions, the agency acknowledged that it shared the petitioners' concern about antibiotic resistance related to antibiotic use in livestock. FDA explained, nevertheless, that rather than withdraw its approval of nontherapeutic uses of antibiotics in livestock, the agency would address the problem by issuing a nonbinding draft guidance document, which recommends that livestock producers voluntarily refrain from using medically important antibiotics for production purposes. FDA defines "production purposes" as using antibiotics to increase the rate of weight gain or to improve feed efficiency, rather than to treat any identified disease.

4. FDA's final responses to the Petitions are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the Food and Drug Act, 21 U.S.C. § 360b, and the Administrative Procedure Act (APA), 5 U.S.C. § 706(2).

5. Plaintiffs Natural Resources Defense Council (NRDC), CSPI, FACT, Public Citizen, and UCS seek a judgment declaring FDA's denials of the Petitions unlawful and setting them aside.

JURISDICTION AND VENUE

6. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(3), because Plaintiff NRDC resides and has its principal place of business in this judicial district.

8. This Court may award Plaintiffs declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and may award all necessary injunctive relief for the claims set forth in the Third Claim for Relief pursuant to the APA, 5 U.S.C. § 706(2).

STATUTORY AND REGULATORY FRAMEWORK

9. The Secretary of the Department of Health and Human Services, "through the Commissioner" of FDA, 21 U.S.C. § 393(d)(2), regulates antibiotics in animal feed as "new animal drugs" under section 512 of the Food and Drug Act, 21 U.S.C. § 360b.

10. FDA is required to withdraw its existing approval of a new animal drug application if information shows that the drug is unsafe or not shown to be safe:

> The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application . . . if the Secretary finds . . . that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved . . . ; [or] that new evidence not contained in such application . . . evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved . . . .

21 U.S.C. § 360b(e)(1).

11. According to FDA's Guidance for Industry No. 152, FDA considers a new animal drug "safe" for human health if it concludes that "there is reasonable certainty of no harm to human health from the proposed use of the drug in food-producing animals."

THE FACTS

FDA's Denial of Plaintiffs' Citizen Petitions

12. Since the 1950s, FDA has approved some medically important antibiotics for growth promotion and disease prevention indications in livestock.

13. On March 9, 1999, CSPI, FACT, Public Citizen, and UCS submitted a petition to FDA requesting that the agency "rescind approvals for subtherapeutic uses in livestock of any antibiotic used in (or related to those used in) human medicine."

14. On April 7, 2005, FACT and UCS submitted a second petition to FDA. The petition requested that the FDA Commissioner "withdraw approvals for herdwide/flockwide uses of [specific] antibiotics in chicken, swine, and beef cattle for purposes of growth promotion (including weight gain and feed efficiency) and disease prevention and control (except for non-routine use where a bacterial infection has been diagnosed within a herd or flock)." The petition covered penicillins, tetracyclines, aminoglycosides, streptogramins, macrolides, lincomycin, and sulfonamides. It did not cover any uses of those drugs to treat disease in individual animals.

15. The Petitions asserted that nontherapeutic uses of medically important antibiotics in livestock present serious risks to human health because they promote the development of antibiotic-resistant bacteria that can be transferred from animals to people.

16. The U.S. Department of Health and Human Services has concluded that "there is a preponderance of evidence that the use of antimicrobials in food-producing animals has adverse human consequences." According to the Centers for Disease Control and Prevention,

there is "strong scientific evidence of a link between antibiotic use in food animals and antibiotic resistance in humans," including "multiple North American studies describing how: [u]se of antibiotics in animals results in resistant bacteria in food animals; [r]esistant bacteria are present in the food supply and transmitted to humans; [and] [r]esistant bacteria result in adverse human health consequences (such as increased hospitalizations). . . . [T]here is a compelling body of evidence to demonstrate this link."

17. FDA itself has concluded that "the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production purposes [in livestock] is not in the interest of protecting and promoting the public health."

18. FDA delayed ruling on the Petitions for twelve and six years respectively.

19. On May 25, 2011, Plaintiffs filed this lawsuit. In their Second Claim for Relief, Plaintiffs claimed that FDA had delayed unreasonably in issuing a final response to the Petitions.

20. On November 7, 2011, one day before FDA's response to Plaintiffs' motion for summary judgment was due in this Court, FDA denied both Petitions.

21. In its final responses to both Petitions, FDA acknowledged that "we share your concern about the use of medically important antimicrobial drugs in food-producing animals for growth promotion and feed efficiency indications (i.e., production uses)."

22. FDA explained that, nevertheless, "for various reasons the Agency has decided not to institute formal withdrawal proceedings at this time and instead" has "proposed a different strategy to promote the [voluntary] judicious use of medically important antimicrobials in food-producing animals" in its Draft Guidance No. 209.

23. FDA issued Draft Guidance No. 209 in June 2010. The Draft Guidance recommends that medically important antibiotics be used in food-producing animals only (1)

when necessary to ensure the animals' health, and not to promote growth or improve feed efficiency, and (2) with veterinary oversight. Like other FDA guidance documents, Draft Guidance No. 209 does "not establish legally enforceable responsibilities."

24. Draft Guidance No. 209 has not yet been finalized.

25. In its final responses to the Petitions, FDA stated, without supporting evidence, that it "believes that the animal pharmaceutical industry is generally responsive to the prospect of working cooperatively with the Agency to implement the principles recommended" in Draft Guidance No. 209. FDA stated that it "intends to work with sponsors who approach FDA and are interested in working cooperatively with the Agency to phase out production uses of medically important antimicrobials."

26. In denying the Petitions, FDA offered no statutory justification for its refusal to address the scientific information and analysis presented by the petitioners, to determine whether the challenged nontherapeutic antibiotic uses in livestock have been shown to be safe for human health, or to pursue withdrawal proceedings.

Harm to Plaintiffs from FDA's Denial of the Petitions

27. The use of antibiotics in livestock promotes the development of antibiotic-resistant bacteria in animals receiving the antibiotics.

28. Antibiotic-resistant bacteria are present in the food supply.

29. Antibiotic-resistant bacteria may be transferred from animals to humans through the consumption and handling of contaminated meat products, through environmental pathways, and through direct contact with livestock.

30. Antibiotic-resistant bacteria that have been transferred from animals to humans may cause drug-resistant infections, or they may transfer resistance traits to other bacteria that can cause infections.

31. The health of Plaintiffs' members is continually threatened by their exposure to meat and poultry products contaminated with bacteria resistant to medically important antibiotics. As a result, some of Plaintiffs' members have reduced their meat consumption or spend more time or money than they otherwise would to buy meat from animals raised without antibiotics.

32. The increased risk that Plaintiffs' members will be exposed to bacteria resistant to medically important antibiotics through the consumption or handling of contaminated meat products is traceable to FDA's failure to withdraw approvals for nontherapeutic uses of medically important antibiotics in livestock.

33. If FDA were to grant the Petitions and withdraw approvals for nontherapeutic uses of medically important antibiotics in livestock, the prevalence of bacteria in livestock with resistance to those drugs would stop increasing, and would likely decrease. As a result, Plaintiffs' members would face a reduced risk of contracting a drug-resistant infection from consuming or handling meat products.

THIRD CLAIM FOR RELIEF

34. Plaintiffs incorporate by reference all preceding paragraphs and their First Amended Complaint for Declaratory and Injunctive Relief.

35. FDA is required by the Food and Drug Act to withdraw approval for an animal drug if the agency finds that the drug is unsafe or not shown to be safe for the uses for which it was approved. *See* 21 U.S.C. § 360b(e)(1).

36. FDA's stated reasons for denying the Petitions, and for refusing to review the safety of antibiotics previously approved for nontherapeutic use in livestock, are not grounded in the Food and Drug Act and contravene the Food and Drug Act.

37. FDA's denials of the Petitions contradict the preponderance of scientific evidence, and FDA's own prior statements, demonstrating that nontherapeutic uses of medically important antibiotics in livestock present serious risks to human health.

38. Because FDA's reasons for denying the Petitions are not grounded in the Food and Drug Act and contravene the Food and Drug Act, and because the denials defy sound scientific evidence that the challenged uses threaten human health, the denials are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the Food and Drug Act, 21 U.S.C. § 360b, and the APA, 5 U.S.C. § 706(2).

REQUEST FOR RELIEF

Plaintiffs request that this Court enter judgment against FDA as follows:

A. Declaring that FDA's denials of the Petitions are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, in violation of the Food and Drug Act, 21 U.S.C. § 360b, and the APA, 5 U.S.C. § 706(2);

B. Setting aside FDA's denials of the Petitions;

C. Awarding Plaintiffs their reasonable costs and attorneys' fees; and

D. Granting such other and further relief as the Court deems just and proper.

Dated: New York, New York
January 6, 2012

Respectfully submitted,

s/ Mitchell S. Bernard
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