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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, 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.	11 CIV 3562 (THK) ECF Case

THE GOVERNMENT'S RESPONSE TO PLAINTIFFS' STATEMENT OF UNDISPUTED MATERIAL FACTS PURSUANT TO LOCAL CIVIL RULE 56.1

Defendants, the United States Food and Drug Administration ("FDA"), Margaret

Hamburg, in her official capacity as Commissioner of Food and Drugs; Center for Veterinary Medicine; Bernadette Dunham, in her official capacity as Director, Center for Veterinary Medicine; United States Department of Health and Human Services ("HHS"); and Kathleen Sebelius, in her official capacity as Secretary, United States Department of Health and Human Services (collectively, the "Government"), by their attorney, Preet Bharara, United States Attorney for the Southern District of New York, respond to the Statement of Undisputed Material Facts Pursuant to Local Civil Rule 56.1 ("Plaintiffs' 56.1 Statement") submitted by Plaintiffs Natural Resources Defense Council, Center for Science in the Public Interest, Food Animal Concerns Trust, Public Citizen, and Union of Concerned Scientists (collectively, "Plaintiffs"). In responding to Plaintiffs' Rule 56.1 Statement, the Government objects to Plaintiffs' Statement to the extent that it relies on inadmissible hearsay as support for its statements, which is not permitted by Local Civil Rule 56.1(d). *See also* Fed. R. Civ. P. 56(c)(2). The Government also does not concede the materiality of any of the statements and specifically reserves the right to object that Plaintiffs' assertedly undisputed facts are immaterial and do not support Plaintiffs' motion for summary judgment. The Government specifically dispute the materiality of all of Plaintiffs' statements to the extent that they relate to the citizen petitions submitted by plaintiffs Center for Science in the Public Interest, Food Animal Concerns Trust ("FACT"), Public Citizen, Inc., and Union of Concerned Scientists, Inc. ("UCS") to FDA on March 9, 1999 (the "1999 Petition") and Citizen Petition submitted by FACT and UCS on April 7, 2005 (the "2005 Petition"), as Plaintiffs' claims in connection with the 1999 Petition and the 2005 Petition have been dismissed as moot. *See* Dkt. No. 37. Further, through the response to the enumerated paragraphs of Plaintiffs' 56.1 Statement, the Government does not concede any statements made by Plaintiffs in their headings and subheadings. The Government responds as follows:

1. “Antibiotics are drugs used for treating infections caused by bacteria. Also known as antimicrobial drugs, antibiotics have saved countless lives. Misuse and overuse of these drugs, however, have contributed to a phenomenon known as antibiotic resistance. This resistance develops when potentially harmful bacteria change in a way that reduces or eliminates the effectiveness of antibiotics.” Decl. of Jennifer A. Sorenson (Sorenson Decl.) Ex. S, at 1; Answer ¶ 1.

NOT CONTROVERTED.

2. When an antibiotic drug is introduced to a population of bacteria, the bacteria that are susceptible to the drug die off, but bacteria that are resistant to the drug survive and reproduce, increasing the proportion of resistant bacteria in the population. Amended Complaint ¶ 35; Answer ¶ 35; Sorenson Decl. Ex. X, at 2.

NOT CONTROVERTED.

3. Through a variety of mechanisms, bacteria may become resistant to multiple classes of antibiotics. For example, the use of any one drug may select for groups of genes that provide resistance not only to the original drug but also to other chemically related drugs. Bacteria can also transfer resistance traits to other bacteria, allowing bacteria that have never been exposed to antibiotics to become resistant to them. Bacteria can transfer resistance genes to bacteria in different species and genera, and from bacteria that do not cause human illness to bacteria that do. Amended Complaint ¶ 36; Answer ¶ 36; Sorenson Decl. Ex. T, at 1.

NOT CONTROVERTED.

4. People who contract antibiotic-resistant infections are more likely to have longer hospital stays, may be treated with less effective and more toxic drugs, and may be more likely to die as a result of the infection. Amended Complaint ¶ 38; Answer ¶ 38; Sorenson Decl. Ex. T, at 1. According to FDA, “[w]hen a person is infected with an antibiotic-resistant bacterium, not only is treatment of that patient more difficult, but the antibiotic-resistant bacterium may spread to other people.” Sorenson Decl. Ex. S, at 1.

NOT CONTROVERTED.

5. In 2009, Cook County Hospital and the Alliance for the Prudent Use of Antibiotics estimated that antibiotic-resistant infections from all sources cost Americans between $16.6 and $26 billion every year. Amended Complaint ¶ 38; Answer ¶ 38.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that in 2009, Cook County Hospital and the Alliance for the Prudent Use of Antibiotics estimated that antibiotic-resistant infections from all sources cost Americans between $16.6 and $26 billion every year. The Government does controvert, as

unsupported by Plaintiffs' citation, that those costs were attributable solely to the use of antibiotics in animals, as that statement is not supported by paragraph 38 of the Government's Answer reflects. The Government also controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

6. FDA considers antibiotic resistance "a serious public health threat" and "a mounting public health problem of global significance." Amended Complaint ¶ 38; Answer ¶ 38; Sorenson Decl. Ex. O, at 3-4.

NOT CONTROVERTED.

7. According to FDA, "[p]reserving the effectiveness of current antimicrobials [or antibiotics] . . . [is] vital to protecting human and animal health against infectious microbial pathogens," Sorenson Decl. Ex. R, at 1, and "[d]eveloping strategies for reducing antimicrobial resistance is critically important for protecting both public and animal health." Sorenson Decl. Ex. O, at 3.

NOT CONTROVERTED.

8. Because the use of antibiotics "contributes to the emergence of drug resistant organisms," FDA has explained that "these important drugs must be used judiciously in both animal and human medicine to slow the development of resistance. . . . Using these drugs judiciously means that unnecessary or inappropriate use should be avoided." Sorenson Decl. Ex. O, at 3.

NOT CONTROVERTED.

9. The Centers for Disease Control and Prevention (CDC), a division of HHS, names antibiotic resistance as one of its "top concerns." Sorenson Decl. Ex. X, at 2.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the Centers for Disease Control and Prevention ("CDC") is a division of HHS and that CDC's website names antibiotic resistance as one of its "top concerns," but does controvert this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

10. Because antibiotic resistance "threatens our ability to treat disease and to protect the advances made in global health in recent decades," the World Health Organization (WHO) urges that "[w]e must do everything in our power to preserve [antibiotics] for future generations." Sorenson Decl. Ex. BB, at 1.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the World Health Organization ("WHO") has published a document entitled "World Health Day 20011, *Frequently Asked Questions*," which contains the statements attributed to it by Plaintiffs in paragraph 10 of Plaintiffs' 56.1 Statement. The Government controverts these statements as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

11. The Institute of Medicine of the National Academy of Sciences has warned that "[t]he specter of untreatable infections—a regression to the pre-antibiotic era—is looming just around the corner." Amended Complaint ¶ 1; Answer ¶ 1; Sorenson Decl. Ex. Z, at 205.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the Institute of Medicine of the National Academy of Sciences has published a book entitled *Microbial Threats to Human Health: Emergence, Detection, and Response* (Mark S. Smolinski, Margaret A. Hamburg & Joshua Lederberg eds.) (the "Institute of Medicine Book"), 2003, which contains the statements attributed to it by Plaintiffs in paragraph 11 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

12. FDA reports that 13,067,100 kilograms of antibiotics were sold or distributed for use in food-producing animals in the United States in 2009. Sorenson Decl. Ex. P, at 3. In comparison, 3,316,906 kilograms of antibiotics were sold in the U.S. market for human use in 2009. Sorenson Decl. Ex. Q, enclosure, at 4. Thus, approximately 80 percent of the more than 16 million kilograms of antibiotics sold in the United States in 2009 went to livestock.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that it reported that approximately 13,067,100 kilograms of antimicrobial drugs (not "antibiotics") were sold or distributed for use in food-producing animals in the United States in 2009, that approximately 3,316,906 kilograms of antibacterial drugs were sold in the U.S. market for human use in 2009, and that 13,067,100 is approximately 80 percent

of 16,384,066 (the sum of 13,067,100 and 3,316,906). The Government does, however, controvert that this comparison has any validity because "antimicrobial drugs" comprises a broader class of drugs than "antibacterial drugs." "Antimicrobial drugs" are drugs that work against a variety of microorganisms, such as bacteria, viruses, fungi, and parasites. Antimicrobial drugs that work specifically against bacteria are called "antibacterial drugs" or "antibiotics." *See* Questions and Answers on FDA's Draft Guidance on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals ("Draft Guidance Q&A") at 1, attached as Exhibit C to the Declaration of Amy A. Barcelo dated January 9, 2012 (the "Barcelo Decl.").

13. Of the antibiotics sold for use in livestock, 11,766,613 kilograms, or 90 percent, were sold for administration via animal feed or water, rather than by injection. Sorenson Decl. Ex. Q, at 1.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that it reported that 11,766,613 kilograms of antibacterial drugs were sold in 2009 for administration via animal feed or water. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

14. According to the Institute of Medicine, the majority of antibiotics used in animal husbandry in the United States are used for growth promotion or preventive therapy in healthy animals. Sorenson Decl. Ex. Z, at 207. These antibiotics are generally given to animals at "subtherapeutic" levels, or in doses too low to treat disease. Sorenson Decl. Ex. H, at iii n.1; Penicillin-Containing Premixes (Penicillin Notice), 42 Fed. Reg. 43,772, 43,773 (Aug. 30, 1977), Ex. A to Sorenson Decl.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the Institute of Medicine Book states that the majority of antibiotics used in animal husbandry in the United States are used for growth promotion or preventive therapy in healthy animals. However, FDA denies that it currently considers the use

of animal drugs to prevent disease to be an injudicious or "subtherapeutic" use. *See* FDA Draft Guidance for Industry #209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (2010), Exhibit B to the Barcelo Decl. at 16 ("FDA considers uses that are associated with the treatment, control, or prevention of specific diseases . . . to be uses that are necessary for assuring the health of food-producing animals"). The Government also controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

15. Since the 1950s, FDA has approved some antibiotics for growth promotion indications in livestock. Some of the antibiotics that were originally approved for growth promotion may be important to human medicine. Answer ¶ 3.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that since the 1950s, FDA has approved some antibiotics for growth promotion indications in livestock and that some of the antibiotics that were originally approved for growth promotion may be important to human medicine. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government to the extent that it refers to antibiotics other than penicillin and tetracycline, because Plaintiffs' claims in connection with such other antibiotics have been dismissed as moot. *See* Dkt. No. 37.

16. Antibiotics used for growth promotion "are typically administered through the feed or water on a herd- or flock-wide basis and are approved for such uses as increasing rate of weight gain or improving feed efficiency." Sorenson Decl. Ex. O, at 4. The approved dose of an antibiotic for growth promotion is typically lower than the approved dose for a disease indication. Answer ¶ 3; Penicillin Notice, 42 Fed. Reg. at 43,773.

NOT CONTROVERTED.

17. Administering medically important antimicrobial drugs to entire herds or flocks of food-producing animals (e.g., for growth promotion) poses a qualitatively higher risk to public health than administering such drugs to individual animals or targeted groups of animals. Answer ¶ 34.

The Government does not controvert that the administration of medically important antimicrobials to entire herds or flocks of food-producing animals (e.g., for production purposes) would represent a use that poses a qualitatively higher risk to public health than the administration of such drugs to individual animals or targeted groups of animals (e.g., to prevent, control, or treat specific disease), which is the statement made by the Government in paragraph 34 of the Answer, and controverts the remainder of paragraph 17 of Plaintiffs' 56.1 Statement as unsupported by Plaintiffs' citation.

18. Since the 1950s, FDA has approved some antibiotics for disease prevention in livestock. Some of the antibiotics that were originally approved for disease prevention may be important to human medicine. Answer ¶ 3.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that since the 1950s, FDA has approved some antibiotics for growth promotion indications in livestock and that some of the antibiotics that were originally approved for growth promotion may be important to human medicine. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government to the extent that it refers to antibiotics other than penicillin and tetracycline, because Plaintiffs' claims in connection with such other antibiotics have been dismissed as moot. *See* Dkt. No. 37.

19. According to the Institute of Medicine, "it has been noted that subtherapeutic antibiotics are most effective in animals under the stress of inadequate nutrition and suboptimal sanitary conditions . . . ; therefore, improved hygiene and changes in animal husbandry practices to control disease could potentially eliminate the need for growth promoters." Sorenson Decl. Ex. Z, at 208.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the Institute of Medicine Book contains the statements attributed to it in paragraph 19 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the

Government.

20. According to FDA, 610,514 kilograms of penicillins were sold or distributed for use in food-producing animals in the United States in 2009. Thus, penicillins accounted for approximately 4.7 percent of all antibiotics sold for use in livestock. Sorenson Decl. Ex. P, at 3.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that it has reported that approximately 610,514 kilograms of penicillins were sold or distributed for use in food-producing animals in the United States in 2009. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

21. According to FDA, 4,611,892 kilograms of tetracyclines were sold or distributed for use in food-producing animals in the United States in 2009. Thus, tetracyclines accounted for approximately 35.3 percent of all antibiotics sold for use in livestock. Sorenson Decl. Ex. P, at 3.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that it has reported that approximately 4,611,892 kilograms of tetracyclines were sold or distributed for use in food-producing animals in the United States in 2009. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

22. FDA has classified penicillins and tetracyclines as "highly important" to human medicine. Sorenson Decl. Ex. M, at 28-29, 30, 32.

NOT CONTROVERTED.

23. Research has shown that the use of antibiotics in livestock leads to the development of antibiotic-resistant bacteria that can be—and have been—transferred from animals to people through direct contact, environmental exposure, and the consumption and handling of contaminated meat and poultry products. Amended Complaint ¶¶ 2, 74; Answer ¶¶ 2, 74; Sorenson Decl. Ex. Y, at 11, 17-23, 89; *id.* Ex. Z, at 207; *id.* Ex. W, cover letter, at 1; Penicillin Notice, 42 Fed. Reg. at 43,776-78; Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes (Tetracyclines Notice), 42 Fed. Reg. 56,264, 56,268-70 (Oct. 21, 1977), Ex. B to Sorenson Decl.

NOT CONTROVERTED.

24. Studies show that the use of antibiotics in livestock, including nontherapeutic uses

in feed, leads to the development of antibiotic-resistant bacteria in the animals receiving the antibiotics. Sorenson Decl. Ex. W, cover letter, at 1; Answer ¶ 41. These bacteria include *Salmonella*, *Campylobacter*, and *E. coli*, all of which may cause foodborne illness in humans. Sorenson Decl. Ex. Y, at 11, 17-23.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. In the first sentence, the Government controverts Plaintiffs' characterization of the studies referenced therein as "showing" that the use of antibiotics in livestock, including nontherapeutic uses in feed, necessarily "leads to" the development of antibiotic-resistant bacteria, because that statement is not supported by Plaintiffs' citation. Rather, Exhibit W to the Declaration of Jennifer A. Sorenson dated October 5, 2011 (the "Sorenson Decl.") and paragraph 41 of the Government's Answer only provide support for the statement that the use of antibiotics in livestock *can contribute* to the emergence of antibiotic-resistant bacteria in the animals receiving the antibiotics. The Government does not controvert the second sentence.

25. The use of penicillin and tetracyclines in animal feed promotes the development of antibiotic-resistant bacteria in livestock. These bacteria may be resistant not only to penicillin or tetracyclines but also to other medically important drugs. Amended Complaint ¶ 73; Answer ¶¶ 37, 73.

NOT CONTROVERTED.

26. Data collected by the National Antimicrobial Resistance Monitoring System (NARMS) in 2009 indicate that *Salmonella* was present on 21.0% of retail chicken breast samples and 14.4% of retail ground turkey samples. Sorenson Decl. Ex. V, at 20 tbl.3. Nearly half (48.4%) of the *Salmonella* on chicken breasts and more than a quarter (26.3%) of the *Salmonella* from ground turkey was resistant to three or more classes of antibiotics. *Id.* at 8; 30 tbl.8. Tetracycline resistance was common among *Salmonella* isolates from chicken and turkey products (59.9% and 65.3%, respectively), while resistance to ampicillin (an antibiotic in the penicillin class), was only slightly less common, at 45.8% of chicken *Salmonella* and 57.9% of turkey *Salmonella*. *Id.* at 23 tbl.5.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the *2009 Retail Meat Report* published by the National Antimicrobial Resistance Monitoring System (the "2009 NARMS Report") contains the data attributed to it in paragraph 26 of Plaintiffs' 56.1 Statement. The Government controverts this

statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

27. The NARMS *2009 Retail Meat Report* shows that *Campylobacter*, including the *Campylobacter jejuni* and *Campylobacter coli* species, was present on 44.1% of retail chicken breasts tested. Sorenson Decl. Ex. V, at 8, 20 tbl.3. Nearly half (46.2%) of the *C. jejuni* isolates and more than a third (38.0%) of the *C. coli* isolates were resistant to tetracycline. *Id.* at 42 tbl.13.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the 2009 NARMS Report contains the data attributed to it in paragraph 27 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

28. The 2009 NARMS report indicates that *E. coli* was highly prevalent on all retail meat types tested: chicken breasts (87.5%); ground turkey (85.0%); ground beef (68.6%); and pork chops (40.8%). Sorenson Decl. Ex. V, at 20 tbl.3. Multidrug resistance was most prevalent among *E. coli* isolates from chicken breasts (37.5%) and ground turkey (66.3%). *Id.* at 70 tbl.24. Approximately 56.2% of *E. coli* isolates from ground turkey were resistant to ampicillin, while 82.0% were resistant to tetracycline. *Id.* at 64 tbl.22.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the 2009 NARMS Report contains the data attributed to it in paragraph 28 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

29. According to the U.S. Government Accountability Office (GAO), epidemiologic studies suggest that antibiotic-resistant *E. coli* bacteria have been transferred from animals to humans, and studies that include molecular subtyping demonstrate that antibiotic-resistant *Salmonella* and *Campylobacter* bacteria have been transferred from animals to humans through the consumption or handling of contaminated meat. Sorenson Decl. Ex. Y, at 17-23.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the 2004 Report to Congressional Requesters by the U.S. General Accounting Office ("GAO") entitled "Antibiotic Resistance: Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals (2004)" (the

"2004 GAO Report") makes the statements attributed to GAO in paragraph 29 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

30. There are several documented cases of the transfer of drug-resistant bacteria from livestock to farmworkers and others who came in contact with the animals. Amended Complaint ¶ 45; Answer ¶ 45.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that there are several documented cases of the transfer of drug-resistant bacteria from livestock to farmworkers and others who came in contact with the animals. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

31. According to GAO, "[r]esistant bacteria may . . . be spread to fruits, vegetables, and fish products through soil, well water, and water runoff contaminated by waste material from animals harboring these bacteria." Sorenson Decl. Ex. Y, at 11.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the 2004 GAO Report contains the statement attributed to it in paragraph 31 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

32. 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. Amended Complaint ¶ 75; Answer ¶ 75.

NOT CONTROVERTED.

33. FDA 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." Sorenson Decl. Ex. O, at 13; *id.* Ex. R, at 2.

NOT CONTROVERTED.

34. FDA recognizes that "[a]ntimicrobial use in animals can contribute to the emergence of antimicrobial resistance which may be transferred to humans, thereby reducing the

effectiveness of antimicrobial drugs for treating human disease." Sorenson Decl. Ex. U, at 2; Amended Complaint ¶ 40; Answer ¶ 40. "FDA believes it is critically important that antimicrobial drugs be used as judiciously as possible in an effort to minimize resistance development." Sorenson Decl. Ex. U, at 2; Amended Complaint ¶ 40; Answer ¶ 40.

NOT CONTROVERTED.

35. HHS has concluded that "there is a preponderance of evidence that the use of antimicrobials in food-producing animals has adverse human consequences." Sorenson Decl. Ex. Y, at 89; Amended Complaint ¶ 39; Answer ¶ 39.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that in a letter dated July 13, 2010, a letter from the the Department of Health and Human Services Office of Inspector General stated that "there is a preponderance of evidence that the use of antimicrobials in food-producing animals has adverse human consequences," but does controvert Plaintiffs' characterization of that statement as a "conclusion." Rather, that statement represented the tentative position of the Department in the form of comments on a draft GAO report. *See* Sorenson Decl. Ex. Y at 87.

36. In a 2004 report, GAO observed that "[m]any studies have found that the use of antibiotics in animals poses significant risks for human health, and some researchers contend that the potential risk of the transference is great for vulnerable populations," while only a "small number of studies contend that the health risks of the transference are minimal." Sorenson Decl. Ex. Y, at 23; Amended Complaint ¶ 39; Answer ¶ 39.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the 2004 GAO Report contains the statements attributed to it in paragraph 36 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

37. In its comments on the 2004 GAO report, HHS urged GAO to note that the only article cited in the report as arguing that the risks were minimal was written by an advisory group to the Animal Health Institute, an industry association representing pharmaceutical companies. Sorenson Decl. Ex. Y, at 89; Amended Complaint ¶ 39; Answer ¶ 39.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the comments from HHS contained in the 2004 GAO

Report contain the statements attributed to it in paragraph 37 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

38. According to CDC, 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." Sorenson Decl. Ex. W, cover letter, at 1.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that in a letter to the Honorable Frank Pallone, Jr. dated July 13, 2010 (the "CDC July 13, 2010 Letter"), CDC made the statements contained in paragraph 38 of Plaintiffs' 56.1 Statement. The Government controverts these statements as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

39. Many organizations that have studied the human health risks linked to the use of antibiotics in livestock, such as WHO and the Institute of Medicine, have recommended that livestock producers be prohibited from using antibiotics for growth promotion if those antibiotics are also used in human medicine. Amended Complaint ¶ 46; Answer ¶ 46; Sorenson Decl. Ex. Z, at 209-11; *id.* Ex. AA, at 2. Eight years ago, the Institute of Medicine explained that "[t]he total burden of human illness due to resistant bacteria that have been transferred from animals to humans is unknown, but the guiding principle should be that we must do what the available evidence suggests will help stem the tide of increasing resistance before it is too late," and "[t]o do nothing is, in effect, to allow the continued evolution of antimicrobial-resistant microbes, which poses serious near- and long-term threats to global health." Sorenson Decl. Ex. Z, at 209.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the Institute of Medicine Book and the WHO, World Health Day 2011, Policy Brief No. 4D, entitled "Reduce Use of Antimicrobials in Food-Producing Animals" have recommend that livestock producers be prohibited from using antibiotics for growth promotion if those antibiotics are also used in human medicine, or that the Institute of Medicine Book contains the statements in quotations in the second sentence of

paragraph 39 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

40. According to the Institute of Medicine, the "main argument" against a ban on the subtherapeutic use of antibiotics for growth promotion in the United States is an economic one. Sorenson Decl. Ex. Z, at 208.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the Institute of Medicine Book contains the statement attributed to it in paragraph 40 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

41. The European Union, Australia, and New Zealand prohibit the use of penicillin and tetracyclines for growth promotion indications, and Japan prohibits the use of penicillin for growth promotion indications. Answer ¶ 46.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the European Union, Australia, and New Zealand prohibit the use of penicillin and tetracyclines for growth promotion indications, and Japan prohibits the use of penicillin for growth promotion indications. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

42. Denmark discontinued the use of antibiotics for growth promotion in broiler chickens and adult swine in 1998, and in young swine in 1999. Danish government and industry data collected since then show that antibiotic-resistant bacteria in livestock and in meat products have declined, and livestock production has increased. Amended Complaint ¶ 47; Answer ¶ 47; Sorenson Decl. Ex. CC, at 40-41.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that Denmark discontinued the use of antibiotics for growth promotion in broiler chickens and adult swine in 1998, and in young swine in 1999, or that Danish government and industry data collected since then show that antibiotic-resistant bacteria

in livestock and in meat products have declined, and livestock production has increased, but does controvert this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

43. According to CDC, "[i]n general, subtherapeutic use has been shown to lead to an increase in resistant strains in animals. The European experience demonstrates that it is possible to stop these uses, reduce overall use of antibiotics in animals, reduce resistant circulating bacteria that can infect humans, and not have industry or consumers affected by decreased production or increased costs." Sorenson Decl. Ex. W, enclosure, at 3.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the CDC July 13, 2010 Letter contains the statements attributed to it in paragraph 43 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

44. FDA approved the use of penicillin as an animal feed additive in the 1950s. Today, penicillin may be used for growth promotion in chickens, turkeys, and swine. 21 C.F.R. § 558.460; Amended Complaint ¶ 48; Answer ¶ 48.

NOT CONTROVERTED.

45. FDA approved the use of chlortetracycline and oxytetracycline as an animal feed additive in the 1950s. Currently, chlortetracycline and oxytetracycline are approved as growth promoters in chickens, turkeys, swine, cattle, and sheep. 21 C.F.R. §§ 558.128, 558.450; Amended Complaint ¶ 49; Answer ¶ 49.

NOT CONTROVERTED.

46. In the mid-1960s, FDA became concerned that the long-term use of antibiotics in animals might pose threats to human and animal health. In 1970, the agency convened a Task Force to study the issue. It staffed the Task Force with scientists from FDA, the National Institutes of Health, the U.S. Department of Agriculture, CDC, universities, and industry. *See* New Animal Drugs; Removal of Obsolete and Redundant Regulations, 68 Fed. Reg. 47,272, 47,273 (Aug. 8, 2003), Ex. E to Sorenson Decl.; Antibiotic and Sulfonamide Drugs in Animal Feeds, 37 Fed. Reg. 2444, 2444 (Feb. 1, 1972), Ex. C to Sorenson Decl.; Amended Complaint ¶ 50; Answer ¶ 50.

NOT CONTROVERTED.

47. The Task Force concluded that (1) the use of antibiotics in animal feed, especially at subtherapeutic levels, favors the development of antibiotic-resistant bacteria; (2) animals receiving antibiotics in their feed may serve as a reservoir of antibiotic-resistant pathogens, which can produce human infections; (3) the prevalence of bacteria carrying transferable resistance genes for multiple antibiotics had increased in animals, and the increase was related to the use of antibiotics; (4) antibiotic-resistant bacteria had been found on meat and meat products; and (5) the prevalence of antibiotic-resistant bacteria in humans had increased. *See* Antibiotic and Sulfonamide Drugs in Animal Feeds, 37 Fed. Reg. at 2444-45.

NOT CONTROVERTED.

48. The Task Force recommended, *inter alia*, that (1) antibiotics used in human medicine be prohibited from use in animal feed unless they met safety criteria established by FDA and (2) several specific drugs, including tetracycline and penicillins, be reserved for therapy unless they met safety criteria for subtherapeutic use. *See id.* at 2445.

NOT CONTROVERTED.

49. In response to the "significant questions" raised by the Task Force's findings, in 1973 FDA issued a regulation providing that the agency would propose to withdraw all approvals for subtherapeutic uses of antibiotics in animal feed unless drug sponsors and other interested parties submitted data within the next two years "which resolve[d] conclusively the issues concerning [the drugs'] safety to man and animals . . . under specific criteria" established by FDA. Antibiotic and Sulfonamide Drugs in the Feed of Animals, 38 Fed. Reg. 9811, 9813 (Apr. 20, 1973) (codified at former 21 C.F.R. § 135.109; renumbered as 21 C.F.R. § 558.15), Ex. D to Sorenson Decl.

NOT CONTROVERTED.

50. One of the "most important" of the human and animal health safety criteria that FDA established for drug safety evaluations under the regulation dealt with the transfer of drug resistance: "An antibacterial drug fed at subtherapeutic levels to animals must be shown not to promote increased resistance to antibacterials used in human medicine. Specifically, increased multiple resistance capable of being transferred to other bacteria in animals or man should not occur." Penicillin Notice, 42 Fed. Reg. at 43,774-75.

NOT CONTROVERTED.

51. After evaluating the information collected under 21 C.F.R. § 558.15, FDA concluded that, at least with respect to penicillin and certain uses of tetracyclines, the drug sponsors had failed to demonstrate that using the drugs subtherapeutically in animal feed was safe. Accordingly, the Director of FDA's Bureau of Veterinary Medicine (now CVM) issued notices of opportunity for hearing on proposals to withdraw approvals for all uses of penicillin in animal feed, *see* Penicillin Notice, 42 Fed. Reg. at 43,772, and, with limited exceptions, all subtherapeutic uses of tetracyclines in animal feed, *see* Tetracyclines Notice, 42 Fed. Reg. at 56,264.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that in 1977 FDA's Bureau of Veterinary Medicine ("BVM") issued a notice of opportunity for hearing on proposals to withdraw approvals for all uses of penicillin in animal feed and, with limited exceptions, all subtheraputic uses of tetracyclines in animals feed (the "1977 NOOHs"), but controverts the remainder of paragraph 51 of Plaintiffs' 56.1 Statement, and, specifically, Plaintiffs' characterization of the issuance of the 1997 NOOHs as reflecting any "conclusion" by FDA with respect to the use of penicillin and tetracyclines in animal feed, which is not supported by Plaintiffs' citation. On the contrary, the issuance of the 1977 NOOHs reflected that BVM's determination that a "reasonable basis from which serious questions about the ultimate safety of [the the use of penicillins and tetracyclines in animal feed] . . . may be inferred." *See* Final Decision of the Commissioner, Withdrawal of Approval of the New Animal Drug Application for Enrofloxacin in Poultry (July 29, 2005) at 7, attached as N to Barcelo Decl.[1] (articulating the standard for this issuance of a notice of opportunity for hearing under 21 U.S.C. § 360b(e)(1)); *see also* Nitrofurans; Withdrawal of Approved New Animal Drug Applications (Nitrofurans), 56 Fed. Reg. 41902, 41903 (Aug. 23, 1991) attached as Exhibit O to the Barcelo Decl., (same); *see also* Diethylstilbestrol; Withdrawal of New Animal Drug Applications (DES), 44 Fed. Reg. 54852, 54861 (Sept. 21, 1979), attached as Exhibit P to the Barcelo Decl.

52. In the Penicillin Notice, the Director reported that "[n]one of the specified human and animal health safety criteria [for the subtherapeutic use of penicillin] have been satisfied." 42 Fed. Reg. at 43,775. With respect to the criterion dealing with the transfer of drug resistance, the Director surveyed the available data and found that (1) the pool of bacteria carrying transferable resistance genes was increasing; (2) the increase was due in part to the subtherapeutic use of penicillin in animal feed; and (3) antibiotic-resistant bacteria were transferred from animals to

[1] FDA announced the availability of its final decision withdrawing approval of Enrofloxacin at 70 Fed. Reg. 44105 (August 1, 2005).

humans as a result of direct human-animal contact, the consumption of contaminated food, and the widespread presence of resistant bacteria in the environment. Studies submitted by or on behalf of the drug sponsors failed to rebut these findings. *See id.* at 43,781.

NOT CONTROVERTED.

53. Following an extensive analysis, the Director indicated that he was "unaware of evidence that satisfies the requirements for the safety of penicillin-containing premixes [i.e., feed supplements] as required by section 512 of the Federal Food, Drug, and Cosmetic Act and § 558.15 of the agency's regulations." Penicillin Notice, 42 Fed. Reg. at 43,792. He proposed to "withdraw approval of new animal drug applications . . . for all penicillin-containing premixes intended for use in animal feed on the grounds that . . . new evidence shows that the penicillin-containing products have not been shown to [be] safe for subtherapeutic use" as required by the Food and Drug Act. *Id.* at 43,772.

NOT CONTROVERTED.

54. The Director undertook a similar analysis, and reached similar conclusions, in the Tetracyclines Notice. For purposes of the notice, FDA treated chlortetracycline, oxytetracycline, and tetracycline identically because it concluded there was no scientific basis for treating them otherwise. *See* Tetracyclines Notice, 42 Fed. Reg. at 56,266. The Director found that "the results of the studies submitted and the data available are clear—the affected parties have failed to show that extensive subtherapeutic use of the tetracyclines is safe." *Id.* at 56,267.

NOT CONTROVERTED.

55. With limited exceptions, the Director proposed to withdraw "all approvals for tetracycline-containing premix products intended for subtherapeutic uses in animal feed . . . on the grounds that they have not been shown to be safe." Tetracyclines Notice, 42 Fed. Reg. at 56,288. The Director carved out limited exceptions related to "unique, essential" drug uses, primarily for the control of specific diseases. *Id.* at 56, 287.

NOT CONTROVERTED.

56. Shortly after FDA issued the two notices of opportunity for hearing, the House Committee on Appropriations requested that FDA, before taking action on its withdrawal proposals, conduct further research on the question whether the subtherapeutic use of antibiotics in animal feed presents a threat to human health. *See* H.R. Rep. No. 95-1290, at 99-100 (1978).

NOT CONTROVERTED.

57. In response, FDA contracted with the National Academy of Sciences to assess the human health consequences of the subtherapeutic use of penicillin and tetracyclines in animal feeds by evaluating existing data, and to recommend areas for additional research. The resulting report by the National Academy, published in 1980, did not conclude that using antibiotics subtherapeutically in animal feed was safe. The Academy recommended additional

epidemiological studies. Sorenson Decl. Ex. F, at 53; Amended Complaint ¶ 61; Answer ¶ 61.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert the first and last sentences. The Government controverts the second sentence to the extent that it would agree only that the referenced report concluded that existing data could neither prove nor disprove the postulated hazards to human health from subtherapeutic antimicrobial use in animal feed and that the lack of data linking human illness with subtherapeutic levels of antimicrobials must not be equated with proof that the proposed hazards do not exist, which is the statement made by the Government in paragraph 61 of the Answer.

58. Soon thereafter, the House Committee on Appropriations requested that FDA undertake additional research in response to the 1980 report of the National Academy, and that in the meantime FDA continue to hold its penicillin and tetracyclines proposals in abeyance. *See* H.R. Rep. No. 96-1095, at 105-06 (1980). The following year, the Senate Committee on Appropriations made the same request. *See* S. Rep. No. 97-248, at 79 (1981).

NOT CONTROVERTED.

59. FDA contracted with the Seattle-King County Department of Public Health and the Institute of Medicine for further research. The Seattle-King County study, published in 1984, contained several important findings that supported FDA's concerns about the risks posed by antibiotics in animal feed. For example, the study found that *Campylobacter* bacteria were likely transferred from chickens to humans through the consumption of poultry products; that samples of such bacteria taken from poultry products and humans exhibited "surprisingly high" and "similar" patterns of tetracycline resistance; and that drug-resistant *Campylobacter* could transfer resistance genes to other bacteria. Sorenson Decl. Ex. G, at 3, 169.

NOT CONTROVERTED.

60. The 1988 report of the Institute of Medicine, like the studies before it, could not conclude that the subtherapeutic use of antibiotics in animal feed was safe. The Institute found several sources of "indirect evidence implicating subtherapeutic use of antimicrobials in producing resistance in infectious bacteria that causes a potential human health hazard." Sorenson Decl. Ex. H, at 194.

NOT CONTROVERTED.

61. FDA has not concluded that the subtherapeutic use of penicillin and tetracyclines

in animal feed is safe. Removal of Obsolete Regulations, 68 Fed. Reg. at 47,275; Answer ¶ 65.

CONTROVERTED. *Following* the initial approvals in the 1950s, and based on research conducted in the 1980s and on other information, FDA "(1) [c]oncluded that the risks were neither proved nor disproved, (2) did not deny there was some degree of risk, and (3) did not conclude that the continued subtherapeutic use of penicillin and the tetracycylines in animal feed is safe." Removal of Obsolete Regulations, 68 Fed. Reg. 47272, 47275 (August 8, 2003).

62. FDA has never revoked the 1977 notices of opportunity for hearing containing the agency's findings that subtherapeutic uses of penicillin and tetracyclines in animal feed are not shown to be safe. Amended Complaint ¶ 66; Answer ¶ 66.

CONTROVERTED. On December 16, 2011, FDA withdrew the 1977 NOOHs. *See* Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline used in Animal Feed (the "NOOH Withdrawals"), 76 Fed. Reg. 79697 (December 22, 2011), attached as Exhibit L the Barcelo Decl.

63. FDA's 1977 Penicillin and Tetracyclines Notices are still pending. Answer ¶ 68.

CONTROVERTED. On December 22, 2011, FDA withdrew the 1977 NOOHs. *See* NOOH Withdrawals, 76 Fed. Reg. 79697.

64. FDA has not withdrawn approvals for penicillin and tetracyclines as proposed in the 1977 notices of opportunity for hearing. Answer ¶ 4.

NOT CONTROVERTED.

65. In 2004, FDA sent letters to several manufacturers of approved animal feed products containing penicillin and tetracyclines, explaining that the administrative record did not contain sufficient information to alleviate FDA's concerns about "the use of these products and their possible role in the emergence and dissemination of antimicrobial resistance." Sorenson Decl. Ex. N, at 1-2. FDA reported that it had conducted a qualitative risk assessment and concluded that the products fell into "Category 1," or "high" risk, and use of the products for growth promotion was therefore not appropriate. FDA invited the manufacturers to meet with the agency to discuss its findings. *Id.* at 3.

NOT CONTROVERTED.

66. In 2003, FDA issued Guidance for Industry No. 152. The Guidance recommended a risk assessment approach that drug sponsors could use to evaluate the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern. Guidance No. 152 made clear that "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities." Sorenson Decl. Ex. M, at 2.

NOT CONTROVERTED.

67. In 2007, the House Committee on Appropriations expressed concern that FDA's Guidance No. 152 "does not assign enough weight to the impact of microbial resistance to drugs that are highly important to human medicine but are not used to treat foodborne illnesses," because "[t]ransferred resistance from antimicrobials used in animals produced for food can also render critically important human antibiotics ineffective." H.R. Rep. No. 110-258, at 98-99 (2007). Because the Committee was "concerned that simply satisfying the requirements of the guidance document is not adequate to protect human health," the Committee "directed FDA to reevaluate the basis on which it makes such decisions and to provide a report to the Committee by November 1, 2007." *Id.* at 99.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that that House Report Number 110-258, a report by the House Committee on Appropriations published in 2007, contains the statement attributed to it in paragraph 67 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

68. In 2010, FDA issued Draft Guidance No. 209, expected to be finalized in 2011, which concludes that "using medically important antimicrobial drugs for production purposes [i.e., increasing rate of weight gain or improving feed efficiency] is not in the interest of protecting and promoting the public health." Sorenson Decl. Ex. O, at 13. The Draft Guidance recommends that medically important antibiotics be used in food-producing animals (1) only when necessary to ensure the animals' health, and not to promote growth or improve feed efficiency, and (2) only with veterinary oversight. *Id.* at 16-17. Like other FDA guidance documents, Draft Guidance No. 209 does "not establish legally enforceable responsibilities." *Id.* at 2.

NOT CONTROVERTED.

69. In 2011, the Senate Committee on Appropriations recommended that "FDA examine medically important antimicrobial drugs currently approved for use in food-producing animals and take steps to assure that such products are aligned with current safety standards." S. Rep. No. 112-73, at 80 (2011).

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The

Government does not controvert that Senate Report Number 112-73, a report by the Senate Committee on Appropriations published in 2011, contains the statement attributed to it in paragraph 69 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government.

70. 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." Sorenson Decl. Ex. I, at 1-2.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that plaintiffs CSPI, FACT, Public Citizen, and UCS submitted the 1999 Petition to FDA, but does controvert this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government, because Plaintiffs' claims regarding the 1999 Petition have been dismissed as moot. *See* Dkt. No. 37.

71. The petition summarized the supporting science, and explained that:

a. Subtherapeutic antibiotics are used widely in livestock.
b. Subtherapeutic antibiotic use in livestock leads to the selection of antibiotic-resistant bacteria.
c. Antibiotic-resistant bacteria can be transferred between animals and from animals to people.
d. Antibiotic-resistant bacteria may transfer resistance genes to other bacteria.
e. Subtherapeutic antibiotic use may select for multi-drug-resistant bacteria that can cause infections that are difficult to treat.
f. Subtherapeutic antibiotic use jeopardizes therapeutic options in veterinary and human medicine.
g. Expert committees and leading scientists support a phase-out of subtherapeutic antibiotic use in livestock.
h. Authoritative scientific bodies such as CDC and WHO consider it a human health risk to permit subtherapeutic use in livestock of antibiotics that are used in (or related to those used in) human medicine. *Id.* at 9-25.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the issues listed in subparts (a) – (h) of paragraph 71 of Plaintiffs' 56.1 Statement were the subject of the 1999 Petition, but controverts this statement as

not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government, in part because Plaintiffs' claims regarding the 1999 Petition have been dismissed as moot. *See* Dkt. No. 37.

72. The petition also addressed the modest economic and environmental impacts of the proposed withdrawals. As evidence, the petition cited the National Academy's estimate that elimination of *all* subtherapeutic use of antibiotics in livestock would lead to approximately $9.72 a year in higher costs for consumers. Sorenson Decl. Ex. I, at 33. The petition also pointed to the experiences of countries such as Sweden and Denmark, which have successfully eliminated some uses of antibiotics in livestock. *Id.* at 33-34.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the 1999 Petition contains the content attributed to it in paragraph 72 of Plaintiffs' 56.1 Statement. The Government controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government, in part because Plaintiffs' claims regarding the 1999 Petition have been dismissed as moot. *See* Dkt. No. 37.

73. 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)." Sorenson Decl. Ex. K, at 1. The petition covered penicillins, tetracyclines, aminoglycosides, streptogramins, macrolides, lincomycin, and sulfonamides. *Id.* It did not cover any uses of those drugs to treat disease in animals. *Id.* at 2.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert the first sentence of paragraph 73 of Plaintiffs' 56.1 Statement. With respect to the second sentence of Plaintiffs' 56.1 Statement, the Government does not controvert that the 2005 Petition states that: "Petitioners do not seek withdrawal of disease prevention or disease control uses where a drug is administered to individual animals, or to select groups or pens of animals, or where a drug is administered in response to a diagnosed outbreak

of bacterial disease within a building, house, or feedlot," but does controvert that the statement supports Plaintiffs' conclusion that the 2005 Petition did not cover any uses of the drugs that were the subject of the 2005 Citizen Petition to treat disease in animals, and controverts this statement as not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government, in part because Plaintiffs' claims regarding the 2005 Petition have been dismissed as moot. *See* Dkt. No. 37.

74. The second petition analyzed the listed antibiotics under the risk assessment approach developed by FDA in Guidance No. 152. The petition demonstrated that herdwide or flockwide uses of the listed drugs—all of which were classified by FDA as "critically important" or "highly important" for human health—were inconsistent with the agency's own risk management criteria. *Id.* at 10-16.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the 2005 Petition analyzed the listed antibiotics under the risk assessment approach developed by FDA in FDA Guidance for Industry #152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern* (2003), and that FDA had classified each of the drugs that were the subject of the 2005 Petition as "critically important" or "highly important." The Government does, however, controvert the rest of this statement as not supported by Plaintiffs' citations, and controvert this entire statement because it is not a statement of fact material to the claims of the Plaintiffs or the defenses of the Government, in part because Plaintiffs' claims regarding the 2005 Petition have been dismissed as moot. *See* Dkt. No. 37.

75. FDA has never issued a final response to either the 1999 or 2005 petition. Amended Complaint ¶ 87; Answer ¶ 87.

CONTROVERTED. On November 7, 2011, FDA responded to the 1999 Petition and the 2005 Petition. *See* November 7, 2011 FDA Final Response to Citizen Petition New Docket No. FDA-1999-P-1286 addressed to Sarah Klein, attached as Exhibit I to the Barcelo Decl;

November 7, 2011 FDA Final Response to Citizen Petition New Docket No. FDA-2005-P-0007, addressed to Andrew Maguire, attached as Exhibit J to the Barcelo Decl.

76. FDA issued tentative responses to the 1999 petition in 1999 and 2001. The second tentative response, dated February 28, 2001, acknowledged concern about "the role that antimicrobial drug use in food-producing animals plays in the emergence of antimicrobial drug resistant bacteria," and asserted that, "[t]o address these issues, the FDA is undertaking an extensive process to evaluate issues related to the use of antimicrobial drugs in both humans and animals, and to develop policies that protect public health." Sorenson Decl. Ex. J, at 3. The agency cited its efforts to develop guidance documents for industry. *Id.*

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that one of FDA's tentative responses to the 1999 Petition was dated February 28, 2001 and contained the statements described in paragraph 76 of Plaintiffs' 56.1 Statement, but does controvert that those statements are statements of fact material to the claims of the Plaintiffs or the defenses of the Government, in part because Plaintiffs' claims regarding the 1999 Petition and the 2005 Petition have been dismissed as moot. *See* Dkt. No. 37.

77. FDA issued a tentative response to the 2005 petition on October 4, 2005. The agency again recognized "the need to address concerns related to the role that antimicrobial drug use in food-producing animals plays in the emergence and selection of antimicrobial drug resistant bacteria," and explained that, "[t]o address these public health concerns, the FDA has developed a regulatory strategy that includes Guidance #152 . . . . Like all FDA guidance documents, Guidance #152 does not establish legally enforceable responsibilities." Sorenson Decl. Ex. L, at 2.

CONTROVERTED IN PART AND NOT CONTROVERTED IN PART. The Government does not controvert that the FDA's tentative response to the 2005 Petition was dated October 4, 2005 and contained the statements described in paragraph 77 of Plaintiffs' 56.1 Statement, but does controvert that these statements are statements of fact material to the claims

of the Plaintiffs or the defenses of the Government, in part because Plaintiffs' claims regarding the 1999 Petition and the 2005 Petition have been dismissed as moot. *See* Dkt. No. 37.

Dated: New York, New York
January 9, 2012

Respectfully submitted,

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