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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY, INSTITUTE FOR AGRICULTURE AND TRADE POLICY, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR BIOLOGICAL DIVERSITY, FOOD ANIMAL CONCERNS TRUST, FOOD AND WATER WATCH, OREGON PHYSICIANS FOR SOCIAL RESPONSIBILITY, HEALTH CARE WITHOUT HARM, and SAN FRANCISCO BAY AREA PHYSICIANS FOR SOCIAL RESPONSIBILITY, *Plaintiffs*, v. KATHLEEN SEBELIUS, SECRETARY OF U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and MARGARET A. HAMBURG, M.D., COMMISSIONER OF U.S. FOOD AND DRUG ADMINISTRATION, *Defendants*.	**Case No. 4:13-cv-01975-DMR** **FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** **Administrative Procedure Act Case**

INTRODUCTION

1. This is an action for declaratory and injunctive relief regarding the failure by the United States Food and Drug Administration (FDA or the agency) to respond within a reasonable time to a petition filed by Center for Food Safety and the Institute for Agriculture and Trade Policy (collectively, Petitioners) requesting that FDA revoke all regulations associated with the approval of all New Animal Drug Applications (NADAs) for arsenic-containing compounds used as feed additives in chicken, turkeys, and swine. Petitioners are requesting immediate action because the use of arsenic-based feed additives in food-producing animals poses a serious yet completely avoidable health risk to humans. Petitioners are joined by petition endorsers Center for Environmental Health, Center for Biological Diversity, Food Animal Concerns Trust, Food & Water Watch, Oregon Physicians for Social Responsibility, Health Care Without Harm, and San Francisco Bay Area Physicians for Social Responsibility (collectively, Plaintiffs).

2. FDA began approving arsenic-containing compounds for use in animal feed in the 1940s. More than seventy years later, arsenic-containing feed additives—namely Roxarsone, arsanilic acid, nitarsone, and carbarsone—are still used in chicken, turkey, and swine production. In 2004 and 2005, Plaintiff Institute for Agriculture and Trade Policy tested for total arsenic residues in retail packages of raw chicken and in "fast food" chicken sandwiches and nuggets. Test results revealed detectable levels of arsenic in the majority of supermarket chicken and in all "fast food" chicken. Arsenic levels in chicken from birds for which there was a claim of "no arsenic given" contained no arsenic or such a small amount that it was below the detection limit. In 2010 and 2011, the Johns Hopkins Center for a Livable Future (CLF) at the Bloomberg School of Public Health analyzed retail chicken breast samples for total and speciated arsenic concentrations. The arsenical Roxarsone was detected in half of the conventional samples, in one of thirteen conventional "antibiotic-free" samples, and in none of the certified organic samples. Inorganic arsenic concentrations were higher in conventional samples than other samples, and were significantly higher in cooked versus raw samples. CLF estimated that consumption of conventionally raised chicken containing inorganic arsenic could result in approximately 3.7 additional cases of bladder and/or lung cancer per 100,000 persons with lifetime exposure.

These results strongly suggest that the use of arsenic-containing compounds in poultry feed leads to arsenic residues in chicken marketed and eaten in the United States.

3. Inorganic arsenic is a known human carcinogen. It can contribute to cancers, heart disease, diabetes, declines in intellectual function, and can decrease a body's ability to respond to viruses. The organic form of arsenic—the form found in arsenic-containing compounds—was once considered safe at low levels. Recent studies show that organic arsenic can easily convert to inorganic arsenic. Further, organic arsenic may also be toxic in its own right, though an earlier history of organic arsenical toxicity has been largely overlooked by FDA.

4. On December 8, 2009, Petitioners submitted a petition to FDA for rulemaking. Docket No. FDA-2009-P-0594-0001/CP (2009 Petition) (filed concurrently as Exhibit A). Pursuant to § 360b of the Federal Food, Drug, and Cosmetic Act (FFDCA), the 2009 Petition requested that FDA immediately suspend all approvals of NADAs for arsenic-containing compounds used as feed additives in food-producing animals; publish a Notice of Opportunity for an Evidentiary Hearing concerning new evidence related to the NADAs; upon completion of the hearing, issue an order withdrawing all approvals of arsenic-containing animal feed additives; and revoke all regulations associated with approval of all NADAs for arsenic-containing animal feed additives.

5. Since the filing of the 2009 Petition, significant events have occurred that demonstrate both an urgent need and incentive for FDA to use its statutory authority to immediately withdraw approval of arsenic-containing feed additives. In February 2011, FDA completed a final report on a study of the safety of edible tissues from chickens treated with arsenicals, particularly Roxarsone. The study concluded that levels of inorganic arsenic in chicken livers were significantly higher for chickens treated with the arsenical Roxarsone than for chickens not treated with Roxarsone.[1] Shortly following the release of FDA's study, in June

[1] U.S. Food and Drug Admin., Final Report on Study 275.30, Provide data on various arsenic species present in broilers treated with roxarsone: Comparison with untreated birds 36 (Feb. 10, 2011), *available at* http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/UCM257545.pdf.

2011, Alpharma (a division of Pfizer) announced it would voluntarily suspend—not revoke—sale of Roxarsone within 30 days.[2] At this time, FDA commented that Roxarsone raised concerns of "completely avoidable exposure to a carcinogen."[3]

6. Even though Pfizer claims it is not currently selling Roxarsone, and Roxarsone raises concerns of "completely avoidable" exposure to a known carcinogen, FDA has not formally withdrawn Roxarsone from the market—the drug could be returned to the market at any time. Nor has FDA studied the other arsenic-containing compounds referenced in the 2009 Petition or evaluated muscle tissue consumed by humans more frequently than chicken livers. No other arsenical drug manufacturers have voluntarily suspended their sales of other arsenicals, even though other arsenicals are just as likely as Roxarsone to convert to inorganic arsenic and to be present in chicken, turkey, or swine. FDA's failure to act has completely failed to close the loop on an avoidable exposure pathway to a known carcinogen.

7. Nearly three and a half years have now passed since FDA docketed the 2009 Petition for rulemaking. Not only has FDA failed to act under the FFDCA, the agency has not meaningfully responded to the 2009 Petition and is in violation of the Administrative Procedure Act (APA). In the interim, evidence of the negative effects of arsenic-based feed additives continues to mount. This Court should order the agency to respond to Plaintiffs' 2009 Petition without further unlawful delay.

JURISDICTION

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1346 (United States as defendant).

9. The relief requested is specifically authorized pursuant to 28 U.S.C. § 1651 (writs) and 28 U.S.C. §§ 2201–02 (declaratory relief). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201 (declaratory judgments).

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[2] Press Release, U.S. Food and Drug Admin., FDA: Pfizer will voluntarily suspend sale of animal drug 3-Nitro (June 8, 2011), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm258342.htm.

[3] *Id.* (emphasis added).

10. Plaintiffs have a right to bring this action pursuant to the APA, 5 U.S.C. § 702.

VENUE

11. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e) because one or more of the Plaintiffs reside in this District.

PARTIES

12. Plaintiff Center for Food Safety (CFS) is a Washington, D.C.-based nonprofit organization located at 660 Pennsylvania Avenue S.E., Washington, D.C. 20003. CFS has nearly 300,000 members, including members in every state across the country, many of whom purchase and consume chicken, turkey, and pork that were fed arsenic-based feed additives, and eggs from chickens that were fed arsenic-based feed additives. CFS and its members are being, and will be, adversely affected by FDA's continued failure to address the risks associated with the use of arsenic-based feed additives.

13. Founded in 1997, CFS is dedicated to addressing the environmental, economic, ethical, human health, and social impacts associated with the development and commercialization of agricultural and food processing technologies. CFS combines multiple tools and strategies in pursuing its goals, including litigation and legal petitions for rulemaking, legal support for various sustainable agriculture and food safety constituencies, public education, grassroots organizing, and media outreach. CFS is actively involved in the campaign against the use of antimicrobials in food animal production and has specifically focused on arsenic-based feed additives since 2008. CFS members support enhanced animal welfare and regularly purchase organic products, including organic meat and dairy, due to concerns about the use of antimicrobials like arsenic in animal production. CFS and its members believe it is imperative that FDA promote a cautious approach to the use of arsenic-based feed additives and other antimicrobials in food in order to protect human health.

14. CFS also sends action alerts to its membership. These action alerts generate public involvement, education, and engagement with governmental officials on issues related to fighting the health and environmental impacts of industrial agriculture and promoting a more sustainable, healthier food system. Collectively, the dissemination of this material has made

CFS an information clearinghouse for public involvement and governmental oversight of food safety issues.

15. Plaintiff Institute for Agriculture and Trade Policy (IATP) is a 501(c)(3) nonprofit organization located at 2105 First Avenue South, Minneapolis, Minnesota 55404. Established in 1986, IATP works locally and globally at the intersection of policy and practice to ensure fair and sustainable food, farm, and trade systems. In 2006, IATP issued a groundbreaking report, *Playing Chicken: Avoiding Arsenic in Your Meat*, examining arsenic residues in retail chicken meat purchased in supermarkets as well as chicken products from "fast food" outlets. Prior to this report, FDA had never tested for the presence of arsenic in chicken muscle, only in chicken liver on a limited basis.

16. Plaintiff Center for Environmental Health (CEH) is located at 528 61st Street, Suite A, Oakland, California 94609. Founded in 1996, CEH is a nonprofit organization dedicated to protecting the public from environmental and consumer health hazards. CEH is committed to environmental justice, reducing the use of toxic chemicals and practices, supporting communities in their quest for a safer environment, and corporate accountability. CEH programs have eliminated health threats to children from pesticides on our food, contamination from lead in imported candies, Polychlorinated Biphenyls (PCBs) in farmed salmon, contamination from harmful chemicals in food packaging, and other food safety threats.

17. Plaintiff Center for Biological Diversity (the Center) is a nonprofit public interest corporation with over 41,000 members and offices throughout the United States. The Center has offices in several locations, including Tucson, Arizona; San Francisco, Los Angeles, and Joshua Tree, California; Portland, Oregon; Silver City, New Mexico; and Washington, D.C. The Center and its members are dedicated to protecting the diverse native species and habitats of North America through science, policy, education, and environmental law. Members of the Center reside or own property and use waterways and environments throughout the United States that are impacted by pollution from animal feeding operations.

18. The Center's Toxics and Endangered Species Campaign employs a broad range of tools to reduce the harmful impacts of toxic contamination from man-made pollution, industrial chemicals, and resource-extractive processes. Through strategic litigation, creative media, policy

advocacy, scientific reports, coalition building, and outreach to our members, the Center has mounted an effective campaign to target some of the most harmful toxins in our environment.

19. Plaintiff Food Animal Concerns Trust (FACT) is a nonprofit organization located at 3525 W. Peterson Avenue, Suite 213, Chicago, Illinois, 60659-3314. FACT is dedicated to improving the welfare of farm animals; addressing public health problems such as the safety of meat, milk, and eggs; broadening opportunities for family farmers; and reducing environmental pollution. FACT has an active Public Health Program that identifies and advocates for steps farmers should take to keep their cattle, pigs, turkeys, and chickens from being the cause of human disease. FACT supports appropriate food safety regulation of farms where animals are raised to produce meat, milk, and eggs. An important part of FACT's public health work is to advocate for actions that reduce the risk that animal products are contaminated by unsafe residues of veterinary drugs including arsenic. FACT does this domestically through engagement with FDA and internationally by participating in the Codex Committee on Residues of Veterinary Drugs in Food.

20. Plaintiff Food & Water Watch (FWW) is a national nonprofit public interest consumer advocacy organization located at 1616 P Street NW, Suite 300, Washington, D.C. 20036, with offices throughout the United States, including New York City, New York, and San Francisco, California. FWW advocates for common sense policies that will result in healthy, safe food and access to safe and affordable drinking water. FWW helps people take charge of where their food comes from; keeps clean, affordable, public tap water flowing freely to our homes; protects the environmental quality of oceans; forces government to do its job protecting citizens; and educates about the importance of keeping the global commons—our shared resources—under public control. To that end, FWW has advocated against various government proposals and polices that would limit consumers' right to healthy and safe products, and negatively impact human health and the overall environment. Specifically on the issue of arsenic, FWW worked for several years in Maryland to support passage of a bill that bans the use of Roxarsone. The bill passed in 2012. FWW has also worked for several years to educate the public about the need for changes to public policy on animal drugs including antibiotics and arsenicals.

21. Plaintiff Oregon Physicians for Social Responsibility (OPSR) is located at 812 SW Washington Street, Suite 1050, Portland, Oregon 97205. It was founded in 1980 as a regional chapter of Physicians for Social Responsibility. Guided by the values and expertise of medicine and public health, OPSR works to protect human life from the gravest threats to health and survival by striving to end the nuclear threat, advance environmental health, and promote peace.

22. Plaintiff Health Care Without Harm (HCWH), founded in 1996, has offices in Reston, Virginia, and worldwide. HCWH works to implement ecologically sound and healthy alternatives to health care practices that pollute the environment and contribute to disease.

23. Since 2005 OPSR has partnered with HCWH on its Oregon Healthy Food in Health Care Project (the Project). The Project employs market-based forces to increase demand for sustainably-produced foods, improve hospital food quality, educate the public, and bolster the local economy. The principal goal of the Project is to leverage the significant purchasing power and influence of hospitals to support regional markets for sustainable food and to model healthy food choices to the public. The Project provides resources, tools, education, and technical assistance to hospital food service departments. Together, OPSR and HCWH have addressed the issue of antimicrobials, and specifically arsenical usage, in poultry production by supporting greater understanding of the environmental health consequences of the practice and then helping institutional food buyers to seek information from their suppliers to make informed purchasing decisions.

24. Plaintiff San Francisco Bay Area Chapter of Physicians for Social Responsibility (SF PSR), founded in 1979, was the first chapter of Physicians for Social Responsibility to be organized in the country and remains one of the largest of the thirty-one U.S. chapters, with over 2000 members. Physicians for Social Responsibility is a nonprofit advocacy organization that combines the power of community activism with the knowledge and credibility of physicians and other health professionals to promote public policies that support human health. SF PSR is the preeminent medical and public health voice in the San Francisco region on a broad range of critical social and environmental health issues, including building a healthier food system.

SF PSR coordinates the Healthy Food in Health Care program in California, a nationwide program of Health Care Without Harm that harnesses the purchasing power and expertise of the health care sector to advance the development of a sustainable food system. Through advocacy and education, SF PSR motivates health care facilities to implement programs that explicitly connect all aspects of the food system with health. SF PSR catalyzes sustainable procurement efforts; organizes clinicians to advocate for local, regional, and national food policy; and inspires health care institutions to become leaders in shaping a food system that supports prevention-based health care.

25. Defendant Kathleen Sebelius is the Secretary of the United States Department of Health and Human Services, and is sued in her official capacity.

26. Defendant Dr. Margaret A. Hamburg is sued in her official capacity as FDA Commissioner. As Commissioner, Dr. Hamburg has the ultimate responsibility for FDA's activities and policies.

27. Dr. Hamburg and the Food and Drug Administration are collectively referred to herein as "FDA" or "the agency."

LEGAL BACKGROUND

Federal Food, Drug, and Cosmetic Act

28. The Secretary of the U.S. Department of Health and Human Services, "through the Commissioner" of FDA, 21 U.S.C. § 393(d)(2), regulates antimicrobials in animal feed as "new animal drugs" under the FFDCA, *id.* § 360b.

29. Under FFDCA § 360b, the Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of a new animal drug if the Secretary finds:

A) "[E]xperience 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 the condition of use authorized under subsection (a)(4)(A)," *id.* § 360b(e)(1)(A);

B) New evidence, tests, or methods developed since approval of the application show that the drug is not safe for use "under the conditions of use upon the basis of which the application was approved," *id.* § 360b(e)(1)(B); or

C) New information, combined with the evidence available at the time the application was approved, shows a "lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof," *id.* § 360b(e)(1)(C).

FDA Regulations on Citizen Petitions

30. FDA's regulations provide that citizens may petition FDA to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25.

31. "The Commissioner shall . . . rule upon each petition . . . ." *Id.* § 10.30(e)(1).

32. "[T]he Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition" by approving, denying, or providing a tentative response to the petition, "indicating why the agency has been unable to reach a decision on the petition. . . ." *Id.* § 10.30(e)(2). "The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished." *Id.*

33. "The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. The petitioner is to be notified in writing of the Commissioner's decision." *Id.* § 10.30(e)(3).

Administrative Procedure Act

34. Under the APA, agencies are required to "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e).

35. The APA requires an agency to conclude a matter presented to it "within a reasonable time." *Id.* § 555(b). "Prompt notice shall be given of the denial [of a petition] in whole or in part. . . ." *Id.* § 555(e).

36. The APA grants a right of judicial review to "[a] person suffering legal wrong

because of agency action, or adversely affected or aggrieved by agency action." *Id.* § 702.

37. Courts "shall compel agency action unlawfully withheld or unreasonably delayed," *id.* § 706(1), and "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.* § 706(2)(A). Courts may only review a final agency action, *id.* § 704, and "agency action" includes a "failure to act," *id.* § 551(13).

STATEMENT OF FACTS

Arsenic

38. Arsenic is a semi-metal element in the periodic table. It is odorless and tasteless. Arsenic occurs naturally in the environment as an element of the earth's crust; it is found in rocks, soil, water, air, plants and animals. It can be further released into the environment through natural activities such as volcanic action, erosion of rocks, and forest fires, or through human actions. Elemental arsenic is combined with other elements such as oxygen, chlorine, and sulfur to form inorganic arsenic compounds.

39. Historically, arsenic compounds were used in many industries, including: as a preservative in pressure treated lumber; as a preservative in animal hides; as an additive to lead and copper for hardening; in glass manufacturing; in pesticides; in animal agriculture; and as arsine gas to enhance junctions in semiconductors. The United States has cancelled the approvals of some of these uses, such as arsenic-based pesticides, for health and safety reasons. Some of these cancellations were based on voluntary withdrawals by producers. For example, manufacturers of arsenic-based wood preservatives voluntarily withdrew their products in 2003 due to safety concerns, and the United States Environmental Protection Agency (EPA) signed the cancellation order. In the Notice of Cancellation Order, EPA stated that it considered the voluntary move a positive step, especially for the nation's children. "[EPA] believes that reducing the potential residential exposure to a known human carcinogen is desirable."[4]

[4] Response to Requests to Cancel Certain Chromated Copper Arsenate (CCA) Wood Preservative Products and Amendments to Terminate Certain Uses of other CCA Products, 68 Fed. Reg. 17366, 17367 (Apr. 9, 2003).

40. Arsenic is an element—it does not degrade or disappear. Therefore, despite efforts to reduce the amount of arsenic in the environment, residual arsenic remains.

Arsenic-Based Feed Additives

41. Arsenic is widely used in animal agriculture, contributing to the overall arsenic burden. FDA first approved the use of an arsenic-containing compound, Roxarsone, for use in animal production in 1944. Since then, FDA has approved more than 100 different arsenical compounds for use in broiler chickens alone.

42. Arsenic-containing compounds are most widely used in chicken production. According to data from the United States Department of Agriculture (USDA), 8,428,847,000 chickens were killed for food in the United States in 2012 alone.

43. In 2002, an estimated seventy percent of chickens were fed arsenic-containing compounds at some point in their lives.[5]

44. Chicken production has changed significantly in the last sixty years. Almost all chickens are now raised indoors. A modern broiler house is typically a single story facility, approximately forty feet wide by 400–500 feet long that holds 25,000 to 30,000 birds. A modern broiler "farm" generally has two to six such houses, with up to 150,000 birds or more. Inside these facilities, animals compete for space, food, and water; breathe contaminated air; and live in their own waste. Conditions of overcrowding and poor sanitation significantly increase the chance of large outbreaks of zoonotic diseases in large chicken operations. The relentless drive to produce more animals in less time, with less space, and at a lower cost is what lies behind the routine addition of antimicrobial drugs such as arsenicals to animal feeds.

45. Arsenic-containing feed additives are approved for both non-therapeutic and therapeutic uses. The thousands of animal feeding operations in the U.S. can use arsenic-containing feed additives for non-therapeutic reasons, such as to increase weight gain, improve feed efficiency, and improve pigmentation in animals, 21 C.F.R. § 558.530, or to

[5] *See* 21 C.F.R. §§ 558.35-558.680; H.D. Chapman, Z.B. Johnson, *Use of Antibiotics and Roxarsone in Broiler Chickens in the USA: Analysis for the Years 1995 to 2000*, 81 Poultry Sci. 356, 356-64 (2002).

prevent and control disease among animals that are raised in crowded, stress-inducing conditions that promote disease.

46. Arsenic, like other antimicrobials, is added to animal feed without a prescription. Most food-producing animals receive multiple drugs in their feed or drinking water for the majority of their lives. For example, broiler chickens are fed pre-starter, starter, and grower feeds containing up to three drug components: an antibiotic to promote growth, an arsenical, and an anti-parasite drug. Finisher feed also contains an antibiotic and arsenical, although arsenic is prohibited the last five days of a broiler's short life.

47. While FDA approves proposed arsenical uses, it does not collect data on arsenical sales or use. The most recent data available indicates that in 2010, 706,530 kilograms (kg) of arsenicals were sold for use in food-producing animals.

Arsenic Residue Testing

48. The U.S. approach to food safety generally does not aim to keep chemical contaminants completely out of the food supply—even cancer-causing arsenic. Rather, FDA determines the maximum exposure to that chemical deemed to be "safe," and then legally allows contamination of a particular food product up to the level of consumption that FDA believes results in maximum "safe" exposure (food tolerance residue levels).

49. For enforcement of food tolerance residue levels, FDA relies on USDA's Food Safety Inspection Service (FSIS). The cornerstone of FSIS's effort is the National Residue Program, which since 1970 has monitored chemical residues in food. According to USDA's "Red Book" data, FSIS conducts very little testing of more commonly consumed poultry and pork products. For example, in 2001, FSIS analyzed just 1,207 of the more than eight billion young chickens produced for total arsenic, and then only chicken kidneys and livers, not the muscle meat that most humans consume.[6] In 2009, FSIS tested just 324 young chickens—more

[6] USDA, FSIS, 2001 FSIS National Residue Program Data, *available at* http://www.fsis.usda.gov/OPHS/red_book_2001/2001_Residue_Program_Data_Sections1-7.pdf.

than twenty-five percent of these chickens tested positive for arsenic residue.[7] In 2010, the most recent year for which the public has data, FSIS did not analyze chickens for total arsenic at all. FSIS residue testing is the only "protection" American consumers have against arsenic exposure from contaminated meat, yet residue testing is weak and funding for the FSIS National Residue Program is, and has been over the years, unstable. The function of FSIS testing is only to monitor the problem; it does not prevent or correct it.

50. Such sparse FSIS testing was the impetus for Plaintiff IATP's 2004 and 2005 independent residue testing and subsequent report. Plaintiff IATP tested for total arsenic in retail packages of raw chicken and "fast food" chicken sandwiches and nuggets. The results suggest that the use of arsenic-containing compounds in poultry feed leads to arsenic residues in chicken marketed and eaten in the United States.

51. In retail packages of raw chicken, IATP tested thighs, breasts, and livers purchased under both "conventional" and "premium" labels. IATP tested chicken from five of the top twenty-five broiler producers nationally, several premium brands, and one kosher/halal brand. Test results revealed detectable levels of arsenic in the majority—fifty-five percent—of supermarket chicken.

52. Plaintiff IATP also tested ninety samples of cooked "fast food" chicken. The tests revealed detectable levels of total arsenic in 100 percent of the samples tested.

53. A study released on May 10, 2013, by researchers at the Johns Hopkins Center for a Livable Future at the Bloomberg School of Public Health (the 2013 Study) confirms that arsenic-containing compounds and inorganic arsenic are present in both raw and cooked chicken breast.[8] The 2013 Study tested for arsenic in retail chicken breast samples purchased between December 2010 and June 2011. In retail packages of raw chicken, the study tested breasts sold under conventional, organic, and conventional "antibiotic-free" labels. The test included sixty

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[7] USDA, FSIS, United States National Residue Program 2009 Residue Sample Results (May 2011), *available at* http://www.fsis.usda.gov/PDF/2009_Red_Book.pdf.

[8] Keeve E. Nachman, et al., *Roxarsone, Inorganic Arsenic, and Other Arsenic Species in Chicken: A U.S.-Based Market Basket Sample*, Envtl. Health Persp. (2013), *available at* http://ehp.niehs.nih.gov/wp-content/uploads/121/5/ehp.1206245.pdf.

unique chicken brands acquired from eighty-two stores (forty-seven supermarket chains).

54. The 2013 Study revealed that Roxarsone was present at detectable levels in twenty out of forty conventional chicken meat samples, yet only one of thirteen conventional "antibiotic-free" samples, and none of twenty-five organic samples. Conventional samples had higher inorganic arsenic concentrations than the conventional "antibiotic-free" and organic samples; in the meat with detectable Roxarsone levels, levels of inorganic arsenic were four times higher than the levels in organic samples.

55. The 2013 Study showed that when Roxarsone was present in raw meat, cooking decreased the levels of Roxarsone and increased the levels of inorganic arsenic. Total arsenic and inorganic arsenic concentrations were significantly higher in cooked meat samples than raw meat samples.

56. These results of the 2013 Study strongly suggest that the use of arsenic-containing compounds in poultry feed contributes to dietary inorganic arsenic exposure in consumers of conventionally-produced chickens.

The Health Effects of Arsenic

57. Inorganic arsenic is a known cause of human cancer. The association between inorganic arsenic and cancer is well documented. As early as 1879, high rates of lung cancer in Saxony miners were attributed in part to inhaled arsenic. By 1992, the combination of evidence from Taiwan and elsewhere was sufficient to conclude that ingested inorganic arsenic, such as is found in contaminated drinking water and food, was likely to increase the incidence of several internal cancers. The scientific link to skin and lung cancers is particularly strong and longstanding,[9] and evidence supports conclusions that arsenic may cause liver, bladder, kidney, and colon cancers as well. Under the law, FDA is restricted from approving substances (including animal drugs) found to induce cancer. 21 U.S.C. § 360b(d)(1)(I). The 2013 Study

[9] *See, e.g.*, Int'l Agency for Research on Cancer, World Health Organization, *Some Metals and Metalloid Compounds: Summary of Data Reported and Evaluation*, 23 IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 39 (1980), *available at* http://monographs.iarc.fr/ENG/Monographs/vol23/volume23.pdf.

provides "strong evidence" that arsenic use in poultry production results in increased inorganic arsenic concentrations in chicken meat.

58. At one time, organic arsenic was considered less toxic than inorganic arsenic, carrying fewer health concerns. Recent science reveals, however, that organic and inorganic forms of arsenic can convert to one another in the body and in the environment. Organic arsenic can convert to inorganic arsenic once ingested by humans and animals. Environmental bacteria, including those residing in chicken litter, as well as in the bacterial microflora of the human or chicken gut, convert organic arsenic into inorganic forms, such as arsenate, As(V), and arsenite, As(III), which are classified as human carcinogens and are therefore potentially more toxic than the parent compound.[10] Further, some organic forms of arsenic created by the body's metabolism appear to be more toxic than inorganic arsenic.

59. A variety of studies in cells demonstrate that exposure to infinitesimally small (nanomolar to low micromolar) concentrations of arsenite stimulates a process of new blood vessel formation called angiogenesis, associated with vascular disease as well as the growth of new tumors.[11] In addition to enhancing tumor growth, increased angiogenesis would contribute to overall growth potential and increased tissue pigmentation—exactly the attributes sought in arsenic-containing compounds' use as a poultry feed additive. Despite arsenic's direct links to cancer, and its use over seventy years in animal agriculture, the effects of arsenic-containing compounds on mammalian cells have not been greatly studied. In one exception, human cells from vascular and lung tissue were studied following exposure to the arsenic-containing

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[10] A.J. Bednar et al., *Photodegradation of Roxarsone in Poultry Litter Leachates*, 302 Sci. Total Env't 237, 237-245 (2002); J.R. Garbarino et al., *Environmental fate of roxarsone in poultry litter. I. Degradation of roxarsone during composting*, 37 Envtl. Sci. & Tech. 1509, 1509-14 (2003); John F. Stolz et al., *Biotransformation of 3-Nitro-4-Hydroxybenzene Arsonic Acid and Release of Inorganic Arsenic by* Clostridium *Species*, 41 Envtl. Sci. & Tech. 818, 818-23 (2007).

[11] Chandrashekhar D. Kamat et al., *Role of HIF Signaling on Tumorigenesis in Response to Chronic Low-dose Arsenic Administration*, 86 Toxicological Sci. 248, 248–57 (2005); Bing Liu et al., *Opposing Effects of Arsenic Trioxide on Hepatocellular Carcinomas in Mice*, 97 Cancer Sci. 675, 675-81 (2006); Nicole V. Soucy et al., *Arsenic Stimulates Angiogenesis and Tumorigenesis in Vivo*, 76 Toxicological Sci. 271, 271–79 (2003); Nicole V. Soucy et al., *Neovascularization and Angiogenic Gene Expression Following Chronic Arsenic Exposure in Mice*, 5 Cardiovascular Toxicology 29, 29-41 (2005).

compound Roxarsone.[12] The study found that like arsenite, As(III), Roxarsone induces an increase in angiogenesis, but it does so more potently. Moreover, Roxarsone acts via a mechanism that is distinct from and independent of the one induced by As(III). In other words, Roxarsone use and exposure could potentially promote angiogenesis—a key element of cancer tumor growth—via two independent processes, one via conversion to As(III), and another via a more direct mechanism.

60. The United States population is regularly exposed to a cumulative burden of arsenic. For example, drinking water is a major source of arsenic exposure.[13] EPA thus sets an enforceable regulation for arsenic, called a maximum contaminant level (MCL). Recognizing the health problems of arsenic in drinking water, EPA in 2001 lowered the MCL from fifty parts per billion (ppb) to ten ppb. The National Academies of Science estimate that Americans who drink water contaminated with arsenic at the ten ppb level—numbering thirteen million in 2001—have a greater than 1-in-300 risk of developing cancer during their lifetime.

61. While EPA has set an MCL for arsenic in water, there is no similar maximum exposure level for apple juice, which is also known to contain high levels of arsenic. In response to studies showing that apple juice regularly contains high levels of arsenic, and in an effort to limit arsenic in apple juice, in 2012 United States Representatives Frank Pallone and Rosa DeLauro introduced H.R. 3984, the "Arsenic Prevention and Protection from Lead Exposure in Juice Act of 2012," otherwise known as the "APPLE Juice Act of 2012." The legislation would require FDA to establish arsenic and lead standards for fruit juices within two years.[14]

62. Arsenic is also pervasive in food. Arsenic is most commonly found in rice, seaweed, seafood, infant formulas containing brown rice syrup, and of course, meat. In 2011, tests performed by Dartmouth College's Children's Environmental Health and Disease

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[12] Partha Basu et al., *Angiogenic Potential of 3-Nitro-4-Hydroxy Benzene Arsonic Acid (Roxarsone)*, 116 Envtl. Health Persp. 520, 520-23 (2008).

[13] *See* Press Release, U.S. Food and Drug Admin., FDA Warns Again About Arsenic in Mineral Water (Mar. 24, 2007), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108875.htm.

[14] *See* H.R. 3984, 112th Cong. (2012).

Prevention Center indicated that consuming slightly more than half a cup of cooked rice per day resulted in total urinary arsenic concentrations nearly equal to consuming a liter of water containing the maximum amount of arsenic allowable in public drinking water. Notably, American-grown rice contains 1.4 to 5 times more arsenic on average than rice from Europe, India, and Bangladesh.

63. The several million Americans who currently drink water contaminated at the ten ppb EPA standard, and/or eat certain foods with a high level of arsenic, are at an increased cancer risk from their additional arsenic exposure from meat produced with arsenic-based feed additives.

64. In 2010, the European Food Safety Authority (EFSA) issued warnings to consumers about the risks of inorganic arsenic in food.[15] Based on new science on the health risks of arsenic exposure in food, the EFSA panel on contaminants in the food chain (CONTAM) recommended that consumers reduce dietary exposure to inorganic arsenic. CONTAM found that consumers of large amounts of rice, such as certain ethnic groups, and consumers of algae-based products are especially at risk of increased arsenic exposure.

65. Arsenic is not poisonous to everyone to the same degree. Children, infants, and the human fetus are among those most vulnerable to arsenic's toxic effects. This is due to differences in arsenic metabolism between an adult and those very early in life. Moreover, arsenic and its organic metabolites easily pass through the placenta.[16] Carcinogens like arsenic are generally more potent in their early life exposures. Following its review of twenty-three peer-reviewed studies of cancer incidence over the past fifty years, EPA concluded that infants up to age two are, on average, ten times more vulnerable to carcinogenic chemicals than adults, and for some cancer-causing agents are up to sixty-five times more vulnerable; children ages two

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[15] European Food Safety Auth. Panel on Contaminants in the Food Chain, European Food Safety Auth. (EFSA), *Scientific Opinion on Arsenic in Food*, 7 EFSA Journal 1351 (2009), *available at* http://www.efsa.europa.eu/en/efsajournal/doc/1351.pdf.

[16] Subcomm. to Update the 1999 Arsenic in Drinking Water Report et al., Nat'l Research Council, *Arsenic in Drinking Water: 2001 Update* (National Academy Press 2001), *available at* http://www.nap.edu/catalog.php?record_id=10194; M. Nathaniel Mead, *Arsenic: In Search of an Antidote to a Global Poison,* 113 Envtl. Health Persp. A378, A378-86 (2005).

to five are three times more vulnerable to carcinogens than adults.[17]

66. An increased risk of cancer is not the only adverse impact of arsenic. Arsenic affects nearly all organ systems because it targets ubiquitous enzyme reactions in cells.[18] Studies of in utero exposure to arsenic indicate that early life exposures to compounds can alter susceptibility of endocrine and reproductive organs. Long-term exposure to arsenic can also cause hyperpigmented skin, skin nodules, vessel disease, and appears to heighten the risk of death from high blood pressure and heart disease. Humans repeatedly exposed to arsenic also have an increased risk of diabetes.[19]

67. Scientists continue to discover new and increasingly dangerous health impacts not previously considered from arsenic exposure. Identification of many of these factors post-date FDA's approval of arsenicals as new animal drugs. For example, evidence now indicates that arsenic is a potent disruptor of hormone function, altering the way in which hormones transmit information between cells at extremely low levels of exposure.[20] Recently, a delayed response in developing immunity to the H1N1 virus was attributed to arsenic exposure in drinking water.[21]

68. The United States population's meat consumption is at a record high. With this increased consumption comes an increased exposure to arsenic. Chicken, pork, and turkey represent the first, third, and fourth most heavily-consumed foods in the United States. Chicken

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[17] Risk Assessment Forum Technical Panel, U.S. Envtl. Prot. Agency, *Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens*, EPA/630/R-03/003F (Mar. 2005), *available at* http://www.epa.gov/ttnatw01/childrens_supplement_final.pdf.

[18] Subcomm. on Arsenic in Drinking Water et al., Nat'l Research Council, *Arsenic in Drinking Water* (National Academy Press 1999), *available at* http://www.nap.edu/catalog.php?record_id=6444; Subcomm. to Update the 1999 Arsenic in Drinking Water Report et al., *supra* note 16.

[19] Subcomm. on Arsenic in Drinking Water et al., *supra* note 18; Subcomm. to Update the 1999 Arsenic in Drinking Water Report et al., *supra* note 16.

[20] M. Nathaniel Mead, *supra* note 16; Ronald C. Kaltreider et al., *Arsenic Alters the Function of the Glucocorticoid Receptor as a Transcription Factor*, 109 Envtl. Health Persp. 245, 245-51 (2001); Jack E. Bodwell et al., *Arsenic at Very Low Concentrations Alters Glucocorticoid Receptor (GR)-Mediated Gene Activation but not GR-Mediated Gene Repression: Complex Dose-Response Effects Are Closely Correlated with Levels of Activated GR and Require a Functional GR DNA Binding Domain*, 17 Chem. Research in Toxicology 1064 (2004).

[21] Courtney D. Kozul et al., *Low-dose Arsenic Compromises the Immune Response to Influenza A Infection in Vivo*, 117 Envtl. Health Persp. 1441, 1441-47 (2009).

represents an increased risk from meat due to the sheer volume of consumption. From 1966 to 2000, annual chicken consumption rose 253 percent, from 32.1 to 81.2 pounds per person.[22] Many people are not average, however. USDA data indicate that African Americans eat about twenty percent more chicken than does the United States population as a whole. Similarly, due to their small size, toddlers eating chicken baby food may ingest chicken at substantially higher-than-average levels, on a weight-adjusted basis. For these subgroups, arsenic ingestion from contaminated chicken may be substantially higher than average. One in 100 Americans now eats more than three-quarters of a pound (>350 grams) of chicken per day. This person could be expected to ingest 32.5 to 47.07 micrograms of total arsenic per day from chicken alone. One in 1000 Americans eats at least one and one-third pounds of chicken per day. For an average-sized person, this could translate into 56.8 to 82.3 micrograms of total arsenic per day, more arsenic than the average American is estimated to receive from *all* dietary sources.[23]

69. The 2013 Study found, based on the test results discussed *supra* and EPA's proposed cancer slope factor for inorganic arsenic, that conventional chicken consumers' average daily exposure to arsenic would result in approximately 3.7 additional cases of bladder and/or lung cancer per 100,000 persons with lifetime exposure. When applied to the United States population in 2011, the 2013 Study suggests that industry-wide use of arsenical drugs will result in 8,661 additional cases of cancer over seventy years, or an average of 124 additional cancers per year. This does not account for consumers with higher than average rates of chicken consumption.

Arsenic and the Environment

70. Agency-approved arsenicals used in poultry production likely have indirect human and environmental impacts beyond the direct effects of ingesting arsenic residues in meat.

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[22] David A. Taylor, *Funky Chicken: Consumers Exposed to Arsenic in Poultry*, 112 Envtl. Health Persp. A50, A50-51 (2004) (reviewing Tamar Lasky et al., *Mean Total Arsenic Concentrations in Chicken 1989-2000 and Estimated Exposures for Consumers of Chicken*, 112 Envtl. Health Persp. 18, 18-21 (2004)).

[23] Tamar Lasky et al., *Mean Total Arsenic Concentrations in Chicken 1989-2000 and Estimated Exposures for Consumers of Chicken*, 112 Envtl. Heath Persp. 18, 18-21 (2004).

The 8.5 billion broiler chickens raised in the United States each year generate twenty-five to fifty-five billion pounds of poultry litter or waste.[24] For example, of the approximately 1.5 million pounds of arsenic-containing compounds fed to animals in 2010—mostly chickens—up to an estimated three-quarters passed unchanged into poultry waste.

71. Poultry litter disposal occurs in several different ways. Around ninety percent is applied to nearby fields and cropland as "fertilizer," which, according to various estimates, may disperse 0.5 to 2.6 million pounds of arsenic-based compounds and their degradation products into the environment annually.[25] Poultry litter containing arsenic is also then fed to beef cattle. In January 2004, FDA proposed banning the practice;[26] however, the agency reversed course in October 2005 and decided to continue allowing it. Poultry litter is also converted into fertilizer pellets to be sold for commercial use on crops, for home landscaping, gardening, and on golf courses. This practice opens up entirely new avenues of the public's exposure to arsenic. Arsenic levels in these pellets are reportedly similar to those found in unprocessed poultry waste.[27]

72. Poultry waste can also contaminate peoples' homes. For example, in the chicken-producing town of Prairie Grove, Missouri, house dust in each of thirty-one homes examined was found to contain at least two kinds of arsenic also found in chicken litter.

73. The rising volume of poultry waste, as well as its geographic concentration, means that larger broiler chicken and other poultry production facilities now generate far more

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[24] Keeve E. Nachman et al., *Arsenic: A Roadblock to Potential Animal Waste Management Solutions*, 113 Envtl. Health Persp. 1123, 1123-24 (2005).

[25] Miguel L. Cabrera & J. Thomas Sims, *Beneficial Use of Poultry By-Products: Challenges and Opportunities, in Land Application of Agricultural, Industrial, and Municipal By-Products* (James F. Power & Warren A. Dick eds., Soil Science Society of America 2000) (2000); D.W. Rutherford et al., *Environmental Fate of Roxarsone in Poultry Litter. Part II. Mobility of Arsenic in Soils Amended with Poultry Litter*, 37 Envtl. Sci. & Tech. 1515, 1515-20 (2003); R.L. Wershaw et al., *Roxarsone in Natural Water Systems*, http://water.usgs.gov/owq/AFO/proceedings/afo/pdf/Wershaw.pdf.

[26] *See* Press Release, U.S. Food & Drug Admin., Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission (Jan. 26, 2004), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108230.htm.

[27] Keeve E. Nachman et al., *supra* note 24.

waste than can easily be disposed of through land application. In late 2002, Minnesota permitted the first incinerator in the United States for the purpose of burning poultry litter for electricity generation.[28] This questionable practice will contribute to air pollution from toxics and heavy metals such as arsenic contained in the waste. Neither pelletization nor incineration can destroy or detoxify arsenic; both would further disperse it into the human environment.[29]

74. Because arsenic is an element, it neither degrades nor disappears. Therefore, the disposal of arsenic compounds only redistributes arsenic in a different form that can lead to soil and water contamination. It is estimated that seventy to ninety percent of arsenic in poultry litter becomes water soluble, meaning it can readily migrate through soils and into underlying groundwater. Airborne drift of poultry litter dust also contaminates groundwater and indirectly exposes neighbors, farmers, and farmworkers to arsenic.[30] Routine arsenic use in animal feed likely adds to the already significant public health burden from arsenic-contaminated drinking water supplies.

FDA and Plaintiffs' 2009 Petition

75. Defendant FDA has a duty to withdraw approvals of new animal drugs that are no longer considered safe. Studies published during the last fifteen years considering the impacts of arsenic-containing feed additives that were approved decades ago indicate that these compounds are no longer safe for use in food animal production. Despite this new evidence, the agency has not addressed the risks to animal health, human health, and the environment, as it is required to pursuant to the FFDCA.

76. On December 8, 2009, Petitioners submitted a Citizen Petition for rulemaking pursuant to 21 C.F.R §§ 10.25(a), 10.30. The 2009 Petition documented the then-existing body of scientific evidence studying arsenic's use as a feed additive, and the risks stemming from this

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[28] Minn. Pollution Control Agency, Fibrominn LLC Air Emission Permit 15100038-001 (Oct. 23, 2002), *available at* http://www.pca.state.mn.us/index.php/view-document.html?gid=10864.

[29] Keeve E. Nachman et al., *supra* note 24.

[30] B.P. Jackson et al., *Trace Element Speciation in Poultry Litter*, 32 J. Envtl. Quality 535, 535-40 (2003); J.R. Garbarino et al., *supra* note 10.

unsafe practice. Additionally, Petitioners have supplemented the docket with the growing body of new evidence further demonstrating the risks.

77. The 2009 Petition requested, pursuant to the U.S. Constitution, the APA, and FDA regulations, that the Commissioner do the following:

(i) Immediately suspend approval of all NADAs for arsenic-containing compounds used as feed additives for food animals.

(ii) Publish a Notice of Opportunity for an Evidentiary Hearing concerning "new evidence" related to the applications.

(iii) Upon completion of the hearing, issue an order withdrawing approval of all NADAs for arsenic-containing compounds used as feed additives for animals.

(iv) Revoke all regulations associated with approval of all NADAs for arsenic-containing compounds used as feed additives for food animals, including regulations 21 C.F.R. §§ 558.62, 558.120, 558.369, 558.530.

78. Since the filing of the 2009 Petition, several additional events have occurred that demonstrate not only increased urgency, but a straightforward path that FDA can take to immediately withdraw FDA approval of arsenic-containing compounds. Despite these events, FDA has not advanced its response to the 2009 Petition.

79. In February 2011, FDA completed a final report on a study that concluded (like much of the existing scientific literature) that organic arsenic could transform into the toxic carcinogen inorganic arsenic, and that levels of inorganic arsenic in chicken livers were substantially higher for chickens treated with the arsenical Roxarsone than for chickens not treated with Roxarsone.[31] As the 2009 Petition described, evidence indicates that human intestinal bacteria can convert organic arsenic to inorganic arsenic, demonstrating an immediate human health risk. FDA's study did not address other arsenic-containing compounds referenced in the 2009 Petition nor did it evaluate muscle tissue consumed by humans more frequently than chicken livers; more than two years later, FDA has yet to take these steps.

[31] U.S. Food and Drug Admin., Final Report on Study 275.30, *supra* note 1.

80. In June 2011, Alpharma (a division of Pfizer) announced it would voluntarily suspend—not revoke—sale of Roxarsone within thirty days following the release of FDA's study.[32] At that time, FDA commented that Roxarsone raised concerns of "completely avoidable exposure to a carcinogen."[33] A voluntary withdrawal of Roxarsone by one manufacturer is not enough to protect human health and the environment, and does not meet FDA's duties under the APA and FFDCA. Of note, neither Alpharma nor other arsenical compound manufacturers voluntarily suspended their sales of additional arsenicals.

81. In August 2011, Plaintiff CFS wrote to FDA, informing the agency that Plaintiffs had not received a status report on the 2009 Petition despite FDA's study and that FDA had not suspended arsenic-containing compounds pending investigation, nor scheduled an evidentiary hearing, pursuant to 21 U.S.C. § 360b(e)(1). Plaintiff CFS informed FDA that should it not prioritize the inquiry, Petitioners would seek redress in court.[34] FDA did not respond.

82. In May 2012 Maryland's Governor signed H.B. 167, a bill banning the use, sale, or distribution of Roxarsone or any other feed additive that contains arsenic or histostat.[35] There are other arsenical compounds that H.B. 167 does not address. Even in light of Maryland's proactive legislation, FDA still failed to respond to the 2009 Petition.

FDA's Failure to Respond to Plaintiffs' 2009 Petition

83. On June 3, 2010, FDA provided an Interim Response in accordance with 21 C.F.R. § 10.30(e)(2), fulfilling the requirement to provide a response within 180 days. The Interim Response stated that FDA was unable to reach a decision on the 2009 Petition "because of the complexity and the number of issues raised in [the] petition." In addition, the Interim

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[32] Press Release, U.S. Food and Drug Admin., *supra* note 2.
[33] *Id.*
[34] Letter from Petitioners to Margaret A. Hamburg, Comm'r, U.S. Food and Drug Admin., and Bernadette Dunham, Dir., Ctr. for Veterinary Med. (Aug. 9, 2011) (filed concurrently as Exhibit B).
[35] H.B. 167, 2012 Reg. Sess. (Md. 2012), *available at* http://mgaleg.maryland.gov/2012rs/bills/hb/hb0167t.pdf .

Response indicated that "FDA will issue a final response to your citizen petition after completing the analyses of all of the legal and policy issues raised in the petition."[36]

84. Since that time the agency has given no further information concerning when, or if, Petitioners may expect a response to the 2009 Petition. Forty months have passed since FDA received the 2009 Petition. To date, FDA has not directly responded to the 2009 Petition.

85. With Roxarsone currently "off the market," FDA need only permanently withdraw the NADAs for Roxarsone to make this voluntary action a permanent ban, protecting human health, environmental health, and food safety.

86. FDA has developed new testing methods to detect inorganic arsenic in chicken meat. Nevertheless, FDA has not used these methods to test for any other arsenical besides Roxarsone.

87. The burdens on human health and the environment are too great for FDA to depend on the voluntary withdrawal of one arsenical.

88. The public has filed approximately 17,500 comments in the FDA docket for Plaintiffs' 2009 Petition, the overwhelming majority calling on the agency to respond and address this pressing issue.

Harm to Plaintiffs

89. The interests of Plaintiffs are being and will be adversely affected by Defendants' continued failure to respond to or act on the 2009 Petition. In particular, Defendants' unreasonable delay in responding to the 2009 Petition injures Plaintiff organizations by, *inter alia*, abridging their procedural right to petition a federal agency for rulemaking under the APA. Defendants' unreasonable delay also directly harms Plaintiffs' goals and functions by impeding their ability as public interest, nonprofit organizations to further facilitate public involvement in governmental decision-making, and by foreclosing the statutory right that allows for public participation through petitions for rulemaking.

[36] Letter from Bernadette Dunham, Dir., Ctr. for Veterinary Med., to Petitioners (June 3, 2010) (filed concurrently as Exhibit C).

90. The interests of Plaintiffs' members are being and will be adversely affected by Defendants' continued failure to respond to the 2009 Petition. Members of Plaintiff organizations suffer procedural injury based on the agency's undue delay in responding to their 2009 Petition. Plaintiffs' members are also suffering or will suffer an ongoing threat to their health and the health of their environment so long as arsenic-containing compounds remain unaddressed by FDA.

91. The requested relief will redress this harm by forcing FDA to respond to the 2009 Petition and address these issues, resulting in either (1) a response fulfilling FDA's statutory duties, aimed at protecting the public health and the environment from the growing risks from arsenic-containing compounds; and/or (2) by providing a final agency action that Plaintiffs may challenge if Plaintiffs disagree with the agency's response, in whole or in part.

CAUSE OF ACTION

92. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 91 *supra*.

93. The APA requires agencies to "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e); *see also id.* § 551(4) (defining "rule" as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy"). The APA's right to petition encompasses the right to petition for a new, revised, or final rule concerning FDA regulation of new animal drug approvals under its statutory purview, including but not limited to arsenical compounds for use in food-producing animals. *See id.* §§ 551-559, 701-706.

94. Upon receipt of an APA petition, the Commissioner and FDA have a duty to respond to the petitioners promptly. *See id.* § 555(e) ("Prompt notice shall be given of the denial in whole or in part of a . . . petition. . . ."). Such response must be substantive, *i.e.*, it must either grant or deny the petition. *See id.*

95. The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." *Id.* § 702. Plaintiffs and their members are adversely affected by FDA's past and continued failure to

respond to the 2009 Petition.

96. The APA states that a reviewing court "shall" interpret statutes and "compel agency action unlawfully withheld or unreasonably delayed," *id.* § 706(1), and "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.* § 706(2)(A). FDA's failure to respond to and take action on the 2009 Petition is arbitrary and capricious and constitutes unlawfully withheld and unreasonably delayed agency action. *See id.*

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

(1) Declaring that the Defendants have violated the APA by failing to respond to the 2009 Petition within a reasonable time;

(2) Declaring that the Defendants continue to be in violation of the APA by failing to respond to the 2009 Petition;

(3) Ordering the Defendants to respond to the 2009 Petition forthwith;

(4) Retaining jurisdiction in this action to ensure compliance with its decree;

(5) Awarding Plaintiffs attorney fees and all other reasonable expenses incurred in pursuit of this action; and

(6) Granting other such relief as the Court deems just and proper.

Respectfully submitted this 13th day of May, 2013.

/s/ Paige M. Tomaselli
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