

**CITIZEN PETITION BEFORE THE
UNITED STATES FOOD AND DRUG ADMINISTRATION**

CENTER FOR BIOLOGICAL DIVERSITY

1212 Broadway, Suite 800
Oakland, CA 94612,

**CENTER FOR ENVIRONMENTAL
HEALTH**

2201 Broadway, Suite 502
Oakland, CA 94612,

**FARMWORKER ASSOCIATION OF
FLORIDA**

1264 Apopka Blvd.
Apopka, FL 32730,

**JOHNS HOPKINS CENTER FOR A
LIVABLE FUTURE**

111 Market Place, Suite 840
Baltimore, MD 21202,

MIGRANT CLINICIANS NETWORK

P.O. Box 164285
Austin, TX 78716,

and

**U.S. PUBLIC INTEREST RESEARCH
GROUP**

600 Pennsylvania Ave. SE, 4th Fl.
Washington, DC 20003,

Petitioners,

Filed With:

FOOD AND DRUG ADMINISTRATION

Division of Dockets & Management
5630 Fishers Lane, rm. 1061
Rockville, MD 20852,

Docket No. _____

STEPHEN HAHN)
Commissioner)
Food and Drug Administration)
10903 New Hampshire Ave.)
Silver Spring, MD 20993,)
)
and)
)
ALEX AZAR II)
Secretary)
Department of Health and Human Services)
200 Independence Avenue SW)
Washington, DC 20201.)

PETITION SEEKING MANDATORY LABELING OF FOODS TREATED WITH MEDICALLY IMPORTANT ANTIBIOTICS

Antibiotic resistance is one of the world's greatest health threats. According to estimates released just last month by the U.S. Centers for Disease Control and Prevention ("CDC"), more than 2.8 million antibiotic-resistant infections occur in the United States each year, and more than 35,000 people die as a result.¹ Experts predict that global annual mortality from antibiotic resistant infections will climb into the millions if urgent action is not taken.²

Use of medically important antibiotics such as streptomycin and oxytetracycline as pesticides on citrus and other crops will increase these health risks. Indeed, as the CDC recently concluded:

1. Resistance to the pesticides is found in bacteria causing human disease;
2. Resistance to the pesticides is often conferred by acquired resistance mechanisms that are known to be transferable from one bacterium to another;
3. Pesticides can select for resistance to related antibiotics (*i.e.*, cross-resistance); and
4. Pesticides can select for bacteria that are resistant to one or more unrelated antibiotics used to treat infections (*i.e.*, co-selection of resistance). This includes selection for *carbapenem* resistant bacteria that have been identified as an *urgent* antibiotic resistant threat, as well as methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant *Enterococcus* which have been identified as *serious* antibiotic resistant threats.³

Today there remains hope for preserving the efficacy of these vital, life-saving drugs and stopping the global spread of antibiotic resistance. But in the words of the Director of the CDC, in order to stop antibiotic resistance, it is imperative for every federal agency and industry to "[s]top referring to a coming post-antibiotic era—it's already here," and "adopt aggressive strategies that keep the germs away and infections from occurring in the first place."⁴ Because "[t]he problem will get worse if we do not act now."⁵

Therefore, pursuant to the right to petition the government as provided in the First Amendment to the United States Constitution,⁶ the Administrative Procedure Act,⁷ and the Food and Drug Administration's ("FDA") implementing regulations,⁸ the Center for Biological

¹ Center for Disease Control and Prevention (hereafter "CDC"), *Antibiotic Resistance Threats in the United States*, (2019), available at <https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf>.

² United Nations, *Agreement reached on Global Plan to Combat Antimicrobial Resistance, as General Assembly Adopts Political Declaration* (Oct. 5, 2016), available at <https://www.un.org/press/en/2016/ga11835.doc.htm>.

³ *Id.*; CDC report to EPA, *Antimicrobial Susceptibility Testing of Human Bacterial Pathogens to Antibiotics Used as Pesticides*, (May 11, 2017), available at https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/CDC-study-from-FOIA.pdf. [Emphasis added].

⁴ CDC, *supra* note 1.

⁵ *Id.*

⁶ U.S. Const. Amend. I. The right to "petition for a redress of grievances [is] among the most precious of the liberties safeguarded by the Bill of Rights." *United Mine Workers v. Ill. State Bar Assn.*, 389 U.S. 217 (1967).

⁷ The Center and its members are "interested persons" within the meaning of the APA. See 5 U.S.C. § 553(e) (granting any "interested person the right to petition for the issuance, amendment, or repeal of a rule"). Should the Services fail to respond to this petition in a timely manner, the Center may pursue relief in federal court.

⁸ 21 C.F.R. §§ 10.20, 10.30.

Diversity, Center for Environmental Health, Farmworkers Association of Florida, Johns Hopkins Center for a Livable Future, Migrant Clinicians Network, and U.S. Public Interest Research Group (“Petitioners”) respectfully request that FDA require foods treated with medically important antibiotics before harvest be labeled under the Federal Food, Drug and Cosmetic Act (“FFDCA” or “Act”) in the manner detailed below.⁹ The requested action is necessary to prevent economic fraud, protect environmental and public health, and protect consumers from being deceived by deceptive labeling practices. Based on the evidence and justification presented in this Petition, failure by FDA to take the requested actions would be arbitrary, capricious, and contrary to law.¹⁰

I. ACTION REQUESTED

Petitioners seek the following:

Issuance of new regulations under 21 C.F.R. § 101 to require labeling for all food covered by the FFDCA that has been treated with medically important antibiotics before harvest. The regulations shall include the following:

a. Definitions

1. “Antibiotics” refers to any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance that is produced by a micro-organism, synthetically or semi-synthetically and that has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.
2. “Medically Important” means any drug from a class of drug or derivative of a class of drug that is:
 - (1)(i) Made from a mold or bacterium that kills or slows the growth of other microbes, specifically bacteria; and
 - (ii) Used in human beings or intended for use in human beings to treat or prevent disease or infection; or
 - (2) Listed in:
 - (i) Appendix A of the federal Food and Drug Administration’s Guidance for Industry #152, including critically important, highly important, or important antimicrobial drugs; or

⁹ 21 U.S.C. § 301 *et seq.*

¹⁰ 5 U.S.C. § 706(2)(A).

- (ii) A subsequent guidance document created by the federal Food and Drug Administration that ranks the medical importance of antimicrobial drugs.
3. “Foods” means (1) articles used for consumption or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
 4. “Treat” means to apply a process or substance to something or give it particular characteristics. This includes any pesticide application process.
 5. “Label” means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appearing on the label shall not be considered to have been complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.
- b. Packaged, or unpackaged food shall be considered misbranded, unless its nutritional information panel indicates which ingredients have been treated with medically important antibiotics as follows:
1. An asterisk appearing after each ingredient indicating it has been treated with medically important antibiotics.
 2. Directly below the list of ingredients, in bold typeface not less than twice the size of the typeface in the ingredients list, a notice as follows:
“**Treated with Antibiotics.**”
- c. Any food treated with antibiotics shall be considered misbranded, unless it contains a label that provides notices in accordance with the following:
1. A notice as follows: “**Treated with Antibiotics.**”
 2. A notice as follows: “United States Government Notice: This Product was Treated with Medically Important Antibiotics.”
 3. The notice required in clause (1) must immediately precede the notice required in clause (2) and must be no less than twice the size of the notice required in clause (2).
 4. The notice required in clause (2) must be the same size as would apply if the notice provided nutritional information.

- d. Any food that has been treated with antibiotics shall be considered misbranded if the average consumer cannot reasonably tell that the product was treated with medically important antibiotics or contains ingredients that have been treated with medically important antibiotics.
- e. Foods that have never been treated with antibiotics may remain unlabeled or labeled as “**Antibiotics Free**”

II. PETITIONERS

A. Center for Biological Diversity

The Center for Biological Diversity is a non-profit environmental organization dedicated to the protection of native species and their habitats through science, policy, and environmental law. The Center has more than 1.6 million members and online supporters dedicated to the protection and restoration of endangered species and wild places. For nearly 30 years, the Center has worked to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of life. The Center’s Environmental Health Program and Pesticides Reduction Campaign aims to improve pesticide regulation in order to reduce the harms of pesticides to the environment as a whole, and to threatened and endangered species in particular.

The Center for Biological Diversity’s contact information is:

Center for Biological Diversity
1212 Broadway, Suite 800
Oakland, CA 94612
Tel: (510) 844-7100

B. Center for Environmental Health

The Center for Environmental Health works to protect people from toxic chemicals by working with communities, consumers, workers, governments, and the private sector to demand and support business practices that are safe for public health and the environment. One of our core values is that: consumers, workers, and communities have (1) the right to know the chemicals to which businesses expose them to, (2) the right to know the health effects of these exposures, and (3) the right to the knowledge, tools and power necessary to eliminate these exposures. We also believe the government has a responsibility to ensure these rights.

Center for Environmental Health’s contact information is:

Center for Environmental Health
2201 Broadway, Suite 502
Oakland, CA 94612
Tel: (510) 655-3900 x 308

C. Farmworkers Association of Florida

The Farmworker Association of Florida is a statewide, grassroots, community-based, non-profit, farmworker membership organization with over 10,000 Haitian, Hispanic, and African American members and five offices in the state of Florida with a 35-year history of working for social and environmental justice with farmworkers. The Farmworker Association of Florida's long-standing mission is to build power among farmworker and rural low-income communities, and to respond to and gain control over the social, political, economic, workplace, health and environmental justice issues that impact their lives. Our guiding vision is a social environment where farmworkers' contribution, dignity, and worth are acknowledged, appreciated, and respected through economic, social, and environmental justice. This vision includes farmworkers being treated as equals, and not exploited and discriminated against based on race, ethnicity, gender, or socioeconomic status.

The Farmworker Association of Florida's contact information is:

Farmworker Association of Florida
1264 Apopka Blvd.
Apopka, FL 32730
Tel: (407) 886-5151

D. Johns Hopkins Center for a Livable Future

The Johns Hopkins Center for a Livable Future was founded in 1996 to understand the relationship between food production, the environment, and public health. The Center focuses on the public health and environmental outcomes from production practices in the dominant industrial system of food production. A major focus of the Center is to develop recommendations to promote regulatory and legislative policy alternatives to solve problems created by the industrial food production system. We have worked for more than 20 years to reduce the misuse of antibiotics in the industrial food animal production system, crop production and energy production.

Johns Hopkins Center for a Livable Future's contact information is:

Johns Hopkins Center for a Livable Future
111 Market Place, Suite 840
Baltimore, MD 21202
Tel: (410) 223-1811

E. Migrant Clinicians Network

Migrant Clinicians Network is a nonprofit organization that provides support, technical assistance, and professional development to clinicians in Federally Qualified Health Centers and other health care delivery sites. Through webinars, on-the-ground trainings, resource development, and advocacy, Migrant Clinicians Network enables clinicians to provide quality health care, increased access, and reduced disparities for people who need ongoing care but are

experiencing outside forces that exacerbate their vulnerability. We also provide virtual case management, through our innovative program Health Network, directly to patients who may otherwise be lost to follow-up because of their need to move. We directly serve anyone with any ongoing health needs who, because of their vulnerabilities, may be unable to continue their needed treatment plan as a result of the choice to migrate or forced displacement. We serve farmworkers and dairy workers, temporary day laborers, short-term migrants returning for a visit to their country of origin, and refugees forced from their homes, fleeing disease, violence, climate catastrophe, or economic instability.

Migrant Clinicians Network's contact information is:

Migrant Clinicians Network
P.O. Box 164285
Austin, TX 78716
Tel: (512) 579-4538

F. U.S. Public Interest Research Group

U.S. Public Interest Research Group is a federation of independent, state-based, citizen-funded Public Interest Research Groups, and is part of the Public Interest Network, which operates and supports organizations committed to a shared vision of a better world and a strategic approach to getting things done. We speak out for a healthier, safer world in which we're freer to pursue our own individual well-being and the common good. The problems we address aren't progressive or conservative — they're just problems that our country shouldn't tolerate in an age of great abundance and technological progress. And these problems affect us all, whether we live in a blue state, red state or purple state. That's why we're working to find common ground around commonsense ideas. One of our top priorities is stopping the overuse of antibiotics.

U.S. Public Interest Research Group's contact information is:

U.S. Public Interest Research Group
600 Pennsylvania Ave. SE, 4th Fl.
Washington, DC 20003
Tel: (202) 546-9707

STATEMENT OF GROUNDS

I. INTRODUCTION

FDA has known for years about the threats antibiotic resistance poses to public health. Yet despite this, FDA's actions to date have been insufficient to reduce these threats. Indeed, despite considering antibiotic resistance a mounting public health problem of global significance,¹¹ FDA has done nothing to warn consumers about the health risks associated with purchasing food treated with antibiotics. Because purchasing, being exposed to, and eating food treated with antibiotics can increase consumer exposure to antibiotic resistant pathogens, such practices must, at a minimum, be identified and labeled to protect public health and the environment.

Specifically, CDC estimates that more than 2.8 million people in the United States are infected with antibiotic-resistant organisms each year, leading to an estimated 35,000 deaths.¹² FDA does not, however, currently require companies to disclose to consumers antibiotic use in their agricultural practices. FDA's failure to require mandatory labeling of food treated with antibiotics, such as citrus and other fruits, accepts that consumers can unknowingly purchase foods that increase their risk of encountering antibiotic residues and resistant bacteria. That outcome is dangerous and will result in consumers unknowingly increasing preventable risks to their health, and public health more generally, and, ultimately, being left in the dark regarding information that they need in order to have the choice of purchasing and eating antibiotic-free food.

Beyond the detrimental human health risks, the overuse of antibiotics has severe environmental impacts as well. Antibiotics are prevalent in U.S. waterways, affecting water quality and aquatic species. Antibiotics also have direct health effects on small mammals like chipmunks, and negatively impact insect populations. For example, studies show that antibiotics can adversely alter the bee gut microbiome, making bees more susceptible to infection and disease.¹³ Widespread antibiotic use has led to soil health degradation and modification of soil microbial communities.¹⁴ These are but a small fraction of the negative environmental effects caused by the overuse of antibiotics. Yet, because food is not being labeled, consumers are unable to make food purchasing decisions, which would avoid these environmental impacts.

FDA has the authority and duty to implement labeling regulations that would provide consumers with the information necessary to make informed decisions about whether to buy products that have been treated with antibiotics. Because product packaging is the primary

¹¹ See, U.S. Food & Drug Administration (hereafter "FDA"), *Fighting the Impact of Antibiotic Resistant Bacteria*, (April, 2013), ("The resistance of bacteria to antibiotics and similar drugs-called antimicrobials-is considered a major public health threat by the FDA") available at <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm349953.htm>.

¹² CDC, *supra* note 1.

¹³ Raymann K et. al. *Antibiotic exposure perturbs the gut microbiota and elevates mortality in honeybees*, (2017), PLOS BIOL 15(3): e2001861. doi:10.1371/journal. Pbio.2001861.

¹⁴ Cycoń M, Mroziak A and Piotrowska-Seget Z., *Antibiotics in the Soil Environment—Degradation and Their Impact on Microbial Activity and Diversity*, (2019), FRONT. MICROBIOL. 10:338, doi: 10.3389/fmicb.2019.00338.

source of information for consumers, a company's failure to reveal the uniquely material facts about antibiotic use creates consumer confusion and prevents informed purchasing choices that would likely diminish individual and public demand for harmful products. The current practice further perpetuates clear and devastating threats to public and environmental health.

The obvious solution is to require a simple disclosure through labeling of medically important antibiotic treatment, and to clarify the standard for "antibiotic free."¹⁵ The fact that producers who do not use antibiotics may voluntarily label their products as such does not solve this problem; it merely compounds consumer misinformation. Indeed, evidence illustrates that these voluntary labels are inherently confusing, and federal precedent confirms some of these labels could constitute false advertising under the Lanham Act.¹⁶

Thus, for the following reasons Petitioners ask that FDA implement the above regulations to bring clarity and guidance to consumers who want to make informed decisions about the food they are purchasing. FDA has the duty and authority to prohibit misleading labeling and must exercise that authority here. FDA must comply with the FFDCA in order to ensure that consumers are not misled about the serious health and environmental effects of food treated with antibiotics.

II. STATEMENT OF LAW

Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

Food and Drug Administration regulations, 21 C.F.R. part 101 *et seq.*

III. PROCEDURAL HISTORY AND STATEMENT OF FACTS

A. History of Antibiotic Use in Agriculture: Animal Agriculture

FDA first approved the use of antibiotics for animal agricultural production in the 1950s in order to stimulate growth and improve feed efficiency in food-producing animals, such as cattle, swine, and chickens.¹⁷ At that time, the mass administration of antibiotics at "subtherapeutic" levels began as a means to increase growth promotion and feed efficiency. However, the antibiotics were administered at doses too low to treat disease.¹⁸

Thereafter, uses of antibiotics, including medically important antibiotics, at subtherapeutic levels became a standard practice in animal agriculture, and in particular in Concentrated Animal Feeding Operations ("CAFOs"). These uses were ostensibly implemented to preemptively avoid increased rates of disease that accompany the high-density, and often

¹⁵ Although this term may not be used on product packaging, Petitioners use it herein to refer to all claims indicating that animals are raised without antibiotics.

¹⁶ *Sanderson Farms, Inc. v. Tyson Foods, Inc.*, 547 F. Supp. 2d 491 (D. Md. 2008).

¹⁷ *National Resources Defense Council v. U.S. Food & Drug Admin.*, 884 F. Supp.2d 127 (2012) at n.3.

¹⁸ *Id.* (Subtherapeutic treatment is in addition to the traditional antibiotic administration at approved doses for disease treatment considered "therapeutic uses").

unsanitary, CAFO model.¹⁹ Stress caused by confinement, the inability to express natural behaviors, and unnatural animal peer groups, present challenges to the immune systems of factory farmed animals, and agribusiness turned to subtherapeutic doses of antibiotics as a quick fix, rather than addressing the unsanitary and unnatural conditions themselves.²⁰ Additionally, some of the drugs appear to promote faster animal growth on less feed, which saves producers money and maintains efficient mass production because the animals reach slaughter weight faster.²¹

By 2009, 80% of antibiotics sold in the U.S. went to livestock, roughly 90% of which was administered at subtherapeutic levels.²² Specifically, the FDA reports that in the U.S. in 2009, just over 13 million kilograms of antibiotics were sold or distributed for use in food producing animals, compared to the estimated 3.3 million kilograms of antibiotics sold for human use that year.²³ Despite efforts by FDA to lower the amount of antibiotics entering the environment, 2018 saw a nine percent *increase* in the amount of medically important antibiotics sold and distributed for food-producing animals.²⁴

In response to widespread criticism of the use of antibiotics in animal production, FDA issued the Veterinary Feed Directive, implemented January 1, 2017.²⁵ The Directive is intended to limit (with the oversight of a veterinarian) the use of antibiotics that are medically important to humans in feed and water to therapeutic use.²⁶ While this move by FDA is important, it is an incomplete solution to the problem of antibiotic resistance by animal agriculture, and does not address other agricultural uses of antibiotics. The Directive also only focuses antibiotics which are listed as medically important for production purposes, but permits the use of older classes of antibiotics, which may still lead to resistance.²⁷ Further, the Directive contains a loophole, in that it allows antibiotic use for disease prevention—meaning that antibiotics, including medically important antibiotics, may still be widely used even in the absence of an actual disease being present in an animal.²⁸

¹⁹ Terry Shistar & Carla Curle, *Agricultural Uses of Antibiotics Escalate Bacterial Resistance*, PESTICIDES AND YOU (Winter 2016-17) available at <https://beyondpesticides.org/assets/media/documents/journal/bp-36.4-w17-Antibiotics-Cited2.pdf>.

²⁰ *Id.*

²¹ *Id.*

²² FDA, *2009 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, (2010), available at <https://www.fda.gov/downloads/forindustry/userfees/animaldruguserfeeactadufa/ucm231851.pdf>; *but see also*, FDA, *2017 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, (2018) (reporting decreases in antibiotic use thanks to new guidance and restrictions.) available at <https://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM628538.pdf>.

²³ FDA, *2009 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, (2010).

²⁴ FDA, *2018 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, (December, 2019), available at <https://www.fda.gov/media/133411/download>.

²⁵ 21 C.F.R. § 558.

²⁶ *Id.*; *see also* Terry Shistar & Carla Curle, *Agricultural Uses of Antibiotics Escalate Bacterial Resistance*, PESTICIDES AND YOU (Winter 2016-17).

²⁷ Terry Shistar *supra* note 19.

²⁸ *Id.*

B. Use of Antibiotics on Crops

Despite the deserved attention by FDA and others on abuses of antibiotics in animal agriculture, the use of antibiotics in other aspects of agriculture, and specifically on crops, has gone largely unnoticed. As with animal agriculture, the present and growing use of antibiotics, and in particular medically important antibiotics such as streptomycin and oxytetracycline, on crops is extremely concerning for public health and the environment.

The process for antibiotics to be approved for use on crops is different than in animal agriculture. When it comes to uses of antibiotics as pesticides on produce, the U.S. Environmental Protection Agency (“EPA”) approves those uses pursuant to its authority under the Federal Fungicide Insecticide and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136 *et seq.* FIFRA is the main federal law that provides for the regulation of pesticide by the federal government for distribution, sale, and use.

Antibiotics have been historically approved for use on crops in extremely limited situations. However, starting in 2016, and then again in 2017, 2018, and 2019, EPA expanded these practices by approving emergency²⁹ applications for the use of two medically important antibiotics, streptomycin and oxytetracycline, as pesticides on crops; those uses, approved under FIFRA, were predominantly for use on citrus crops. As a result of these approvals, approximately 80,000 pounds each of streptomycin and oxytetracycline have been used on plants in 2016.³⁰ These use amounts are believed to have increased significantly in the subsequent years.

This is a significant problem, because streptomycin is an antibiotic of the aminoglycoside class.³¹ The World Health Organization (“WHO”) considers aminoglycoside antibiotics to be “critically important to human medicine” because they are “the sole, or one of limited available therapies, to treat serious bacterial infections in people,” including tuberculosis.³²

Oxytetracycline is a member of the tetracycline class of antibiotics, a group of human and animal broad-spectrum antibiotics.³³ Historically, oxytetracycline has been relied upon in human and veterinary medicine to treat bacterial diseases and as an alternative antibiotic for people allergic to penicillin.³⁴ Oxytetracycline is also used as a second line of defense for bacteria that

²⁹ Section 18 of FIFRA permits EPA to “exempt any Federal or State agency from any provision of this Act if the [EPA] determines that emergency conditions exist which require such exemption.” 7 U.S.C. § 136p ; see also Center for Biological Diversity, *Poisonous Process: How the EPA’s Chronic Misuse of ‘Emergency’ Pesticide Exemptions Increases Risks to Wildlife* (2017), available at https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/Poisonous_Process.pdf.

³⁰ Donley Nathan, *The US lags behind other agricultural nations in banning harmful pesticides*, ENVIRONMENTAL HEALTH, (2019), available at <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-019-0488-0>

³¹ *Final Rule Registering streptomycin*, 82 Fed. Reg. 13759, (March 15, 2017).

³² World Health Organization [hereafter (“WHO”)], *Critically Important Antimicrobials for Human Medicine 5th Revision*, (2016) at 8, 21, available at <https://apps.who.int/iris/bitstream/handle/10665/255027/9789241512220-eng.pdf>.

³³ *Final Rule Registering oxytetracycline*, 83 Fed. Reg. 62489, (Dec. 4, 2018).

³⁴ *Id.*

pose significant health threats, such as anthrax.³⁵ The WHO considers tetracyclines to be "highly important."³⁶

In addition to the WHO's rankings, in 2003 FDA issued a guidance that included a list of antibiotics that are considered to be important to human medicine.³⁷ In that list, FDA separated antibiotics into the following three categories in accordance with their importance in human medicine: critically important, highly important, and important.³⁸ Both the tetracycline class, including oxytetracycline, and the aminoglycosides class, including streptomycin, are ranked in that list as being "highly important" to human medicine.³⁹

One of the main reasons for EPA approving these medically important antibiotics to be used on citrus crops as a pesticide is for managing Huanglongbing ("HLB") disease, also referred to as citrus greening disease, and citrus canker.⁴⁰ Yet EPA, as well as experts in the field, have acknowledged that these antibiotic uses will not be effective in curing HLB, but rather will be used to control the pathogen in the hopes of reducing transmission of the disease.⁴¹ Moreover, because the pathogens causing HLB and citrus canker have not been shown to be eliminated by antibiotic treatment, one use begets another as treatment for this disease requires continued, long-term disease management.⁴² Given this lack of efficacy, EPA's approval for these medically important antibiotics for use to combat HLB disease are no silver bullet. Indeed, existing data demonstrates that long-term uses of these antibiotics may be required, and are expected, which, if realized, can be expected to exacerbate antibiotic resistance concerns.⁴³

Despite that EPA's continuing registrations of oxytetracycline and streptomycin as pesticides is dangerously ineffective, adds to the already pervasive use of antibiotics in our food supply and natural environment, and has faced significant opposition,⁴⁴ the agency is expected to continue approving these medically important antibiotics for such uses. For example, following the emergency approvals of oxytetracycline and streptomycin, in December 2018 the EPA approved the registration of oxytetracycline for use on citrus crops, and has proposed to do the same with streptomycin.⁴⁵

³⁵ *Id.*

³⁶ World Health Organization [hereafter ("WHO")], *Critically Important Antimicrobials for Human Medicine 5th Revision*, (2016) at 8, 21, available at <https://apps.who.int/iris/bitstream/handle/10665/255027/9789241512220-eng.pdf>.

³⁷ FDA, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regards to Their Microbiological Effects on Bacterial of Human Health Concern*, Guidance for Industry #152 (2003).

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Final Rule Registering streptomycin*, 82 Fed. Reg. 13759, (March 15, 2017).

⁴¹ *Final Rule Registering oxytetracycline*, 83 Fed. Reg. 62489, (Dec. 4, 2018).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Speier, Jackie, *Rep Speier, Sen. Warren and Colleagues Urge EPA to Reconsider Allowing Expanded Use of Antibiotics as Pesticides, Ignoring Threats to Public Health*, (August 28, 2019), available at <https://speier.house.gov/media-center/press-releases/rep-speier-sen-warren-and-colleagues-urge-epa-reconsider-allowing>

⁴⁵ *Final Rule Registering oxytetracycline*, 83 Fed. Reg. 62489, (Dec. 4, 2018).

In summation, combined with the heavy use of antibiotics in animal agriculture, the use of medically important antibiotics for agricultural pest management is dangerous to human health and can be expected to lead to antibiotic resistance. It is, therefore, up to FDA to warn consumers about the presence of antibiotic residue and resistant bacteria on their food and give consumers an option to avoid the increased health risks associated with foods treated with antibiotics.

C. Dangers of Antibiotic Resistance

The misuse of antibiotics has led to a phenomenon known as antibiotic resistance. That is, “the misuse of antibiotics creates selective evolutionary pressure that enables antibiotic resistant bacteria to increase in numbers more rapidly than antibiotic susceptible bacteria, increasing the opportunity for individuals to become infected by resistant bacteria.”⁴⁶ Once resistant bacteria are present, single resistance genes are capable of jumping among different bacteria in the same family, creating new superbugs on the spot.⁴⁷ The WHO cautions, “[t]he fact that greater quantities [of antibiotics] are used in healthy animals than in unhealthy humans is cause for *serious concern*, particularly as some of the same antibiotics are involved, and food animals have been shown to carry resistant human pathogens.”⁴⁸ Empirical studies extensively document that food animals have become “reservoirs”⁴⁹ of antibiotic-resistant pathogens – including *Salmonella*, *Campylobacter*, and *E. coli*.⁵⁰ It is likely that the increased use of antibiotics on crops will also create “reservoirs” of antibiotic resistant pathogens.

i. Dangers to Human Health from Antibiotic Resistance

The WHO has warned that we are rapidly approaching a “post-antibiotic” era in which antibiotics used to treat common infections no longer work.⁵¹ This would mean “an end to modern medicine as we know it.”⁵² However, Robert Redfield, the Director of the CDC, believes we are already in the post-antibiotic era, and we need to act now, as miracle drugs are no longer performing miracles and families are being ripped apart by a microscopic enemy.⁵³

⁴⁶ *NRDC v. U.S. FDA*, 884 F. Supp. 2d 127 (S.D.N.Y. 2012).

⁴⁷ Peter Eisler, *Drugs Can’t Stop This Killer*, USA TODAY, (Nov. 29, 2012), at 1A, available at <https://www.usatoday.com/story/news/nation/2012/11/29/bacteria-deadly-hospital-infection/1727667/>.

⁴⁸ WHO, *The Evolving Threat of Antimicrobial Resistance: Options for Action*, (2012), Ch. 4 n. 9 at 50 (emphasis added), available at https://apps.who.int/iris/bitstream/handle/10665/44812/9789241503181_eng.pdf;jsessionid=62C73C6BDA71824237BB116C3FA59AC3?sequence=1.

⁴⁹ *Id.*

⁵⁰ Government Accountability Office, *Antibiotic Resistances: Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals*, GAO-04-490 (April 2004), at 11, 17-23; FDA, 2009 *Retail Meat Report, National Antimicrobial Resistance Monitoring System*, (2009), available at <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM257587.pdf>.

⁵¹ WHO, *Antibiotics Resistance Fact Sheet*, available at <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>, (last visited Nov. 20, 2019).

⁵² *Id.*

⁵³ CDC, *supra* note 1.

The WHO has listed antibiotic resistance as a top ten threat to global health in 2019.⁵⁴ Dr. Margaret Chan, Director General of the WHO, has stated that if important antibiotics become useless, “things as common as strep throat or a child’s scratched knee could once again kill.”⁵⁵ The CDC estimates that, every year, antibiotic-resistant bacteria infect at least 2.8 million people in the U.S. and kill 35,000 of them.⁵⁶ This problem does not appear to be going away and in fact new resistant strains of bacteria are emerging.⁵⁷

There are approximately 48 million cases of food borne illness that occur each year in the U.S., some of which tie directly to antibiotic resistance.⁵⁸ For example, in 2011 ground turkey was linked to 136 illnesses and one death, all caused by a strain of *Salmonella* that was resistant to four different antibiotics: ampicillin, streptomycin, tetracycline and gentamicin, resulting in the recall of an estimated 36 million pounds of ground turkey.⁵⁹ In another case in 2011, ground beef sold by the Hannaford supermarket chain was linked to 19 infections and seven hospitalizations, caused by a strain of *Salmonella* resistant to multiple antibiotics, including amoxicillin/ clavulanic acid, ampicillin, ceftriaxone, cefoxitin, kanamycin, streptomycin, and sulfisoxazole.⁶⁰

Industry experts and federal officials have confirmed that manufacturers “have no new antibiotics in development that show promise” and there is little financial incentive to develop them since resistant bacteria adapt quickly to resist new drugs.⁶¹ Therefore, relying on modern medicine to catch up with evolving bacteria is not a solution. The only solution is to limit the use of antibiotics to curb the growing resistance.

ii. Increased Risk and Danger to Farmworkers

While the risk of antibiotic resistance threatens everyone, it poses an even higher risk to farmworker communities. Farmworkers have higher exposure levels to antibiotics and resistant bacteria compared to the general population, as they are the pesticide handlers, working in the citrus groves after application of streptomycin and other pesticides/antibiotics. Because of their higher health risks, farmworkers are vulnerable to antibiotic resistance and need to take precautions to lower their exposure levels. One way to lower their non-occupational exposure is by avoiding food that has been treated with antibiotics. But the lack of federal regulated labels makes that difficult to almost impossible. Thus, the failure of the FDA to label food treated with antibiotics increases farmworkers’ already high health risks.

⁵⁴ WHO, *Ten Threats to Global Health in 2019*, available at <https://www.who.int/emergencies/ten-threats-to-global-health-in-2019>, (last visited Nov. 20, 2019).

⁵⁵ Undurraga Dawn, *Supermarket Meat Still Superbugged*, *Federal Data Show*, ENVIRONMENTAL WORKING GROUP, (June 28, 2018), available at <http://www.ewg.org/meateatersguide/superbugs/>.

⁵⁶ CDC, *supra* note. 1.

⁵⁷ *Id.*

⁵⁸ Consumer Reports, *The Overuse of Antibiotics in Food Animals Threatens Public Health*, CONSUMERSUNION, (Nov. 9, 2012), available at https://advocacy.consumerreports.org/wpcontent/uploads/2013/02/Overuse_of_Antibiotics_On_Farms.pdf.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Drugs Can’t Stop This Killer*, USA TODAY, (Nov. 29, 2012), at 1A.

These risks are compounded by the fact that farmworkers often do not have health insurance and may have limited access to health care, making them particularly vulnerable to environmental and occupational health hazards.⁶² In fact, 71% of workers reported that their employer did not provide health insurance or pay for medical treatment for injuries or illnesses suffered outside of work.⁶³ Only around 18% of agricultural employers offer health insurance to their workers.⁶⁴

Executive Order 12,898 directs federal agencies to “achieve environmental justice by identifying and addressing . . . [the] disproportionately high and adverse human health or environmental effects of [their] programs, policies, and activities on minority populations and low-income populations.”⁶⁵ FDA has committed to incorporating environmental justice into its policies, programs, and rulemaking. However, EPA’s proposal to approve streptomycin and oxytetracycline failed to adequately discuss the increased risks to farmworker communities.⁶⁶ Thus, it is up to FDA to at the very least label food treated with antibiotics so that farmworkers, who are already at higher risks of acquiring antibiotic resistant infections, can make informed food purchasing decisions to lower their risk of harm.

EPA’s risk assessment for streptomycin found margins of exposure (“MOE”) that are not of concern when label-required personal protective equipment (PPE; use of a dust/mist respirator) is used.⁶⁷ The problem with the EPA’s risk assessment, however, is that it assumes pesticide handlers will be wearing the label-specified PPE, which includes wearing long sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, and a dust/mist respirator.⁶⁸ In practice, the available evidence demonstrates that pesticide handlers frequently do not and cannot use PPE, often for reasons beyond their control. Analogously, in a study of 220 randomly selected dairy farmers interviewed after pesticide application, less than 15% complied with the gear use requirements and, for three pesticides applied, the percentages of farmers using none of the required gear were 56.9%, 38.6%, and 47.5%.⁶⁹ A survey of grain farm operators in central Ohio, found that more than 40% saw no need for PPE during pesticide application operations.⁷⁰ Similarly, in Minnesota, 44% of farm operators did not wear chemically resistant gloves, and 78% did not wear other protective gear, at least three quarters of the time when handling pesticides.⁷¹

⁶² U.S. Dept. of Labor, *Findings from the National Agricultural Workers Survey (NAWS) 2015-2016*, at 41 (Jan. 2018), available at https://wdr.doleta.gov/research/FullText_Documents/ETAOP_2019-01_NAWS_Research_Report_13.pdf.

⁶³ *Id.* at 25.

⁶⁴ *Id.* at 25.

⁶⁵ Exec. Order No. 12,898; *Federal Actions to Address environmental Justice in Minority Populations and Low-Income Populations*, 59 Fed. Reg. 7,629 (Feb. 11, 1994).

⁶⁶ See Earthjustice’s, Comments Opposing EPA’s Proposed Registration Decision for the New Use of Active Ingredient Streptomycin, Docket # EPA-HQ-OPP-2016-0067; EPA Reg. No. 71185-4, 80990-3, 80990-4.

⁶⁷ EPA, *Risk Assessment* at 26, Dkt. EPA-HQP-OPP-2016-0067-0020.

⁶⁸ *Id.*

⁶⁹ Melissa J. Perry et. al., *Compliance with Required Pesticide-Specific Protective Equipment Use*, 41 AM. J. INDUS. MED. 70, 70-71 (Jan. 2002).

⁷⁰ David H. Pedersen et al., *Agricultural Hazard Data from a Population-Based Survey of Cash Grain Farms: Ohio Observations*, 14 APPLIED OCCUPATIONAL & ENVTL. HYGIENE 299, 304 (1999).

⁷¹ Jeffrey H. Mandel et al, *Factors Associated with Safe Use of Agricultural Pesticides in Minnesota*, 12 J. RURAL ENVTL. HEALTH 301, 303 (1996).

Further, EPA's risk assessment fails to take into consideration certain exposures that place farmworkers and their families at even greater risks. These exposures include pesticide residues on boots, tools, work clothes, and skin of a family member who handles pesticides or works in areas where they are applied and then returns home.⁷² Exposure may also be present from soil or from pesticides drifting through the air into farmworkers' homes, schools, and playgrounds.⁷³ In the risk assessment, EPA does not assess the take-home exposures or assess the risks they pose to farmworkers and their families. EPA also fails to consider the cumulative effects of take-home exposures which can occur via food, drinking water, and residential use. It is up to FDA to act to better protect farmworkers and their families by warning them which food contains resistant bacteria so that they can make informed food choices and avoid increased health risks.

Therefore, to protect farmworkers and achieve environmental justice FDA needs to recognize the health risks antibiotics pose to farmers and address the issue by labeling food that has been treated with antibiotics. This small and simple step will go a long way and have a significant impact in better protecting minority populations from the health risks associated with antibiotic resistance.

iii. Dangers to the Environment from Antibiotics

Not only does antibiotic resistance pose a threat to human health, it also poses a serious threat to the environment. Antibiotics are prevalent in U.S. waterways, which can affect aquatic species. They also can have direct effects on small mammals and can negatively impact insect populations like bees.⁷⁴ Eighty percent of antibiotics sold in the U.S. in 2010 were used for livestock.⁷⁵ Studies estimate that about seventy-five percent of antibiotics used in animals are not absorbed by the animal, but instead are passed to waste that is applied to agricultural land.⁷⁶ Following land application, antibiotics can enter water bodies.

In 2008, the Associated Press reported that pharmaceutical residues were detected in the drinking water of 24 major metropolitan areas, serving 41 million people.⁷⁷ This included antibiotics, anticonvulsants, and mood stabilizers. These results were supported by findings of a U.S. Geological Survey ("USGS") study that sampled 139 streams in 30 states and found organic wastewater contaminants and pharmaceuticals in 80% of sampled sites – including antibiotics,

⁷² Chensheng Lu et al., *Pesticide Exposure of Children in an Agricultural Community: Evidence of Household Proximity to Farmland and Take Home Exposure Pathways*, 84 ENVTL. RES. 290, 290-91 (2000).

⁷³ Nat'l Res. Council, *Pesticides in the Diets of Infants and Children*, 308-09 (1993), available at <https://www.ncbi.nlm.nih.gov/books/NBK236275/>; See e.g., Soren Thiele-Bruhn, *Pharmaceutical Antibiotic Compounds in Soils — A Review*, 166 J. PLANT NUTRI. SOIL SCI. 145 (2003) (discussing antibiotics in soil and degradation).

⁷⁴ Raymann, *supra* note 13.

⁷⁵ FDA, *supra* note 23.

⁷⁶ Terry Shistar & Carla Curle, *supra*, n. 19.

⁷⁷ Barber, L.B., et al, *Chemical loading into surface water along a hydrological, biogeochemical, and land use gradient — A holistic watershed approach*, ENVIRONMENTAL SCIENCE AND TECHNOLOGY, (2006) v. 40, no. 2, p. 475-86, available at http://toxics.usgs.gov/highlights/pharm_watershed/.

hypertensive and cholesterol-lowering drugs, antidepressants, analgesics, steroids, caffeine, and reproductive hormones.⁷⁸

Further, a USGS report found that “the most widespread potential impact of pesticides on water quality is adverse effects on aquatic life and fish eating wildlife, particularly in streams draining watersheds with substantial agricultural and urban areas.”⁷⁹ The report noted that “concentrations of pesticides were frequently greater than water-quality benchmarks for aquatic life and fish-eating wildlife.”⁸⁰ The report sampled 186 stream sites nationwide, and found that 83 percent of 30 urban streams had concentrations of at least one pesticide that exceeded one or more aquatic-life benchmarks at least one time during the year, and 42 percent of 65 mixed-land-use streams had concentrations of at least one pesticide that exceeded one or more aquatic life benchmarks at least one time during the year.⁸¹ Maximum antibiotics concentrations ranged from 12 nanograms per liter up to 1.8 micrograms per liter (parts per billion), with many sites hosting multiple antibiotics. Concentrations of just 0.5 micrograms per liter have been shown to change aquatic microbial communities.⁸² One risk of these microbial changes is that the antibiotics suppress beneficial bacteria in the water, thereby harming aquatic organisms that rely on healthy levels of “good” bacteria.

iv. Effects of Antibiotics on Small Mammals

A recent report found that harbor seals and porpoises in the Puget Sound carried antibiotic resistant bacteria and in some cases bacteria that were resistant to multiple antibiotics.⁸³ These animals function as indicator species providing insight into the overall health of other species in the Puget Sound. The report points out that antibiotics and other chemicals persistent in the waterways are the likely cause of these species developing resistant bacteria. This can be problematic when endangered species, or species in general, become injured, as antibiotics will not be able to save them.⁸⁴ The situation is worsened by the fact that EPA has refused to comply with the Endangered Species Act to ensure pesticides, including antibiotics, are not jeopardizing the continued existence of threatened and endangered species.

v. The Effects of Antibiotics on Bees

Bees are important pollinators and serve a vital role in agricultural production. Pollination is the highest agricultural contributor to yields worldwide.⁸⁵ The price tag of global crops directly relying on pollinators is estimated to be between 235 and 577 billion dollars a

⁷⁸ *Id.*

⁷⁹ Gilliom, R.J., et al, *The Quality of Our Nation's Waters Pesticides in the Nation's Streams and Ground Water*, U.S. GEOLOGICAL SURVEY CIRCULAR 1291, 1992–2001, (2007), available at <http://pubs.usgs.gov/circ/2005/1291/pdf/circ1291.pdf>.

⁸⁰ *Id.* at 8.

⁸¹ *Id.*

⁸² *Id.*

⁸³ Hannah Thomasy *Antibiotic-Resistant Bacteria Are Turning Up in Puget Sound Marine Life*, HAKIA MAGAZINE, (March 4, 2019), available at <https://www.hakaimagazine.com/news/antibiotic-resistant-bacteria-are-turning-up-in-puget-sound-marine-life/>.

⁸⁴ *Id.*

⁸⁵ Food and Agriculture Organization of the United Nations, *Why bees Matter*, (May, 20, 2018) available at <http://www.fao.org/3/i9527en/i9527en.pdf>.

year.⁸⁶ Three out of four crops across the globe depend at least in part on pollinators like bees.⁸⁷ Yet, their very existence and role in agricultural production is being threatened by the use of pesticides, particularly antibiotics.

Antibiotics like oxytetracycline and streptomycin have been found to cause detrimental alterations to the bee gut microbiota, which increases the chances of pathogen invasion.⁸⁸ Honey bee and bumble bee gut microbiota are important to the health of the bee and its defense against pathogens.⁸⁹ Normal microbiota protect against infections in both daughter and queen bees. Alteration of this microbiome (dysbiosis) is linked to infections, disease, and causes a reduction in bee fitness and health.⁹⁰

Further, studies have shown tetracycline used at below field levels results in altered bee gut microbiota that is linked to reduced fitness, decreased survival rates, and increased susceptibility to pathogens.⁹¹ Changes in microbial community structure can also alter the absorption of nutrients or secondary metabolites and inhibit the removal of toxic metabolites reducing the health and survivorship of a hive.⁹² Tetracycline exposure has been shown to result in instantaneous changes in gut microbiota for several core gut bacteria.⁹³ Tetracycline was even detected in treated hives three months after a one-time application.⁹⁴ Exposure through foraging on plants treated with antibiotics such as oxytetracycline and streptomycin poses the risk of further disrupting a bee's microbiome and health, causing the bee to be more susceptible to opportunistic pathogens. The effects of these antibiotic treatments on a plant foraged by bees can act synergistically with other factors, causing higher rates of death.⁹⁵

LEGAL ARGUMENT

I. The FFDCA Prohibits the Marketing and Sale of Misbranded Food

Public outcry about dangerous and deceptive food and medicinal products in the marketplace helped spur the passage of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ Raymann, *supra* note 13.

⁸⁹ *Id.*; Tian, B. et al., *Long-term exposure to antibiotics has caused accumulation of resistance determinants in the gut microbiota of honeybees*, MBIO, 3(6), e00377-12, (2012); Koch, H., & Schmid-Hempel, *Socially transmitted gut microbiota protect bumble bees against an intestinal parasite*, PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES, 108(48), 19288-19292, (2011); Hamdi, C. et al., *Gut microbiome dysbiosis and honeybee health*. JOURNAL OF APPLIED ENTOMOLOGY, 135(7), 524-533, (2011); Cariveau, D. P., et al., *Variation in gut microbial communities and its association with pathogen infection in wild bumble bees (Bombus)*, ISME J., 8(12), 2369-2379, (2014); Engel, P., et al., *Functional diversity within the simple gut microbiota of the honey bee*. NATIONAL ACADEMY OF SCIENCES, 109(27), 11002-11007, (2012).

⁹⁰ Tian, B. et al., *Long-term exposure to antibiotics has caused accumulation of resistance determinants in the gut microbiota of honeybees*, MBIO, 3(6), e00377-12, (2012).

⁹¹ Hamdi, C. et al., *Gut microbiome dysbiosis and honeybee health*. JOURNAL OF APPLIED ENTOMOLOGY, 135(7), 524-533, (2011).

⁹² *Id.*

⁹³ *Id.*

⁹⁴ Tian, B. et al., *Long-term exposure to antibiotics has caused accumulation of resistance determinants in the gut microbiota of honeybees*, MBIO, 3(6), e00377-12, (2012).

⁹⁵ *Id.*

301-394, in 1938. In support of Congress passing the law, FDA assembled what it deemed “The American Chamber of Horrors,” an exhibit of defective products that were killing Americans daily but were perfectly legal to exist.⁹⁶ Examples included eyelash dye that blinded people, tea containing radium and Elixir Sulfanilamide, a marketed children’s medicine that contained antifreeze. Additionally on exhibit were misleading packages that contained false bottoms, tomato paste and jams that contained no tomatoes or fruits, and wheat noodles that were wrapped in light-yellow packaging to make them appear to be egg noodles.⁹⁷ Recognizing the ongoing danger of these deceptive products to consumer health, safety, and confidence, Congress implemented the FFDCA to regulate the safety and labeling of foods, drugs, and cosmetics. The Act’s primary purpose is to protect consumers by prohibiting fraudulent and misleading labeling.⁹⁸

Articles covered under the FFDCA include a wide range of food, drugs, and other public health products. In regulating these products, the FFDCA makes it illegal to distribute a covered product in interstate commerce that is “adulterated” or “misbranded.”⁹⁹ To fulfill this important mandate, Congress granted FDA broad authority to oversee the safety of food, drugs, medical devices, and cosmetics, and to “promulgate regulations for the efficient enforcement of the Act.”¹⁰⁰ FDA’s responsibilities under the FFDCA complement the general mission of the agency, which is to promote and protect public health by ensuring the safety, efficacy, and truthful labeling of the products it regulates.¹⁰¹

Sections 403 and 201 of the Act further define the scope of the Act’s prohibitions against adulterated and misbranded products. These sections address when a food shall be deemed misbranded (and how it can be labeled to avoid that fate).¹⁰² In prohibiting misbranded foods, these sections ensure that consumers are provided with essential and accurate information in making purchasing decisions. Specifically, in section 403 the FFDCA states a “food shall be deemed to be misbranded if (1) its labeling is false or misleading *in any particular*, or (2) its advertising is false or misleading in a material respect.”¹⁰³ The statute further defines misbranding as:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, *but also the extent to which*

⁹⁶ FDA, *The American Chamber of Horrors*, available at <https://www.fda.gov/about-fda/histories-product-regulation/american-chamber-horrors> (last visited Nov. 1, 2019).

⁹⁷ *Id.*

⁹⁸ See, e.g., *United States v. Lee*, 131 F.2d 464, 466 (7th Cir. 1941) (noting Congress’s interest in promoting public health and preventing fraud); *United States v. Sullivan*, 332 U.S. 689, 696 (1948).

⁹⁹ 21 U.S.C. § 331(a) (prohibiting “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded”).

¹⁰⁰ 20 C.F.R. § 371(a); see also 21 U.S.C. § 393(a).

¹⁰¹ FDA, *What We Do*, available at <https://www.fda.gov/about-fda/what-we-do>, (last visited Nov. 20, 2019); see also 21 U.S.C. § 393(b).

¹⁰² 21 U.S.C. §§ 343, 321(n); see also 21 U.S.C. § 321(f) (defining “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article”).

¹⁰³ 21 U.S.C. § 343(a) (emphasis added).

*the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.*¹⁰⁴

At a minimum, these requirements establish that the FFDCA prohibits false or misleading labeling of foods and provides a primary test for determining whether a label is false or misleading. That test is whether the label “fails to reveal facts . . . material with respect to the consequences which may result from the use of the article,” or that are “material in light of . . . representations.”¹⁰⁵ The FFDCA requirement that FDA “shall” take “other things” into account further demonstrates that the considerations in the statute are not exhaustive, but rather that the FFDCA requires that FDA take a holistic approach when considering if a food is misbranded.

The legislative history of the FFDCA supports this broad, public safety-based interpretation. The legislative history shows that Congress intended FDA to focus on the consumer’s informational expectations as the primary focus of the agency’s determination as to whether facts were “material.” As an example, the FFDCA’s legislative history provides that the term “materiality,” as it is used in the Act, should be considered to have the same meaning as the term “false advertising” as it is used in another act passed by Congress that same year, the Wheeler-Lea Act.¹⁰⁶ (In turn, under this parallel approach, the definition of “false advertising” under the Wheeler-Lea Act is the same as the definition for “misbranded” under the FFDCA.¹⁰⁷).

While the Wheeler-Lea Act is different from the FFDCA in that it gives the Federal Communications Commission authority to prohibit false advertising (rather than misleading labeling), the goals of the two remain the same: to protect consumers against false and misleading commercial activities. Congress provided that an *intent* of an advertiser to defraud was not essential for finding an advertisement to be misleading in a material respect.¹⁰⁸ Rather, Congress provided that the burden is on the advertiser to ensure that the advertisement is not misleading.¹⁰⁹ Similarly, under the FFDCA, FDA is charged with implementing the prohibition on misbranded food ensuring misbranded food does not enter the marketplace.¹¹⁰ In that respect, it is the FDA’s duty to ensure food labels entering into the marketplace are truthful. In support for this burden placement, Congress explained that “material” should be interpreted as “broad enough to cover every form of advertisement deception over which it would be humanly practicable to exercise governmental control.”¹¹¹ Congress anticipated uncertainties in interpretation, but stated these difficulties should not prevent necessary and adequate consumer

¹⁰⁴ 21 U.S.C. § 321(n) (emphasis added).

¹⁰⁵ *Id.*

¹⁰⁶ S.5, H.R. Conf. Rep. No. 2139, 75th Cong., 3rd Sess. 3 (April 14, 1938), reprinted in FDA, *A Legislative History of the Food, Drug & Cosmetic Act*, Vol. 6 at 302 (1979); see also S.1077, H.R. Conf. Rep. No. 1774, 75th Cong. 3d Sess. § 15 (February 8, 1938).

¹⁰⁷ 21 U.S.C. § 321(n); 15 U.S.C. § 55.

¹⁰⁸ H.R. Conf. Rep. No. 1613, 75th Cong., 1st Sess. at 4 (Aug. 19, 1937).

¹⁰⁹ *Id.*

¹¹⁰ 21 U.S.C. § 321(n).

¹¹¹ H.R. Conf. Rep. No. 1613, *supra* note 108.

protection.¹¹² Thus, what is “material” under the FFDCA should be interpreted broadly and FDA, in making its interpretation, should lean on the side of protecting consumers.

As the Congressional record for the FFDCA simply states, the “purpose [of the term misbranded] is obvious.”¹¹³ This indicates the words should carry their usual and plain meaning. Webster's Dictionary defines material as “having real importance or of great consequence.”¹¹⁴ This plain meaning of material reiterates Congress’s intention that material be interpreted broadly to encompass information effecting consumers.

II. FDA’s Consistent Interpretation of Materiality Further Reinforces the Importance of Reliable Labeling to Public Health and Safety and Consumer Protection

FDA has yet to publish a formal interpretation regarding its application of “material” under the FFDCA.¹¹⁵ FDA has, however, made consistent statements regarding when a fact should be considered “material.”¹¹⁶ These statements are instructive and, as further detailed below, support FDA finding for Petitioners in this instance.

In the past the FDA has found information to be material and required additional labeling in cases where the absence of information may: (1) pose special health risks for some people;¹¹⁷ (2) mislead the consumer in light of other statements made on the label;¹¹⁸ or (3) mislead the consumer in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not.¹¹⁹

Regarding the first situation, FDA has previously required label warnings for low calorie high protein diet products.¹²⁰ FDA’s primary reasoning for requiring labeling was due to reported health risks resulting from such diets. In making this determination, FDA connected 17 deaths to the diet strategy and found the diet strategy to be a danger to human health.¹²¹ For the same reason 35,000 projected annual deaths from antibiotic resistance should trigger the FDA to act to warn consumers about the risks of exposing themselves to food products containing antibiotic resistant bacteria. The adverse health effects from drug interactions and the increases in food borne illnesses should compel FDA to pass labeling regulations. Any decision not to warn

¹¹² *Id.*

¹¹³ S.5, H.R. Conf. Rep. No. 2139, 75th Cong., 3rd Sess. 3 (April 14, 1938), reprinted in FDA, *A Legislative History of the Food, Drug & Cosmetic Act*, Vol. 6 at 302 (1979).

¹¹⁴ Material, *Merriam-Webster’s collegiate dictionary* (10th ed.) (1999).

¹¹⁵ FDA, *Voluntary labeling Indication Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants: Guidance for Industry*, (March 2019).

¹¹⁶ *Id.*

¹¹⁷ 21 C.F.R. 101.17(d).

¹¹⁸ 21 C.F.R. 101.13(j).

¹¹⁹ 21 C.F.R. 101.13(d)(1).

¹²⁰ *Food labeling; Protein Produces; Warning Labeling*, 49 Fed. Reg. 13679, (April 6, 1984).

¹²¹ *Id.*

consumers would be arbitrary and capricious and against the great weight of scientific evidence.¹²²

FDA previously held that omission of labeling is material when certain nutrient content claims are made absent quantitative nutrient information. There FDA was considering regulations on relative food labeling claims such as “low,” “free,” “reduced,” “light,” “high,” and “more.”¹²³ FDA held even though the claims “will be defined by regulation the claims may be misleading unless they are accompanied by certain material facts that are necessary if consumers are to understand the change that has been made.” FDA found in the presence of a relative claim: (1) the percent of change in the nutrient level, and (2) amounts of nutrient in the labeled food and reference food are material facts under sections 403(a) and 201(n) of the [FFDCA].” Thus, FDA found relative labeling, even if regulated, could still be misleading unless accompanied with information informing consumers about the actual nutrient information.

We urge FDA to take a similar approach to require food treated with antibiotics to be labeled. There are many relative labels on the market, some regulated, others not, which trick consumers into thinking their product does or does not have antibiotic residue and resistant bacteria on it. Some of these labels are “fresh,” “organic,”¹²⁴ “locally grown,” and “handpicked.” These labels are misleading as they have no bearing on, or information regarding, antibiotic treatment, but consumers can read them, believing they do. The presence and level of residue and resistant bacteria is a material fact and needs to be labeled to better explain other claims which are being placed on produce.

III. The Use of Medically Important Antibiotics as Pesticides on Food Crops is a Material Fact Under the FFDCA

The medical importance of antibiotics, such as streptomycin and oxytetracycline, to public health and society, as well as concerns related to adverse reactions from unexpected exposure and augmented risk of developing antibiotic resistance, demonstrate that the introduction or delivery of foods, such as citrus and pome fruits that were produced using human antibiotics, into interstate commerce, is unquestionably a fact that is material for consumers. The lack of a label for food treated with antibiotics can have devastating health consequences because it will withhold from consumers information critical to identifying and assessing potential risks that may come from food-borne exposure to these essential antibiotics and any resistance problems that they may breed. Failing to require the labeling of foods treated with antibiotics that are critically important to human medicine, therefore, will necessarily conceal facts materially consequential to the health of the consumer, thus creating a misbranded product. For these reasons, FDA must require a mandatory label to prevent misbranding of these products.

¹²² *Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms*, 56 Fed. Reg. 60421-01 at 60446, (Nov. 27, 1991).

¹²³ *Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food*, 58 Fed. Reg. 2302-01, (Jan. 6, 1993).

¹²⁴ Consumer Reports, *Organic Food Labels Don't Always Mean What You Think*, (May 2, 2014) (use of streptomycin on apples and pears is an exemption to the organic requirement).

A. Foods Treated with Medically Important Antibiotics Present a Unique Risk to Consumer Health that Requires Labeling

1. Public Health Related to Human Medicine and Antibiotic Resistance

Close to 3 million people are infected, and over 35,000 die each year in the U.S., of antibiotic-resistant infections.¹²⁵ These estimates are considered to be extremely conservative, with some infectious disease experts recently estimating an annual mortality rate is up to 7 times higher.¹²⁶ The toll on the economy each year from these deaths, plus the exorbitant expense of treating more than 2 million drug-resistant infections annually, could be up to \$55 billion.¹²⁷ Due to growing public health, resistance, and mortality concerns, the WHO warns we are rapidly approaching a “post-antibiotic” era in which antibiotics used to treat common infections will no longer work.¹²⁸ Industry experts and federal officials have confirmed that manufacturers “have no new antibiotics in development that show promise” and there is little financial incentive to develop them since resistant bacteria adapts quickly to resist new drugs.¹²⁹ This very well could lead to “an end to modern medicine as we know it.”¹³⁰ Dr. Margaret Chan, Director General of the WHO, has said that if important antibiotics become useless, “things as common as strep throat or a child’s scratched knee could once again kill.”¹³¹ Owing to this extremely unique and critical risk, the WHO has listed antibiotic resistance as a top ten threat to global health.¹³²

The key factor driving the epidemic of antibiotic resistance is the overuse and misuse of antibiotics in both human medicine and agriculture, which “creates selective evolutionary pressure that enables antibiotic resistant bacteria to increase in numbers more rapidly than antibiotic susceptible bacteria, increasing the opportunity for individuals to become infected by resistant bacteria.”¹³³ Once resistant bacteria are present, single resistance genes are capable of jumping among different bacteria in the same family, creating new superbugs on the spot. Despite the FDA considering antibiotic resistance a mounting public health problem of global significance, it has done nothing to warn consumers that their food has been processed with antibiotics that can present unique health risks.¹³⁴

¹²⁵ CDC, *supra* note 1.

¹²⁶ Jason P. Burnham, et al., *Re-estimating annual deaths due to multidrug-resistant organism infections*, 40 INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY 112–113, (2019).

¹²⁷ S. Gandra et. al, *Economic burden of antibiotic resistance; how much do we really know*, CLINICAL MICROBIOLOGY AND INFECTION Vol. 20 N. 10, (Oct. 2014), available at <https://onlinelibrary.wiley.com/doi/pdf/10.1111/1469-0691.12798>.

¹²⁸ WHO, *supra* note 51.

¹²⁹ Peter Eisler, *supra* note 47.

¹³⁰ WHO, *Antibiotic Resistance – Key Facts*, (Feb. 2018), available at <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>, (last visited Nov. 1, 2019).

¹³¹ Undurraga, *supra* note 55.

¹³² WHO, *supra* note 54.

¹³³ *Id.*

¹³⁴ FDA, *Fighting the Impact of Antibiotic Resistant Bacteria*, (April, 2013) available at <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm349953>; *See also*, *NRDC v. FDA*, 884 F. Supp. 2d 127 (2012) at 132 (“[p]eople who contract antibiotic-resistant bacterial 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.”).

Two of the more widely used antibiotics on crops, streptomycin and oxytetracycline, have been identified by the WHO as “critically important to human medicine” and “highly important” to human medicine, respectively.¹³⁵ Streptomycin is “critically important” because it is part of a class of antibiotics that are “the sole, or one of limited available therapies, to treat serious bacterial infections in people.”¹³⁶ FDA has recognized the human health importance of these antibiotics and has implemented regulations for “food-producing” animals in an effort to reduce the overuse of antibiotics. FDA needs to continue this effort by implementing labeling regulations for produce treated with antibiotics.¹³⁷

The CDC has specifically studied the use of antibiotics as pesticides and found that (1) resistance to antibiotics used as pesticides can be found in bacteria causing human disease, (2) resistance is often conferred by a mechanisms that can be transferred from one bacteria to another, (3) mechanisms of resistance to the pesticide can confer resistance to related antibiotics including antibiotics commonly used in human medicine (i.e., cross-resistance) and (4) resistance often occurs in isolates that are resistant to unrelated resistance (i.e., use of the pesticide could select for resistance to the pesticide and to unrelated antibiotics including antibiotics commonly used in human medicine).¹³⁸ FDA must heed the warnings from the CDC and the scientific community. These scientific reports demonstrate the very real health risks to consumers who are exposing themselves when purchasing products treated with antibiotics. Those treated commodities contain antibiotic residue and higher amounts of resistant bacteria, which puts consumer’s health at risk. FDA needs to take into account the human health risks described by these studies and use them to develop a label to protect consumers from the adverse health effects from produce treated with antibiotics.

2. Public Health Related to Food Safety and Antibiotic Resistance

There have been several reports of foodborne illness from consumption of citrus products involving non-typhoidal serovars of *Salmonella*.¹³⁹ This is concerning because there are multiple drug resistant forms of *Salmonella* that could be preferentially selected by any streptomycin or oxytetracycline residues. If citrus is being sprayed with streptomycin or oxytetracycline, then these drug resistant forms of *Salmonella* are going to be selected for and become more common on treated produce. This will lead to an increased exposure to consumers who unknowingly purchase and consume these fruits. Exposure to drug resistant forms of *Salmonella* will lead to adverse health problems causing serious injury or death. It will also lead to widespread recalls of all citrus products which might contain the resistant bacteria.

As discussed previously, there are approximately 48 million cases of food borne illness that occur each year in the U.S., some of which tie directly to antibiotic resistance. For example,

¹³⁵ WHO, *Critically Important Antimicrobials for Human Medicine 5th Revision* (2016) at 8, 21, available at <https://apps.who.int/iris/bitstream/handle/10665/255027/9789241512220-eng.pdf>; FDA, *supra* note 42.

¹³⁶ WHO, *Critically Important Antimicrobials for Human Medicine 5th Revision* (2016) at 8, 21.

¹³⁷ FDA, *supra* note 42.

¹³⁸ CDC report to EPA, *supra* note 3; Andrew Jacobs, *Citrus Farmers Facing Deadly Bacteria Turn to Antibiotics, Alarming health Officials*, N.Y. TIMES, (May 17, 2019), available at <https://www.nytimes.com/2019/05/17/health/antibiotics-oranges-florida.html>.

¹³⁹ Seema Jain, et al., *Multistate Outbreak of Salmonella Typhimurium and Saintpaul Infections Associated with Unpasteurized Orange Juice—United States, 2005*, *Clinical Infectious Diseases*, Volume 48, Issue 8, (April 15, 2009), Pages 1065–1071, <https://doi.org/10.1086/597397>.

in 2011, ground turkey was linked to 136 illnesses and one death, all caused by a strain of *Salmonella* that was resistant to four different antibiotics: ampicillin, streptomycin, tetracycline and gentamicin—resulting in the recall of an estimated 36 million pounds of ground turkey.¹⁴⁰ In another case in 2011, ground beef sold in Hannaford grocery stores was linked to 19 infections and seven hospitalizations, caused by a strain of *Salmonella* resistant to multiple antibiotics, including amoxicillin/ clavulanic acid, ampicillin, ceftriaxone, cefoxitin, kanamycin, streptomycin, and sulfisoxazole.¹⁴¹ These examples demonstrate the real and material health risks associated with exposure to food containing resistant bacteria and the health risks of over using antibiotics.

Further, additional scientific evidence suggests that meat from animals raised with antibiotics contains more antibiotic-resistant superbugs *in the meat itself* than meat that comes from animals that are antibiotic-free.¹⁴² One study performed by Consumer Reports found ground turkey that came from birds fed subtherapeutic levels of antibiotics was shown to contain bacteria that was more likely to resist drugs that could help cure illness than ground turkey that was antibiotic-free.¹⁴³ Another recent study found poultry which was antibiotic free was half as likely to contain resistant forms of *Salmonella*.¹⁴⁴ Thus, the two packages of meat in consumers' hands are, in fact, materially different in a way that could have devastating medical consequences to consumers. Yet consumers remain completely uninformed of this difference, because no label exists to inform them. Crops sprayed with antibiotics may also carry higher levels of residue and antibiotic resistant bacteria than produce which is not treated. Antibiotics even have the potential of seeping into the produce and being absorbed by it. Thus, when considering what food to buy there is a material difference, as the food itself is different in regards to the level of antibiotic residue and level of resistant bacteria, which poses varying and profound health risks to consumers.

3. Adverse Drug Reactions/Interactions

The presence of antibiotic residue and resistant bacteria requires labeling due to adverse drug reactions which can pose a serious health risk to consumers. Every year, there are more than 140,000 emergency department visits for reactions to antibiotics.¹⁴⁵ Almost four out of five emergency department visits for antibiotic-related adverse drug events are due to an allergic reaction.¹⁴⁶ These reactions can range from mild rashes and itching to serious blistering, swelling and respiratory problems.¹⁴⁷ Most of these reactions come from high levels of exposure to

¹⁴⁰ *Id.*

¹⁴¹ Consumer Reports, *supra* note 58.

¹⁴² Underrage, *supra* note 55; Consumer Reports, *Consumer Reports Investigation: Talking Turkey*, CONSUMER REPORTS (June 2013), available at <http://www.consumerreports.org/cro/magazine/2013/06/consumer-reports-investigation-talkingturkey/index.htm>.

¹⁴³ Consumer Reports, *Consumer Reports Investigation: Talking Turkey*, CONSUMER REPORTS (June 2013).

¹⁴⁴ Infectious Diseases Society of America, *Antibiotic-Free or Organic Poultry Half as Likely to be Contaminated with Multidrug-Resistant Salmonella*, New Research Finds, IDWEEK, (Oct. 2, 2019), available at <https://www.idsociety.org/news--publications-new/articles/2019/antibiotic-free-or-organic-poultry-half-as-likely-to-be-contaminated-with-multidrug-resistant-salmonella-new-research-finds/>.

¹⁴⁵ CDC, *Antibiotic Resistance threats in the United States, 2013*, (April 23, 2013), available at <https://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

antibiotics, however there is a lack of data on adverse reactions to lower levels that may be encountered in food. The CDC states minimizing unnecessary antibiotic use is the best way to reduce the risk of adverse drug events.¹⁴⁸ Yet, consumers have no way of knowing if antibiotic residue on their produce is potentially increasing their chances of having an allergic reaction or other adverse drug reactions.

Antibiotics can also adversely react with other drugs and natural bacteria. Antibiotics can interact with other drugs a person has taken, making those drugs more or less effective.¹⁴⁹ Some drug combinations can worsen side effects, like nausea, diarrhea, and stomach pain.¹⁵⁰ Additionally, when a person takes or is exposed to an antibiotic, good bacterium that protects against infection, are also destroyed, sometimes for up to several months. During this time people are at an increased risk of getting sick from an infection or disease. People are also at a higher risk of getting an infection from *C. difficile*, which can cause diarrhea and is responsible for at least 12,800 American deaths each year.¹⁵¹ *C. difficile* is normally prevented from spreading due to communities of microbes in the gut, but antibiotics can alter the microbiota community in such a way that *C. difficile* is able to spread, which is concerning because *C. difficile* is naturally resistant to many common antibiotics used to treat it.¹⁵²

IV. Products Treated with Medically Important Antibiotics Differ Materially from the Products they Purport to Be, Making the Products Misleading in Light of Other Representations Made

FDA has found information to be material and required additional labeling in cases where the absence of such information may mislead the consumer in light of other statements made on the label.¹⁵³ In regard to retail produce there are many claims made which can mislead consumers into thinking the food does not contain antibiotics. The FDA needs to require labeling in order to stop consumers from being misled.

As an example, a Consumer Reports study of 136 supermarkets in 23 states, found that meat producers currently use a wide array of labels to indicate their use (or lack thereof) of antibiotics, such as “never ever given antibiotics,” “humanely raised on family farms without antibiotics,” “natural,” “antibiotic-free,” “no antibiotic residues,” and “no antibiotic growth promotants.”¹⁵⁴ These labels are misleading because there is no uniform definition that has been approved for use by a federal agency. They also rely on arbitrary distinctions between which antibiotics have been used and at what stage in the food process it was used. Still, other terms like “natural” just mean no artificial flavors, but consumers can easily think the label has some bearing on whether antibiotics were used. Since there is no enforcement of antibiotic labeling companies are free to use terms as they see fit.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ 21 U.S.C. § 321(n).

¹⁵⁴ Consumer Reports, *Meat on Drugs*, CONSUMER REPORTS, (June 2012), at 3, available at <https://foodpoisoningbulletin.com/wp-content/uploads/CR-Meat-On-Drugs-Report-06-12.pdf>.

The situation does not get any better when it comes to labeling produce either. Similar labels like “natural,” “fresh,” “locally grown,” “organic,”¹⁵⁵ and “non-gmo” are all used to describe produce. But these terms have little usefulness to consumers when trying to figure out if their fruits and vegetables contain antibiotics or resistant bacteria. Further, many consumers are completely unaware that produce is being treated with antibiotics and would not expect their produce to have varying levels of resistant bacteria. A direct and clear label is needed in order to inform consumers about the presence of antibiotics in or on their produce.

V. Failing to Label Foods Treated with Medically Important Antibiotics Is Misleading to the Reasonable Consumer

FDA must endeavor to see that food products are labeled so that a consumer would know that there has been no misrepresentation as to its substance, and that the food purchased is what is purports to be.¹⁵⁶ Failure to label food treated with antibiotics critical to human health is misleading because it prevents consumers from obtaining information necessary to make an informed decision.¹⁵⁷ The below examples clearly demonstrate that a reasonable consumer would want to know about medically important antibiotic use, and, in fact, consumers have already been demanding more information.

In March 2012, Consumer Reports, conducted a survey of 1,000 U.S. consumers to explore their views on meat and poultry raised with or without antibiotics.¹⁵⁸ The vast majority of respondents were “extremely” or “very” concerned about the role of the widespread use of antibiotics in creating new superbugs and negatively impacting the environment.¹⁵⁹ Moreover, 86% believed that they should be able to buy “antibiotic-free” meat at their regular grocery stores.¹⁶⁰ Of those polled who could not purchase “antibiotic-free” meat at their regular grocery store, 82% stated that they would buy antibiotic-free meat or poultry if it was available. Further, 61% of respondents said that they would pay more for antibiotic-free meat or poultry.¹⁶¹ From this survey it is easy to infer that consumers who are demanding antibiotic free meat would also demand antibiotic free produce.

Currently consumers are forced to rely on voluntary, unverified labeling claims to determine how a producer raises animals or grows their crops. Some antibiotics can also be used while maintaining the organic label.¹⁶² Mandatory labeling would shift this balance of power back into the hands of consumers. This, in turn, will spur producers to adopt antibiotic-free production methods, thereby greatly reducing the threat of antibiotic resistance to public health.

¹⁵⁵ Consumer Reports, *supra* note 124.

¹⁵⁶ *United States v. 55 Cases Popped Corn*, 62 F. Supp. 843 (D. Idaho 1943).

¹⁵⁷ See Milton Handler, “The Control of False Advertising Under the Wheeler-Lea Act,” 6 LAW & CONTEMP. PROBS. 91, 97–98 (1939) (In interpreting the Wheeler-Lea Act language which is connected to Sec. 201(n) of the FFDCA, the language has been traced back to the 1938 Restatement of Torts § 538, which defines a fact to be material “if its existence or nonexistence is a matter to which a reasonable man would attach importance in determine his choice of action in a transaction in question.”).

¹⁵⁸ Consumer Reports, *supra* note 154.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² Consumer Reports, *supra* note 124.

In March 2019, conservation groups delivered 45,000 petition signatures to the EPA, calling on the agency to deny a proposal that would allow for expanded antibiotic spraying on citrus fields.¹⁶³ The groups are concerned about the threat of antibiotic resistance and the widespread use of medically important antibiotics. These signatures make clear that people want to stop the use of antibiotics and don't want it sprayed on their food. People do not want to be left in the dark about which produce contains different levels of resistant bacteria. They want to be made aware of these facts so they will know about potential adverse health effects and make informed purchasing decisions.

The above examples demonstrate that consumers want to exercise an important choice regarding products produced with medically important antibiotics -- a choice with massive implications for their and the public's health. However, they are prevented from doing so because the current labeling practices do not require producers to distinguish between those products produced with antibiotics and those produced without. There is no way to tell the difference. Because current labeling regulations fail to require disclosure of these material facts, and in fact mislead consumers as described, consumer choice is being frustrated.

VI. NEPA Gives the FDA Supplemental Authority to Base Substantive Decisions on Environmental Impacts

A federal court held FDA has not just the authority, but also a statutory mandate to base substantive decisions such as labeling on environmental concerns.¹⁶⁴ In *Environmental Defense Fund v. Mathews*, the plaintiffs challenged FDA's regulations implementing the National Environmental Policy Act ("NEPA"), arguing that the FDA improperly limited the scope of its obligations under the FFDCA.¹⁶⁵ FDA had amended its implementing regulations to state that NEPA did not provide the Agency with any additional authority to act apart from authority otherwise granted in authorizing statutes, such as the FFDCA.¹⁶⁶ The court disagreed, stating that "[t]his limitation of the agency's discretion to act in accordance with environmental considerations directly contravenes the mandate of NEPA"¹⁶⁷ The court then elaborated:

The FDCA does not state that the listed considerations are the only ones which the Commissioner may take into account in reaching a decision. . . . It merely lists criteria which the Commissioner must consider in reaching his decision. In the absence of a clear statutory provision excluding consideration of environmental factors, and in light of NEPA's broad mandate that all environmental considerations be taken into account, we find that NEPA provides FDA with supplementary authority to base its substantive decisions on all environmental considerations including those not expressly identified in the FDCA and FDA's other statutes.¹⁶⁸

¹⁶³ University of Minnesota, *EPA Urged to Deny Proposal for More Antibiotic Spraying on Citrus Fields*, CENTER FOR INFECTIOUS DISEASE RESEARCH AND POLICY, (March 13, 2019), available at <http://www.cidrap.umn.edu/news-perspective/2019/03/stewardship-resistance-scan-mar-13-2019>.

¹⁶⁴ 410 F. Supp. 336 (D.D.C. 1976).

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 338.

Judicial recognition of the environmental impacts of antibiotics underscores that the use of antibiotics in food production falls within the scope of these “environmental considerations” that the FDA must take into account when making its substantive decisions, including the decision whether to mandate labeling.¹⁶⁹ Specifically, the environmental considerations FDA needs to take into account are the detrimental effects the overuse of antibiotics has on water quality, soil health, and biodiversity. As discussed earlier, antibiotics can have detrimental effects on pollinators like bees, and cause hormone imbalance in amphibians.¹⁷⁰ We implore the FDA to take environmental effects of antibiotics into consideration when making its decision.

VII. International Bans Limiting the Use of Medically Important Antibiotics for Use as a Pesticide Support a Finding of Materiality

Internationally, in January 2014, the WHO recommended that the World Health Assembly (“WHA”) adopt a resolution on antibiotic resistance that urges countries to take action on the national level to combat the emergence of antibiotic resistant bacteria, and in 2015, the WHA adopted a Global Action Plan on Antimicrobial Resistance.¹⁷¹ In that Global Action Plan, the Director of the WHO was clear, “[w]ithout harmonized and immediate action on a global scale, the world is heading towards a post-antibiotic era in which common infections could once again kill.”¹⁷²

In fact, countries all over the world are taking notice of the threat of antibiotic resistance. Sally Davies, the chief medical officer of England, recently stated that antibiotic resistance poses a “catastrophic threat” to public health and the country needs to do more to combat resistance.¹⁷³ Both the European Union and Brazil have banned the use of oxytetracycline and streptomycin for use as a pesticide on agricultural plants.¹⁷⁴ A ban by the Danish government on the subtherapeutic use of antibiotics has further proven the correlation between subtherapeutic use and antibiotic resistance.¹⁷⁵ The ban of subtherapeutic antibiotic use has resulted in the reduction in antimicrobial resistance as measured among several different bacterial species in food

¹⁶⁹ *NRDC v. FDA*, 872 F.Supp.2d 318 (2012); *See also NRDC v. FDA*, 884 F. Supp. 2d 127 (2012) at 132 (“[p]eople who contract antibiotic-resistant bacterial 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.”).

¹⁷⁰ National Institute of Environmental Health Sciences, *Endocrine Disruptors*, available at <http://www.niehs.nih.gov/health/topics/agents/endocrine/>, (last visited Nov. 20, 2019).

¹⁷¹ WHO, *Global Action Plan on Antimicrobial Resistance (2015)*, available at <https://www.who.int/antimicrobial-resistance/global-action-plan/en/> (last visited Nov. 1, 2019).

¹⁷² *Id.*

¹⁷³ Kate Kelland, *Antibiotic Resistance Poses “Catastrophic Threat” to Medicine, says Britain’s Top Health Official*, HUFFINGTON POST (March 10, 2013), available at https://www.huffpost.com/entry/antibiotic-resistance-catastrophic-threat_n_2850651.

¹⁷⁴ EU Pesticides Database, available at <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>; Anvisa National Health Surveillance Agency, *Product Regulations – Pesticides*, available at <http://portal.anvisa.gov.br/registros-e-autorizacoes/agrotoxicos/produtos/monografia-de-agrotoxicos/excluidas>.

¹⁷⁵ Per Hennksen, DVM, PhD, Ministry of Food, Agriculture & Fisheries, *Danish Testimony on the July 14th Hearing about Antibiotic Resistance in the Livestock Industry*, Organized by the Subcommittee on Health (July 12, 2010).

animals.¹⁷⁶ Furthermore, the food safety of Danish products of animal origin have significantly improved as it relates to *Salmonella* and *Campylobacter* bacteria.¹⁷⁷

The fact that other countries are prohibiting spraying and use of antibiotics in agriculture demonstrates the human health risks. Further, people from other countries visiting America who expect their food not to be treated with antibiotics are left unable to decipher American food labels. Some counties are even exploring the idea of including an antibiotic footprint label tracking the amount of antibiotics used throughout the lifecycle of the animal or crop.¹⁷⁸ The FDA needs to modernize and keep up with the rest of the world or else Americans will be left suffering from antibiotic resistance.

VIII. Executive Order No. 13,676 Demands Federal Agencies Coordinate to Combat Antibiotic Resistance

Due to the gravity of antibiotic resistance concerns, former president Obama issued an Executive Order (“EO”) in September 2014 that, among other things, established an interagency Task Force for Combating Antibiotic-Resistance Bacteria, and directed that agencies - including the FDA - work together to detect, prevent, and control antibiotic resistance through strategic, coordinated, and sustained efforts. The specific goals detailed in that EO include:

minimize the emergence of antibiotic-resistant bacteria; preserve the efficacy of new and existing antibacterial drugs; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance efforts in public health and agriculture; develop and promote the use of new, rapid diagnostic technologies; accelerate scientific research and facilitate the development of new antibacterial drugs, vaccines, diagnostics, and other novel therapeutics; maximize the dissemination of the most up-to-date information on the appropriate and proper use of antibiotics to the general public and healthcare providers; work with the pharmaceutical industry to include information on the proper use of over-the-counter and prescription antibiotic medications for humans and animals; and improve international collaboration and capabilities for prevention, surveillance, stewardship, basic research, and drug and diagnostics development.¹⁷⁹

In September 2014, the President's Council of Advisors on Science and Technology released a report on antibiotic resistance that recommended strong federal coordination and oversight of efforts to combat antibiotic resistance.¹⁸⁰ Thus, FDA has a duty to label food treated with antibiotics under its duty to: (1) strengthen surveillance efforts in public health and agriculture, (2) maximize the dissemination of the most up-to-date information on the appropriate and proper use of antibiotics to the general public, (3) improve international

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ Gumphol Wongsuvan et al., *Antibiotic use in poultry: A Survey of Eight Farms in Thailand*, BULLETIN WORLD HEALTH ORGANIZATION, (Nov. 27, 2018), available at <https://www.who.int/bulletin/volumes/96/2/17-195834.pdf?ua=1>.

¹⁷⁹ Exec. Order No. 13,676, *Combating Antibiotic-Resistant Bacteria*, 79 Fed. Reg. 56,931 (Sept. 18, 2014).

¹⁸⁰ *Id.*

collaboration, and (4) minimize the emergence of antibiotic-resistant bacteria. Failure to label food treated with antibiotics would be an outright defiance of the Executive Order.¹⁸¹

IX. Consumers Have the Right to Receive Information Based on the Freedom of Speech Found in the First Amendment of the U.S. Constitution

U.S. courts have recognized a “right-to-know” rooted in the U.S. Constitution and in the common law. For example, in *American Meat Institute v. Ball*, a Michigan statute required sellers to disclose meat quality standards to their customers.¹⁸² Meatpackers challenged the statute, arguing that it was preempted by a less stringent federal labeling law.¹⁸³ The court agreed in part, but stated that:

[C]onsumers often knowingly buy items which are not the least expensive or the most nutritious. They base their purchasing decisions on many factors, but one of these should not be ignorance imposed by government and the product manufacturers. Michigan’s consumers have a right, protected by the First Amendment, to receive this relevant product information which the state seeks to disseminate to them.¹⁸⁴

The court thus recognized consumers’ right-to-know, regardless of whether that information was relevant in the judgment of regulators or producers.

Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., similarly stands for a consumer’s right-to-know.¹⁸⁵ At issue in that case was a Virginia statute that made a pharmacist guilty of unprofessional conduct if he published, advertised, or promoted any price for prescription drugs.¹⁸⁶ The U.S. Supreme Court struck down the statute, finding that just as advertisers had a First Amendment right to disseminate advertising information, consumers had a First Amendment right to receive the information.¹⁸⁷ In invalidating the statute, the court stated, “[i]t is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us.”¹⁸⁸ The court continued, “people will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication rather than to close them.”¹⁸⁹ The First Amendment thus protects consumers’ right to receive relevant product information, not just producers’ right to disseminate it.

State courts have also recognized a consumer’s common law right-to-know. For example, in *Paraco v. Dept. of Agriculture*, vendors challenged a California statute that required used motor oil that had been reprocessed to be labeled as “reclaimed.”¹⁹⁰ In upholding the

¹⁸¹ *Id.*

¹⁸² 424 F. Supp. 758 (W.D. Mich. 1976).

¹⁸³ *Id.*

¹⁸⁴ *Id.* at 769.

¹⁸⁵ 425 U.S. 748 (1976).

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 756–57.

¹⁸⁸ *Id.* at 770.

¹⁸⁹ *Id.*

¹⁹⁰ 118 Cal. App. 2d 348, 257 (Cal. 1953).

labeling requirement, the court stated that members of the public “have a right to know what they are buying. If this great buying public, consisting in this state of many millions of motorists and other users of lubricating oils, want to buy oils never before used, they have a right to do so and appellants have no constitutional right to sell them something else against their will.”¹⁹¹ In construing this common law right, the court focused on the importance of the information to consumers, not the relative performance of “reclaimed” oil compared to unused oil.

In *Ex parte Hayes*, the government prosecuted a fruit vendor for misbranding grapefruit with the word “Coachella,” falsely implying they had been grown in the Coachella Valley.¹⁹² The court rejected the defendant’s facial challenge to the statute, stating that “the matter of mislabeling is not dependent on whether the article so marked is of the same or equal quality with the article imitated. It is entirely a question of deception and the buyer has the right to know what he is purchasing.”¹⁹³ Thus, consumers’ right-to-know was not limited to information resulting in differences in quality; it encompassed the information that consumers found significant to their purchases.

Similarly, whether the FDA believes that food treated with antibiotics are “of the same or equal quality” as their conventional counterparts is irrelevant to the question of whether it is misleading. The proper focus is whether consumers are deceived, and whether their common law right-to-know is being abridged. In the case of unlabeled food sprayed with antibiotics, opinion polls overwhelmingly demonstrate that consumers find antibiotic use material when making a purchase.¹⁹⁴ Moreover, consumers do not expect food to be treated with antibiotics absent specific labeling. Consumers therefore have a right-to-know whether foods are treated with antibiotics and contain higher levels of resistant bacteria—a right that is compromised by FDA’s current policy.

X. ENVIRONMENTAL IMPACT

The specific actions requested by Petitioners are categorically excluded under 21 C.F.R. §§ 25.30(h), (k) and therefore do not require the preparation of an environmental assessment.

XI. CONCLUSION AND CERTIFICATION

Antibiotic resistance is one of the world’s greatest health threats. According to the CDC, in order to stop antibiotic resistance and save the lives of potentially millions of people, it is imperative for every federal agency and industry to “[s]top referring to a coming post-antibiotic era—it’s already here,” and “adopt aggressive strategies that keep the germs away and infections from occurring in the first place.” In accordance with the FFDCA, FDA’s governing regulations, and the APA, the mandatory labeling of foods treated with medically important antibiotics is necessary to protect public health and prevent consumer deception and fraud.

¹⁹¹ *Id.* at 353–54.

¹⁹² 134 Cal. App. 312 (Cal. 1933).

¹⁹³ *Id.* at 318 (citing *In re Bear*, 216 Cal. 536 (Cal. 1932); *U.S. v. 100 Cases of Tepee Apples*, 179 F. 985 (W.D. Mo. 1908)).

¹⁹⁴ Consumer Reports, *supra* note 154.

The undersigned certify that to their best knowledge and belief this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Respectfully Submitted,



Perry Elerts
Center for Biological Diversity
1212 Broadway, St. #800
Oakland, CA 94612
pelerts@biologicaldiversity.org
(510) 844-7100



Hannah Connor
Senior Attorney
Center for Biological Diversity
P.O. Box 2155
St. Petersburg, Florida 33731
hconnor@biologicaldiversity.org
(202) 681-1676

Jeannie Economos
Pesticide Safety and
Environmental Health Project Coordinator
Farmworker Association of Florida
1264 Apopka Blvd.
Apopka, Florida 32730
farmworkerassoc@aol.com
(407) 886-5151

Kate Kruse
Project Coordinator
Migrant Clinicians Network
P.O. Box 164285
Austin, TX 78716
kkruse@migrantclinician.org
(512) 579-4538

Matt Wellington
Director
U.S. PIRG
142 High St. Ste 624
Portland, ME 04101
mwellington@pirg.org
(845) 591-5646

Robert Martin
Director, Food System Policy
Johns Hopkins Center for a Livable Future
111 Market place, Ste. 840
Baltimore, Maryland 21202
rmarti@jhu.edu
(410) 223-1821

Caroline Cox
Senior Scientist
Center for Environmental Health
2201 Broadway #502
Oakland, CA 94612
Caroline@ceh.org
(510) 655-3900 x 308