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Via Electronic and U.S. Mail

RE: Petition No. 13-03: *Citizen's Petition Seeking Mandatory Meat and Poultry Labeling to Prevent the Sale of Misbranded Products*

Dear Administrator Almanza and Petitions Manager Porretta,

Over three years ago, on June 3, 2013, the Animal Legal Defense Fund (ALDF) submitted a petition for rulemaking to the Food Safety Inspection Service (FSIS) (petition no. 13-03), asking the agency to require mandatory labeling of meat and poultry products to disclose routine antibiotic use in meat and poultry production, and to clarify the standard for “no antibiotics”-type labeling claims.

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As detailed in the petition, mandatory labeling to disclose routine antibiotic use is necessary to combat consumer misperceptions and reform the labeling that consumers rely on when making food purchasing decisions. Current trends show increased consumer demand for products derived from animals not fed antibiotics, implicating the need for clear and truthful standards to effectively manage public health and safety concerns raised by the growing threat of antibiotic resistance.

On August 2, 2013, ALDF followed up on petition 13-03 with a letter presenting new supporting information. Some of the major findings included:

- Support for ALDF's petition from Representative Louise Slaughter (D-NY-25) and a coalition of non-profit organizations, including The Sierra Club, Johns Hopkins Center for a Livable Future, the Socially Responsible Agricultural Project, and Friends of Family Farmers.
- Federal legislation introduced to combat antibiotic resistance and the excessive use of antibiotics in agriculture, including:
 - The Preservation of Antibiotics for Medical Treatment Act of 2013
 - The Antimicrobial Data Collection Act

- The Delivering Antimicrobial Transparency in Animals Act
- Consumer surveys and campaigns indicating heightened concern about antibiotic use in meat production.
- Studies documenting the transference of drug-resistant bacteria between farm animals and human hosts as well as the spread of these dangerous strains of bacteria into and out of agricultural settings.

On September 24, 2013, ALDF followed up with a second letter to the agency, providing additional supporting information and evidence for petition 13-03, including legal developments, scientific studies, and articles.

In the more than three years since ALDF submitted the petition, the need for antibiotics labeling of meat and poultry has only grown, as concern towards antibiotic resistance increases worldwide. The World Health Organization (WHO) now declares antibiotic resistance as a serious and emerging hazard to human health that threatens the practice of modern medicine as we know it.¹ Enabling consumers to make informed purchasing decisions through antibiotics labeling can help fight this global crisis while addressing the need for stricter oversight of meat and poultry antibiotics labeling.

Today, ALDF writes to present yet *more* evidence in support of petition 13-03. This information, in addition to that already provided to the agency in the petition and 2013 updating letters, demonstrates the urgent need for mandatory antibiotics labeling of meat and poultry. Broadly, frightening trends in antibiotic resistance clearly show increasing evidence of widespread antibiotic use as a detriment to human health. In the last three years, there have been a number of outbreaks demonstrating the presence of increasingly virulent bacterial strains in human and animal reservoirs, most notably the recent appearance of colistin-resistant bacteria in the United States. The progression towards antibiotic resistance traits is raising the specter of invincible bacteria. In turn, a number of elected officials have responded to growing public concern by pressuring agencies to exert stronger oversight of antibiotic use in food-producing animals. Initiating the rulemaking outlined in ALDF's 2013 petition would be a vital step towards protecting public health, allowing American consumers to choose between products that have an impact on their health, and promoting more responsible practices in meat and poultry production in the United States.

Trends in Antibiotic Resistance

According to the CDC, at least 2 million people in the United States are diagnosed each year with a serious infection that is resistant to at least one or more antibiotic treatments. Of these cases, over 23,000 are fatal with many more deaths following indirect complications from

¹ World Health Organization. (2014). *Antimicrobial resistance: Global report on surveillance*. p. ix. Retrieved from http://apps.who.int/iris/bitstream/10665/112642/1/9789241564748_eng.pdf?ua=1 (Attached hereto as Ex. A)

antibiotic-resistant infections.² Antibiotic resistance, due in significant part to misuse and overuse of the drugs in animal agriculture, is a growing concern and is forecast to increase over the coming decades. The following data present recent trends in antibiotic use in livestock production as well as the projected outcomes of increased antibiotic use.

- In 2014, the WHO published a report on antimicrobial resistance that aimed to determine the global scope of this issue as well as address gaps in observation throughout WHO member states. The ultimate goal is to develop cooperation between participating nations to create unified methodologies for surveillance of antimicrobial resistance trends to determine the full scope of the issue and effectively combat the development of antimicrobial-resistant bacteria. As the WHO stated, “The problem is so serious that it threatens the achievements of modern medicine. A post-antibiotic era—in which common infections and minor injuries can kill—is a very real possibility for the 21st century.”³
- A study published by Van Boeckel et al. (2015), estimates that global consumption of antimicrobials used in livestock production was approximately 63,000 tons per year in 2010 and projects that by 2030 consumption will rise 67%, exceeding 100,000 tons annually.⁴ While the implementation of industrialized farming systems accounts for approximately a third of this shift, Van Boeckel et al. (2015) conclude that the total number of animals raised to meet demands for meat and poultry account for the remaining two-thirds.⁵
- In December 2015, the FDA reported a 22% increase in the sale and distribution of antimicrobial drugs in animals used for food production between 2009 and 2014.⁶ Of the antimicrobials sold for use in food-producing animals in 2014, 62% were identified as medically important, as outlined in Appendix A of FDA’s Guidance for Industry #152.⁷
- A review conducted at the behest of former UK Prime Minister David Cameron estimated that antimicrobial resistance would contribute to 300 million deaths

² Centers for Disease Control and Prevention. (2013). *Antibiotic resistance threats in the United States, 2013*. Centers for Disease Control and Prevention. p. 11. Retrieved from <http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf> (Ex. B)

³ See Ex. A, World Health Organization, *supra* note 1 at ix.

⁴ Van Boeckel, T. P., Brower, C., Gilbert, M., Grenfell, B. T., Levin, S. a, Robinson, T. P., ... Laxminarayan, R. (2015). Global trends in antimicrobial use in food animals. *Proceedings of the National Academy of Sciences of the United States of America*, 112, 5650. <http://doi.org/10.1073/pnas.1503141112> (Ex. C)

⁵ *Id.*

⁶ Food and Drug Administration. (2015, December). 2014 Summary report on antimicrobials sold or distributed for use in food-producing animals. p. 6. *Food and Drug Administration: Department of Health and Human Services*. Retrieved from <http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM476258.pdf> (Ex. D)

⁷ *Id.* at 28.

worldwide over the next 35 years.⁸ Furthermore, the damage to the global economy was projected between 60 and 100 trillion USD in terms of losses of economic output. It was also estimated that by 2050 deaths worldwide as a result of antimicrobial resistance would reach 10 million people a year, overtaking current cancer-related death rates, which is approximately 8.2 million people a year.⁹ In a May 2016 follow-up report, Jim O’Neill, chairman of The Review on Antimicrobial Resistance stated:

“As with all forecasts of this sort, it is of course possible that our estimates may turn out to be too large, but we believe it is even more likely that they could be too small. This is because we did not even consider the secondary effects of antibiotics losing their effectiveness, such as the risks in carrying out caesarean sections, hip replacements, or gut surgery. And in the short 19 months since we started, new forms of resistance have emerged that we did not contemplate occurring so soon, such as the highly disturbing discovery of transferable colistin resistance, reported in late 2015.”¹⁰

Included in the 2016 report are ten recommended interventions that focus on reducing global demand for antimicrobials, improving the production and dissemination of effective medicines, and creating a global coalition to provide vigilant oversight of the supply and demand of antimicrobial drugs. The third intervention proposed by O’Neill recommends reducing antimicrobial use in the agriculture sector. In a survey of peer-reviewed papers from NCBI’s PubMed database, O’Neill and his team found that almost three quarters of those published by academics reported a link between antibiotic use in agriculture and resistance in humans.¹¹ Of the academic papers surveyed, 100 were in support of limiting antibiotic use in agriculture, versus only seven who opposed this stance.¹² Based on their analysis, **O’Neill concluded that there is sufficient and growing scientific evidence supporting a link between the administration of antibiotics in food-producing animals and human infection with drug-resistant bacteria.**¹³

The following studies collectively indicate growing trends of antibiotic-resistant bacteria and its potential threats to public health.

- Testing conducted by Consumer Reports published in February 2014 found that 49.7% of poultry samples collected from stores nationwide contained one or more

⁸ O’Neill, J. (chair). (2014, December). Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. *Review on Antimicrobial Resistance*. p. 7. Retrieved from https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf (Ex. E)

⁹ *Id.* at 5.

¹⁰ O’Neill, J. (chair). (2016, May). Tackling drug-resistant infections globally: Final report and recommendations. *Review on Antimicrobial Resistance*. p. 1. Retrieved from http://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf (Ex. F)

¹¹ *Id.* at 24.

¹² *Id.* at 25.

¹³ *Id.* at 24.

species of bacteria that was resistant to three or more classes of antibiotics.¹⁴ Of the 252 total samples taken, 11.5% contained two or more multidrug-resistant species of bacteria. Troublingly, resistance was significantly higher to classes of drugs currently approved by the FDA for poultry production, compared to those not currently in use.¹⁵ This evidence indicates the development of antibiotic-resistance in response to the antimicrobials currently in use in agriculture and the possibility of progressive resistance to those essential for use in human medicine.

- A study published by Limayem et al. in 2015 found *Enterococcus* species present in 72% of poultry samples tested.¹⁶ Their findings documented *Enterococcus* contamination in **100%** of the 30 turkey samples and 35% of the 20 chicken samples. Of those that tested positive, 27.7% (10 samples of the 36 that were positive) also contained *E. faecium* species. Alarmingly, all of those positive for *E. faecium* demonstrated multi-drug resistance, including resistance to quinupristin/dalfopristin, which is a last-resort treatment for Vancomycin-resistant *E. faecium* (VRE) infections in hospitals.¹⁷ Vancomycin-resistant strains of *E. faecium* have risen in prevalence from 1 to 80% over the past 27 years and account for approximately 10,000 infections and 650 deaths annually in the United States.¹⁸ The unabated use of virginiamycin in food-producing animals poses additional concerns due to its close relatedness to quinupristin/dalfopristin. These findings indicate that the presence of VRE species in livestock populations could have potentially devastating threats to human health if current last-resort antimicrobials continue to fail in providing adequate treatment.
- A 2014 study published in the *International Journal of Food Microbiology* detected the presence of multi-drug resistant *Clostridium difficile* in two pork samples taken from food retailers around Connecticut.¹⁹ While Mooyottu et al. (2015) determined that the occurrence of *C. difficile* was low, the positive samples possessed resistance to several medically-important drugs.²⁰ While these samples were non-toxicogenic, the antibiotic-resistant nature of this particular strain of *C. difficile* raises concerns as it may enable the emergence of additional, and potentially more virulent, strains as a result of interactions between toxigenic and non-toxigenic variants of bacteria within the gut.
- As noted in ALDF's August 2013 updating letter, the work of Dr. Lance Price has reinforced the connection between antibiotics use in food-producing animals and

¹⁴ Consumer Reports. (2014, February). The high cost of cheap chicken. *Consumer Reports*, 79(2), 32. Retrieved from <http://www.consumerreports.org/cro/index.html> (Ex. G)

¹⁵ *Id.* at 34.

¹⁶ Limayem, A., Donofrio, R.S., Zhang, C., Haller, E. & Johnson, M.G. (2015). Studies on the drug resistance profile of *Enterococcus faecium* distributed from poultry retailers to hospitals. *Journal of Environmental Science and Health, Part B*, 50(11), 830. doi: 10.1080/03601234.2015.1058106 (Ex. H)

¹⁷ *Id.* at 827.

¹⁸ *Id.*

¹⁹ Mooyottu, S., Flock, G., Kallanoor-Johny, A., Ypadhyaya, In., Jayarao, B. & Venkitanarayan, K. (2015). Characterization of a multidrug resistant *C. difficile* meat isolate. *International Journal of Food Microbiology*, 192, 112-113. doi: 10.1016/j.ijfoodmicro.2014.10.002 (Ex. I)

²⁰ *Id.*

infection in humans.²¹ His research has successfully matched strains of antibiotic resistant *E. coli* found in grocery store meat and poultry samples in Flagstaff, Arizona, to those identified in local hospital patients presenting with drug-resistant urinary tract infections. In his address to the President's Council of Advisors on Science and Technology on April 4, 2014, Price testified, "...Bacteria continue to develop resistance at an alarming pace, paying no heed to the politics and protocols of the rulemaking process. The public cannot wait much longer for a solution that is comprehensive and bold enough to effectively fight this growing epidemic."²²

Antibiotic-resistant Bacteria Outbreaks

According to global antibiotic resistance monitoring, increased meat consumption and the spread of industrialized meat production models that rely heavily on antimicrobials present a growing potential for antibiotic resistance.²³ According to Consumer Reports (2016), "Once resistant bacteria are in the environment, they can mingle with other bacteria and share genetic material, which could contribute to additional antibiotic-resistant infections in hospitals and communities."²⁴ The following data represent some of the recent documented cases of antibiotic-resistant bacteria.

- On May 26, 2016, the American Society for Microbiology published a manuscript documenting the first reported incidence of colistin-resistant bacteria in the United States.²⁵ *Escherichia coli* bacteria containing the *mcr-1* gene for colistin resistance was found in the urine of a 49-year-old woman, who presented with symptoms of a urinary tract infection. The report also states that she had not traveled within the five months leading up to her consult, suggesting that the patient acquired the infection within U.S. borders. The emergence of the *mcr-1* gene in the United States follows last November's discovery, by Chinese and British researchers, of colistin-resistant bacteria in swine, pork meat, and a number of people in China.²⁶ Since then, it has also been documented in Europe and other parts of the world. While this particular strain was found to be treatable with alternative antibiotics, there is concern that over time bacteria will continue to mutate and eventually develop pan-resistance to all of the drugs currently at our disposal. Colistin currently serves as a last-resort drug for

²¹ Price, L.B. (testimony). April 4, 2014. Testimony of Lance B. Price, Ph.D. *President's Council of Advisors on Science and Technology Meeting* (transcript). Retrieved from https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/price_lance.pdf (Ex. J)

²² *Id.* at 3.

²³ See Ex. C, Van Boekel et al., *supra* note 4, at 5649.

²⁴ Consumer Reports. (2016, January). Making the world safe from superbugs. Consumer Reports, 81(1), 42. Retrieved from <http://www.consumerreports.org/cro/index.html> (Ex. K)

²⁵ McGann, P., Snesrud, E., Maybank, R., Corey, B., Ong, A.C., Clifford, R. ... Schaecher, K.E. (2016, May 26). *Escherichia coli* harboring *mcr-1* and *blaCTX-M* on a novel IncF plasmid: First report of *mcr-1* in the USA. *Antimicrobial Agents and Chemotherapy*. 1-10. doi: 10.1128/AAC.01103-16 (Ex. L)

²⁶ Sun, L.H. & Dennis, B. (2016, May 27). The superbug that doctors have been dreading just reached the U.S. *The Washington Post*. Retrieved from <https://www.washingtonpost.com/news/to-your-health/wp/2016/05/26/the-superbug-that-doctors-have-been-dreading-just-reached-the-u-s/> (Ex. M)

carbapenem-resistant *Enterobacteriaceae* infections, which have been known to have a mortality rate as high as 50%.²⁷ Additionally, researchers at the U.S. Department of Agriculture and the Department of Health and Human Services recently reported colistin-resistant bacteria in a pig intestine sample collected through routine testing of livestock and retail meats, the country's second known documented case of colistin-resistant bacteria.²⁸

- In a recent letter to the Editor of the American Society for Microbiology, Castanheira et al. (2016) document the presence of the *mcr-1* gene in the United States from a global surveillance program whereby *E. coli* and *K. pneumoniae* isolates from hospital samples were screened for the colistin resistance gene.²⁹ These results predate those reported by McGann et al. (2016) from May, suggesting that colistin resistance is not a newly emerging phenomena in the United States.³⁰ Of the 21,006 isolates screened, approximately 1.9% (390 samples) demonstrated elevated colistin resistance. The sample that tested positive for the *mcr-1* gene from the United States was collected in May 2015 in addition to 18 other positive samples (out of 390 total) gathered worldwide between 2014 and 2015.³¹ Of the 59 total *E. coli* samples screened for the *mcr-1* gene, 19 tested positive, indicating that more than 30% of those with colistin-resistance carried the *mcr-1* gene.³² These findings demonstrate the critical need for increased surveillance of emerging strains of drug-resistant bacteria and further research efforts towards the development of novel antimicrobials to combat resistance.
- As cited in part 3 of *America's Antibiotic Crisis*, published by Consumer Reports in January 2016, data from the CDC reveal that there have been six food poisoning epidemics since 2011 that span multiple states and involve antibiotic-resistant bacteria.³³ The most notable of these outbreaks was the emergence of a virulent strain of salmonella that was linked to Foster Farms chicken and resulted in 634 reported cases over 29 states between spring 2013 and the following summer.³⁴ According to the CDC, the strain of salmonella identified in this outbreak was resistant to a number of routinely prescribed antibiotics, resulting in a hospitalization rate of 38% of those who were infected,³⁵ around double the typical rate for salmonella infections.³⁶ The

²⁷ *Id.*

²⁸ *Id.*

²⁹ Castanheira, M., Griffin, M.A., Deshpande, L.M., Mendes, R.E., Jones, R.N. & Flamm, R.K. [Letter to the Editor]. (2016, July 11). Detection of *mcr-1* among *Escherichia coli* clinical isolates collected worldwide as part of the SENTRY Antimicrobial Surveillance Program during 2014-2015. *American Society for Microbiology*. doi: 10.1128/AAC.01267-16. (Ex. N)

³⁰ See *id.*; Ex. L, McGann et al., *supra* note 25.

³¹ See Ex. N, Castanheira et al., *supra* note 29, at 3.

³² *Id.* at 8.

³³ See Ex. K, Consumer Reports, *supra* note 24, at 41.

³⁴ *Id.* at 41-42.

³⁵ Centers for Disease Control and Prevention. (2014, July 31). Multistate outbreak of multidrug-resistant *Salmonella* Heidelberg infections linked to Foster Farms brand chicken (final update). Retrieved from <http://www.cdc.gov/salmonella/heidelberg-10-13/> (Ex. O)

³⁶ See Ex. K, Consumer Reports, *supra* note 24, at 42.

same report also references a recall of pork in August 2015,³⁷ which according to the CDC resulted in a total of 192 cases and 30 hospitalizations as a result of salmonella infection.³⁸ According to the CDC, “All 10 isolates (100%) were multidrug resistant. This included resistance to ampicillin, streptomycin, sulfisoxazole, and tetracycline.”³⁹

Response from Elected Officials to Antibiotic Resistance

The issue of antibiotic resistance has not only captured the attention of the American public, but also elected officials, as the public health crisis increases pressure on them to respond. The following are recent developments from elected officials on the subject of antibiotic resistance and food-producing animals.

- On March 23, 2015, Representative Louise Slaughter of New York introduced a bill known as the Preservation of Antibiotics for Medical Treatment Act (PAMTA) for the fifth time, calling antibiotic resistance “the most pressing public health crisis of our time.”⁴⁰ She continued:

“Both the American people and the U.S. government need to give this issue the attention it demands. Right now, we are allowing the greatest medical advancement of the 20th century to be frittered away, in part because it’s cheaper for factory farms to feed these critical drugs to animals rather than clean up the deplorable conditions on the farm.”⁴¹

- On October 10th, 2015 California Governor Jerry Brown signed Senate Bill 27, which restricts the routine use of antibiotics in livestock, with the exception of veterinary approval for specific cases, such as treating an active infection or after a medical procedure whereby antibiotics are required to prevent infection.⁴² The law will take effect in 2018 and is the strictest legislation to date proposed to address antibiotic use in farm animals. Upon signing the bill, Brown stated:

“SB 27 addresses an urgent public health problem. The science is clear that the overuse of antibiotics in livestock has contributed to the spread of antibiotic resistance and the undermining of decades of life-saving advances in medicine... Recently, American poultry producers have shown leadership by voluntarily committing to better husbandry practices and eliminating the sub-

³⁷ *Id.*

³⁸ Centers for Disease Control and Prevention. (2015, December 2). Multistate outbreak of multidrug-resistant *Salmonella* I 4,[5],12:i:- and *Salmonella* *Infantis* infections linked to pork (final update). Retrieved from <http://www.cdc.gov/salmonella/pork-08-15/> (Ex. P)

³⁹ *Id.*

⁴⁰ Cox, K. (2015, March 24). Bill seeks (again) to end over-use of antibiotics in farm animals. *Consumerist*. Retrieved from <https://consumerist.com/2015/03/24/bill-seeks-again-to-end-over-use-of-antibiotics-in-farm-animals/> (Ex. Q)

⁴¹ *Id.*

⁴² CBS & Associated Press (2015, October 12). California enacts strictest law limiting antibiotics in livestock. *CBS News*. Retrieved from <http://www.cbsnews.com/news/california-enacts-strictest-law-limiting-antibiotics-in-livestock/> (Ex. R)

therapeutic use of antibiotics. This is an example that the rest of the livestock industry should follow.”⁴³

- In a press release on February 9th, 2016, Rep. Louise Slaughter responded to President Obama’s budget proposal, which allocated \$1.1 billion to the federal government for the purpose of research and prevention of antibiotic resistance.⁴⁴ According to Rep. Slaughter (2016):

“One area of disagreement is the president’s funding for antibiotic resistance. While this budget makes efforts to fund data collection, we need a robust investment that recognizes the staggering need to combat this growing public health crisis. We have already reached the post-antibiotic era, and we need an all-in approach.”⁴⁵

- Shortly after reports surfaced of the discovery of the mcr-1 gene in the United States, Senator Robert P. Casey Jr. shared his support for legislation relating to antibiotic resistance, and stated, “[antibiotic resistant bacteria] present an urgent public health problem that we must focus on intensively.”⁴⁶
- On April 12th, 2016, Senators Elizabeth Warren, Dianne Feinstein, Kirsten Gillibrand, Richard Blumenthal, Edward J. Markey, and Cory A. Booker submitted a letter to Robert Califf, M.D., commissioner of the FDA.⁴⁷ The letter requests that Commissioner Califf address current policy gaps in antibiotic use in animals by creating a plan for reform. The Senators call for increased efforts in FDA enforcement, data collection, and the creation of metrics for evaluation.⁴⁸ They point out that by enforcing stronger regulations the FDA will ensure that compliance is not reliant on stakeholders for the responsible use of antimicrobials in the production process. Recommendations include a publicly available timeline for proposed data collection followed by the implementation of metrics and benchmarks to guide future policy goals. If granted, the Senators state, the proposed policy reforms would improve policy gaps and promote the stewardship of antimicrobial use.⁴⁹

⁴³ Zuraw, L. (2015, October 10). California governor signs bill regulating animal antibiotics. *Food Safety News*. Retrieved from <http://www.foodsafetynews.com/2015/10/california-governor-signs-groundbreaking-bill-regulating-animal-antibiotics/#.VzCSHmPFzww> (Ex. S)

⁴⁴ Slaughter, L. (2016, February 9). Slaughter on President Obama’s Budget Proposal [Press release]. Retrieved from <https://louise.house.gov/media-center/press-releases/slaughter-president-obama-s-budget-proposal> (Ex. T)

⁴⁵ *Id.*

⁴⁶ See Ex. M, Sun & Dennis, *supra* note 26.

⁴⁷ Warren, E., Feinstein D. Gillibrand, K., Blumenthal, R., Markey, E.J., Booker, C.A. [Letter to FDA Commissioner Robert Califf, M.D.]. (2016, April 12). Retrieved from <http://www.warren.senate.gov/files/documents/04122016%20-%20Letter%20to%20Califf%20Antiboitic%20Resistance.pdf> (Ex. U)

⁴⁸ *Id.*

⁴⁹ *Id.*

Consumer Response to Antibiotic Resistance and Labeling

The antibiotic resistance crisis has created public pressure to improve animal raising and production practices and ensure that foods are labeled in a way that is transparent to the consumer. Petition 13-03 clearly demonstrates the legal basis, under the Poultry Products Inspection Act (PPIA) and Federal Meat Inspection Act (FMIA), for labeling that informs consumers about the antibiotic-use practices of meat and poultry producers. Such labeling is necessary to provide transparency, reduce labeling confusion, and further encourage more responsible antibiotic practices that promote animal welfare and human health.

The following reports and surveys from Consumer Reports and the Consumer Reports National Research Center, conducted and published between 2014 and 2016, illustrate the need for uniform antibiotics labeling:

- A nationally representative Food Labels Survey, of 1,001 adults in the United States, released in April 2016, overwhelmingly found that consumers want standards for meat raised with antibiotics.⁵⁰ The survey found:
 - Large majorities of consumers reported being extremely or very concerned about the problems associated with routinely feeding healthy animals antibiotics and other drugs:
 - 68% of consumers were concerned that administering antibiotics and other drugs to healthy animals contributes to overcrowding and unsanitary conditions for food-producing animals;
 - 65% were concerned that these practices also foster the development of new bacteria that promote illnesses that cannot be cured by antibiotics;
 - over half (53%) were further concerned that these practices may contribute to environmental pollution; and
 - just over half (51%) had concerns that antibiotics artificially promote growth.⁵¹
- Crucially, for the purposes of petition 13-03, this survey also demonstrates extreme consumer confusion about antibiotics labeling:
 - Only *half* of consumers understand that the label ‘raised without antibiotics’ means no antibiotics were administered to the animal; furthermore, a quarter falsely believe that this claim means no antibiotics *or any other drugs* were administered to the animal.⁵²
 - **Moreover, a large majority of consumers believe the government should do precisely what ALDF’s petition asks; 84% think the government should require that meat from healthy animals routinely fed antibiotics be labeled with a ‘raised with antibiotics’ disclosure.**⁵³

⁵⁰ Consumer Reports National Research Center. (2016, April 6). Food labels survey: 2016 nationally-representative phone survey. *Consumer Reports*. Retrieved from http://www.consumerreports.org/content/dam/cro/news_articles/health/PDFs/ConsumerReports-Food-Labels-Survey-April-2016.pdf (Ex. V)

⁵¹ *Id.* at 3.

⁵² *Id.*

⁵³ *Id.*

- Consumers also overwhelmingly (88%) favor mandatory labeling of meat from animals raised with hormones/ractopamine, and 87% believe that animals should not be given hormones, ractopamine or other growth promoting drugs at all.⁵⁴
- The 2016 report *Making the World Safe from Superbugs* from Consumer Reports noted that between 2011 and 2014, **packaging claims for meat and poultry products derived from animals raised without antibiotics more than doubled**, demonstrating both consumer demand for antibiotic labeling and increased market response.⁵⁵
- In a phone survey of 1,005 adults in the United States, conducted in December 2015, Consumer Reports reported:⁵⁶
 - 82% of respondents felt it was important or very important to reduce antibiotic use in foods.⁵⁷
 - Comparing results from the 2014 to the 2015 survey, 37% felt it was *very important* to reduce antibiotics in food production in 2014 versus 54% in 2015, demonstrating a 17% increase in the importance of this issue to consumers.⁵⁸
 - Illustrating consumer confusion over labeling, 57% of respondents believed that the ‘natural’ label meant that no antibiotics or other drugs were used – 82% felt that this is what the label *should* mean. Similarly, 60% of consumers felt the ‘organic’ label meant that no antibiotics or other drugs were ever used, while 72% felt that this is what the label should mean.⁵⁹

These findings clearly demonstrate consumer demand for meat raised without antibiotics, and for accurate and consistent antibiotics labeling of meat. Moreover, responses to what consumers feel labels currently mean and what they *should* mean illustrate the information gap between food producers and consumers. In order to resolve this gap, labeling standards must match consumer expectations, and with regard to antibiotics, must include uniform, mandatory labeling.

- Increased awareness of factory farm conditions and antibiotic use in agriculture has driven consumer purchasing decisions as well. Another nationally representative survey of 1,008 adults conducted by the Consumer Reports National Research Center in September 2015, found more than one in four Americans report purchasing more meat and poultry products raised without antibiotics than in the previous year; furthermore, approximately half look for ‘no-antibiotics’ claims on product

⁵⁴ *Id.*

⁵⁵ See Ex. K, Consumer Reports, *supra* note 24, at 47.

⁵⁶ Consumer Reports National Research Center. (2015). Natural food labels survey: 2015 nationally-representative phone survey. *Consumer Reports*. Retrieved from https://www.consumerreports.org/content/dam/cro/magazine-articles/2016/March/Consumer_Reports_Natural_Food_Labels_Survey_2015.pdf (Ex. W)

⁵⁷ *Id.* at 3.

⁵⁸ *Id.*

⁵⁹ *Id.* at 4-5.

packaging.⁶⁰ A similar, earlier Consumer Reports survey, from 2014, showed that 39% of respondents look for no-antibiotics claims on their food packaging, reflecting a growing trend.⁶¹

- Finally, similar to the 2016 Food Labels Survey, noted above, an April 2014 Consumer Reports survey of 1,004 adults in the United States revealed that **83% of respondents demand government-enforced labeling of meat products from animals routinely administered antibiotics.**⁶² The 2014 report also indicated that 80% of those interviewed support humane living conditions in food-producing animals.⁶³ Given that antibiotics were introduced in part to combat conditions in industrial farming systems, consumer demand for higher welfare products not only promotes better living conditions for animals, but also enables producers to reduce their dependency on antibiotics by protecting animal health and preventing animal infections more holistically.

Other surveys and studies similarly demonstrate the need for uniform antibiotics labeling:

- According to analysis from Bowman et al., “voluntary labeling improves market efficiency if consumers receive the product characteristics they demand and producers are compensated for producing these characteristics. For this to occur, label claims have to be truthful, credible, and understandable.”⁶⁴ Bowman et al. used the *Sanderson and Perdue v. Tyson* lawsuit (discussed in ALDF’s petition) as a case study that exemplifies how animal-raising claims contribute to consumer confusion when regulatory agencies fail to provide universally accepted definitions for them.⁶⁵ As the study authors pointed out, FSIS’ inability to impose strict penalties for false or misleading claims incentivizes producers to continue to promote voluntary claims that are unverified or deceptive purely for economic gain.⁶⁶ According to the authors:

“The presence of information asymmetries in the absence of verification or certification may give firms the ability to charge a price premium without producing a credence attribute. Penalties for using misleading and/or false label claims may not dissuade firms from pursuing this path if the payoffs for introducing label claims are sufficiently high.”⁶⁷

Consequently, information asymmetries in labeling practices can lead to market failure

⁶⁰ See Ex. K, Consumer Reports, *supra* note 24, at 47.

⁶¹ Consumer Reports National Research Center. (2014). Food labels survey: 2014 nationally-representative phone survey. *Consumer Reports*. p. 17. Retrieved from <http://greenerchoices.org/pdf/consumerreportsfoodlabelingsurveyjune2014.pdf> (Ex. X)

⁶² *Id.* at 22.

⁶³ *Id.* at 5.

⁶⁴ Bowman, M., Marshall, K.K., Kuchler, F. & Lynch, L. (2016, March). Raised without antibiotics: Lessons from voluntary labeling of antibiotic use practices in the broiler industry. *American Journal of Agricultural Economics*. 98(2), 622. doi: 10.1093/ajae/aaw008 (Ex. Y)

⁶⁵ *Id.*

⁶⁶ *Id.* at 636.

⁶⁷ *Id.* at 623.

in two forms:

- Consumer doubts about labeling claims mean that they will not pay the premium for the product they demand, therefore the producer will not supply what is demanded by consumers.⁶⁸
- Consumers believe the label and are willing to pay a premium, however, they are not supplied with, and have no reliable means for verifying claims for, the product they demand. (The Tyson lawsuit is an example of this type of market failure).⁶⁹

Reducing market failure requires the implementation of labeling standards that harmonize consumer expectations and producer fulfillment. As a result of the demonstrated market failures surrounding antibiotics meat labeling, mitigation necessitates implementing a single, uniform labeling standard to disclose whether meat is derived from animals fed antibiotics.

- As cited in the 2016 O’Neill report, mentioned above, “We must improve transparency from food producers on the antibiotics used to raise the meat that we eat, to enable consumers to make more informed purchase decisions.”⁷⁰ This transparency is best facilitated through uniform antibiotics labeling requirements. The report continues, “Convincing the public that we should stop using antibiotics unnecessarily would not be effective if most people cannot recognise which drugs are antibiotics in the first place. Labelling of antimicrobials, especially antibiotics, is crucial.”⁷¹ In addition to improving industry transparency, improved labeling serves to educate the public and increase their general understanding of this important health issue.

Increased consumer demands for meat raised without antibiotics have also started to impact the restaurant industry. For example:

- On September 15, 2015, over 100 independent organizations submitted a letter to the CEO’s of the 25 top restaurant chains in the United States, expressing growing concern about antibiotic resistance.⁷² The letter urged the CEO’s to consider adopting no antibiotics policies and to pressure their meat and poultry suppliers to provide meat raised without antibiotics.
- Also in September 2015, a report published in collaboration with Friends of the Earth, National Resources Defense Council, Keep Antibiotics Working, Consumer Union, Center for Food Safety, and the Food Animal Concerns Trust ranked the restaurants

⁶⁸ *Id.* at 624.

⁶⁹ *Id.*

⁷⁰ *See* Ex. F, O’Neill, *supra* note 10, at 5.

⁷¹ *Id.* at 20.

⁷² Academy of Integrative Health & Medicine, AFGE Local 3354, Albert Einstein College of Medicine, AllergyKids Foundation, Alliance for Prudent Use of Antibiotics... World Farmers. (2015, September 15). Letter to the US chain restaurant industry: Prohibit the routine use of antibiotics in your meat supply. Retrieved from <https://consumersunion.org/wp-content/uploads/2015/09/Letter-to-the-US-Chain-Restaurant-Industry.pdf> (Ex. Z)

on antibiotic use policies and meat purchasing decisions.⁷³ Of the 25 surveyed, five restaurants had policies that limit antibiotic use, and only two sourced the majority of their meat from animals not raised with routine antibiotics.⁷⁴ These rankings encourage restaurants to answer consumer demand and serve meat raised without antibiotics.

Lastly, the following citizen petitions demonstrate consumers' desire for antibiotics labeling and show support for ALDF's petition:

- A Change.org petition, delivered to FSIS and the Office of USDA Secretary Tom Vilsack, has gathered 168,971 signatures in support of ALDF's petition.⁷⁵
- A TakePart petition introduced on June 24, 2015, urging the House Energy and Commerce Committee members to support PAMTA, has garnered 45,236 signatures.⁷⁶
- A similar petition launched in August 2014 by Dr. Mark Hyman, also urging Congress to adopt PAMTA and the Preventing Antibiotic Resistant Act, has gathered 131,741 signatures,⁷⁷ 128,000 of which came in the first two weeks of its launch.⁷⁸

Conclusion

The abovementioned studies, surveys, news articles, actions, petitions, and congressional efforts collectively demonstrate both the urgent need to restrict the use of antibiotics in animal agriculture, and the overwhelming consumer desire and need for clear, uniform labeling of meat from animals raised with routine antibiotics. Voluntary labeling claims are inadequate to address consumer deception with regard to antibiotics, because of the varying standards such labels represent and language they employ. In short, in order to reduce this confusion, protect human health, and improve animal welfare, mandatory antibiotics labeling is necessary—and in fact required by the FMIA and PPIA, as explained in ALDF's petition.

⁷³ Friends of the Earth, Natural Resources Defense Council, Consumers Union, Food Animal Concerns Trust, Keep Antibiotics Working, & Center for Food Safety. (2015, September). Chain reaction: How top restaurants rate on reducing use of antibiotics in their meat supply. Retrieved from <https://www.nrdc.org/sites/default/files/restaurants-antibiotic-use-report.pdf> (Ex. AA)

⁷⁴ *Id.* at 7.

⁷⁵ Molidor, Dave. (n.d.). Require that meat produced from animals fed antibiotics be labeled accordingly. *Change.org*. Retrieved from <https://www.change.org/p/tom-vilsack-require-that-meat-produced-from-animals-fed-antibiotics-be-labeled-accordingly> (Ex. BB)

⁷⁶ TakePart. (2015, June 24). Superbugs in my steak? Stop antibiotic abuse in factory farms! *TakePart*. Retrieved from <https://takeaction.takepart.com/actions/stop-unnecessary-antibiotic-use-animals?cmpid=tp-ptnr-tab-d84909c52edcceb20c7bba62052b1b01> (Ex. CC)

⁷⁷ Hyman, M. (2014). Tell Congress: Stop the use of antibiotics in factory farms. *Credo Mobilize*. Retrieved from <https://www.credomobilize.com/petitions/tell-congressional-republicans-stop-the-use-of-antibiotics-in-factory-farms> (Ex. DD)

⁷⁸ News Desk. (2014, August 16). Petitions urge Congressional action on antibiotics legislation. *Food Safety News*. Retrieved from <http://www.foodsafetynews.com/2014/08/petitions-attempt-to-prompt-congressional-action-to-antibiotics-legislation/#.V1cunleOqf5> (Ex. EE)

Indeed, it has become evident, since ALDF first filed its petition, that consumers increasingly view meat and poultry antibiotics labeling as critically important to both ensuring safe food choices and protecting public health. The first recommendation made in the seminal O’Neill report is to improve global awareness of antimicrobial resistance.⁷⁹ Labeling products derived from animals routinely fed antibiotics unquestionably raises awareness and pressures producers to reduce their dependence on these drugs.

FSIS has had over three years to consider petition 13-03. In that time, the urgency of and need for the regulations requested in the petition have only grown more severe. ALDF again respectfully urges FSIS to initiate rulemaking to require mandatory, uniform antibiotics labeling—without further delay.

Thank you very much for your attention to this important matter. Please feel free to contact us at the numbers or email addresses below with any questions.

Sincerely,



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⁷⁹ See Ex. F, O’Neill, *supra* note 10, at 19.