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REPORT ON LEGISLATION BY THE COMMITTEE ON LEGAL ISSUES PERTAINING TO ANIMALS

S. 619 H.R. 1549 Sen. Snowe Rep. Slaughter

AN ACT to amend the Federal Food, Drug, and Cosmetic Act to preserve the effectiveness of medically important antibiotics used in the treatment of human and animal diseases by reviewing the safety of certain antibiotics for non-therapeutic purposes in food-producing animals.

Preservation of Antibiotics for Medical Treatment Act of 2009 (PAMTA)

THIS BILL IS APPROVED

S.619/H.R.1549 is intended to alleviate the negative effects that the industrial farm animal production system (IFAP) poses on public health, the environment, rural communities and animal welfare due to the non-therapeutic uses of certain drugs on foodproducing animals. The Act would amend the Federal Food, Drug, and Cosmetic Act (21 U.S.C. sec. 321) to require the Secretary of Health and Human Services to (1) deny an application for a new animal drug that is a critical antimicrobial animal drug¹ unless the applicant demonstrates that there is a reasonable certainty of no harm to human health due to the development of antimicrobial resistance attributable to the non-therapeutic use of the drug and (2) withdraw approval of a non-therapeutic use of such drugs in foodproducing animals two years after the date of the Act's enactment unless certain safety requirements are met. By targeting only non-therapeutic use, the bill allows for sick animals to continue to receive appropriate medical treatment and for legitimate prophylaxis. Moreover, farmers would continue to have the option to use other nontherapeutic antibiotics that are not used in human medicine, as well as improved animal husbandry practices, for which the Association of the Bar of the City of New York (ABCNY) has advocated.²

The bill follows on the heels of the findings and recommendations of the Pew Commission on Industrial Farm Animal Production (PCIFAP) which concluded that

¹ A "critical antimicrobial animal drug" is defined as a drug intended for use in food-producing animals that contains specified antibiotics or other drugs or drug derivatives used in humans to treat or prevent disease or infection caused by microorganisms. The term "non-therapeutic use" is defined as any use of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention or other routine purpose.

² E.g., Letter from Jane Hoffman, Chair of the Committee on Legal Issues Pertaining to Animals, New York City Bar, to Tom Vilsack, Secretary, U.S. Dept. of Agriculture (Feb. 25, 2009), *available at* http://www.nycbar.org/pdf/report/20071682USDA_Policies.pdf (last visited Nov. 29, 2009).

"(t)he present system of producing food animals in the United States is not sustainable and presents an unacceptable level of risk to public health and damage to the environment, as well as unnecessary harm to the animals we raise for food." The PCIFAP further identified the routine use of antibiotics and antimicrobials in food-producing animals as a major public health risk because of the potential for the evolution and proliferation of antibiotic-resistant strains of bacteria as well as the interspecies transfer of resistance determinants.⁴

Background

Antibiotics are used for three main purposes in livestock production: (1) as therapeutics for managing clinically apparent diseases, (2) as prophylactics, and (3) to promote growth.⁵ The use of antibiotics to promote the growth of farm animals began in the 1940s in the poultry industry.⁶ Over the ensuing years, the practice of using antibiotics and hormones for non-therapeutic purposes, including to stimulate growth and production, has increased exponentially.⁷ This is partly because antibiotics' effectiveness as a growth promoter has declined and more antibiotics are needed.⁸ Today, an estimated 70 percent of the antibiotics produced in the United States are given to farm animals for non-therapeutic purposes and to compensate "for crowded, unsanitary, and stressful farming and transportation conditions." Over 80 percent of swine farms, cattle feedlots, and sheep farms administer drugs in feed or water. And roughly 100 percent of chickens and turkeys receive antibiotics in their food. And

Research strongly suggests that an increase in the use of antibiotics in farm animals is accompanied by an increased threat to human health. Bacteria from IFAP facilities can reach humans directly, through food, water, air, or contact, or indirectly through the transmission of resistant bacteria that mutate in the environment. ¹² In 1969,

⁷ Robyn L. Goforth & Carol R. Goforth, *Appropriate Regulation of Antibiotics in Livestock Feed*, 28 B.C. ENVTL. AFF. L. REV. 39, 46 (2000).

http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf (last visited Nov. 29, 2009) (stating that "human exposure through the ingestion of antimicrobial resistant bacteria from animal-derived foods represents the most significant pathway for human exposure to bacteria that have emerged or been selected as a consequence of antimicrobial drug use

³ PCIFAP, Putting Meat on the Table: Industrial Farm Animal Production in America viii (Ap. 29, 2008), *available at* http://www.ncifap.org/_images/PCIFAPFin.pdf (last visited Nov. 22, 2009).

⁵ U.S. Dept. of Agriculture, Animal and Plant Health Inspection Service et al., Antimicrobial Resistance Issues in Animal Agriculture 16 (May 2007), *available at*

http://www.aphis.usda.gov/vs/ceah/cei/taf/emerginganimalhealthissues_files/antiresist2007update.pdf (last visited Nov. 22, 2009).

⁶ *Id.* at 15.

⁸ *Id.* at 46-47.

⁹ S. 619, 111th Congress 3:18-25 (2009) & H.R. 1549, 111th Congress 6:23-7:6 (2009).

¹⁰ S. 619, 111th Congress 4:4-14 (2009) & H.R. 1549, 111th Congress 4:10-20 (2009).

¹¹ BOARD ON AGRICULTURE, THE USE OF DRUGS IN FOOD ANIMALS: BENEFITS AND RISKS 181 (1999), available at http://books.nap.edu/openbook.php?record_id=5137&page=181.

¹² PCIFAP, *supra n. 2*, at 16; *see also* FDA Guidance for Industry #152, Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to The Microbiological Effects on Bacteria of Human Health Concern 3, *available at*

policy makers in the United Kingdom called for an end to non-therapeutic use of antibiotics in farm animals.¹³ In 2000, a World Health Organization (WHO) report expressed alarm at the spread of resistant infectious disease agents and observed that the use of antibiotics in farm animals "inevitably results in the development of resistance in bacteria in or near livestock, and also heightens fears of new resistant strains 'jumping' between species." As one example of the risk of the use of antibiotics in farm animals, the WHO report cited an outbreak in America in 1998 involving roughly 5,000 individuals who fell ill with multi drug-resistant campylobacteriosis caused by contaminated chicken. Also, studies suggest that hog farms are a source of a new strain (ST398) of MRSA (Methicillin-resistant *Staphylococcus aureus*, commonly known as "staph"). Numerous other studies link bacteria resistance with the consumption of animal products.

In addition to entering consumers' bodies through the food supply, animal waste discharged by large IFAPs can contaminate surface waters with pollutants such as antibiotics in a variety of ways including spills and overflows from waste storage "lagoons", discharge to the air and subsequent redeposition on the landscape, and improper land application that can run off into waterways or leach into soil and groundwater. Nearby residents may be completely unaware of the possibility that antibiotics may enter their environment from IFAPs. For example, in *U.S. Public Interest Research Group v. Atlantic Salmon of Maine, LLC.*, a Federal district court noted that hundreds of pounds of drugs, which were mixed into commercial salmon feed, were discharged into commercial salmon farm sites and subsequently released into nearby bays. The farms did not post warning signs for the public about the use of medicated feed or chemical discharge and did not monitor the environment for the effects of chemical usage. ²⁰

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in animals"); Robyn L. Goforth & Carol R. Goforth, *Appropriate Regulation of Antibiotics in Livestock Feed*, 28 B.C. ENVTL. AFF. L. REV. 39, 43 (2000) (explaining various ways in which antibiotic resistance can occur); Michael Barza, *Potential Mechanisms of Increased Disease in Humans from Antimicrobial Resistance in Food Animals*, Clinical Infectious Disease 1 (June 2002), *available at* http://www.journals.uchicago.edu/doi/pdf/10.1086/340249 (last visited Nov. 29, 2002).

¹³ Goforth & Goforth, *supra* note 7 at 54-64 (2000) (discussing several studies including one in which a 72-year old woman died after an outbreak of salmonella poisoning connected to drinking raw milk from a particular dairy)

particular dairy). ¹⁴ World Health Organization, Report on Infectious Diseases (2000), *available at* http://www.who.int/infectious-disease-report/2000/other_versions/index-rpt2000_text.html (last visited Nov. 23, 2009).

¹⁵ *Id*.

¹⁶ PCIFAP, *supra* note 3, at 21.

¹⁷ Goforth & Goforth, *supra* note 7 at 49-50 (2000).

¹⁸ Waterkeeper Alliance v. U.S. Environmental Protection Agency, 2005 U.S. App. LEXIS 6522, *13-*14 (2d Cir. 2005).

¹⁹ U.S. Public Interest Research Group v. Atlantic Salmon of Maine, LLC, 257 F. Supp. 2d 407, 422 (Dist. Me. 2003); see also Graham Wilson, Note: A Day On The Fish Farm: FDA and the Regulation of Aquaculture, 23 VA. ENVTL. L.J. 351, 361-62 (discussing fish farms' use of antibiotics and the impact on the environment).

²⁰ U.S. Public Interest Research Group, supra note 19 at 422.

In May 2002, the Alliance for the Prudent Use of Antibiotics (APAU), a non-profit organization whose mission is to improve control of infectious disease worldwide through the promotion of appropriate use of antimicrobials and reduction of antimicrobial resistance, issued a report (based on approximately 500 published studies on the topic of antimicrobial use in agriculture) - the FAAIR Report.²¹ The FAAIR Report made policy recommendations - consistent with those of the PCIFAP - which include the following:

- 1. Antimicrobial agents should not be used in agriculture in the absence of disease.
- 2. Antimicrobials should be administered to animals only when prescribed by a veterinarian.
- 3. Quantitative data on antimicrobial use in agriculture should be made available to inform public policy.
- 4. The ecology of antimicrobial resistance should be considered by regulatory agencies in assessing human health risk associated with antimicrobial use in agriculture.
- 5. Surveillance programs for antimicrobial resistance should be improved and expanded.
- 6. The ecology of antimicrobial resistance in agriculture should be a research priority.

The FAAIR Report focused on the same areas of concern addressed by S.619/H.R1549, for example, antimicrobial use as a major cause of antimicrobial resistance; growing resistance to antibiotics from antimicrobial use; largely non-therapeutic use (*e.g.*, growth promotion and disease prevention) of antimicrobials to food-producing animals; and the alteration of microbial ecosystems of humans, animals and the environment from exposure to antimicrobials.

In addition to reducing a health hazard, S.619/H.R.1549 may reduce indirect costs of production despite a potential nominal increase in the retail cost of meat. A 1999 report of the National Research Council estimated that average annual per capita cost to consumers of a ban on sub-therapeutic drug use in animal agriculture due to increased retail costs of meat and poultry would be in the range of \$4.84 to \$9.72 per year, or a total of \$1.2 billion to \$2.5 billion per year. Supporters of the bills observe that hidden costs, especially hidden health costs, would probably decrease, though to what extent is unknown. In the late 1990s, it was estimated that the overall cost to the United States of antibiotic resistance was roughly \$4.5 billion per year; however, it is unclear what portion of that cost is attributable to the use of antibiotics in food producing animals.

²²Board on Agriculture, The Use of Drugs in Food Animals: Benefits and Risks 184 (1999), available at http://books.nap.edu/openbook.php?record_id=5137&page=184 (last visited Nov. 29, 2009).

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²¹ APUA "FAAIR Report," entitled *The Need to Improve Antimicrobial Use in Agriculture: Ecological and Human Health Effects*, was published as a Supplement to the June 1, 2002 edition of the journal *Clinical Infectious Diseases* (Vol 34, Supplement 3). In 2005, the FAAIR Report was entered into evidence in the FDA deliberations to ban the use of enrofoxacin in poultry. *See* note 25.

²³ Goforth & Goforth, *supra* note 7 at 67 (2000) (discussing estimates of the U.S. Office of Technology Assessment and the U.S. Department of Agriculture).

Legislative History

PAMTA is not a first-time bill. It was introduced in 2003 in the House and the Senate by Representative Sherrod Brown and Senator Edward Kennedy, respectively.²⁴ The introduction of the bill came in the wake of the release of an action plan, created by a federal interagency task force, designed to address the continuing decline of the effectiveness of antibiotics. Revised versions of the bill were introduced in 2005, 2007, and 2009. In 2009, the bill was introduced as S.619 by Senator Kennedy and was referred to the Committee on Health, Education, Labor, and Pensions. In the House, Representative Louise Slaughter (D-NY) introduced the companion bill, H.R. 1549, which was referred to the House Committee on Energy and Commerce and House Rules, where a hearing was held on July 13, 2009.

There is no legitimate dispute that antibiotic resistance poses a public health threat and that Congressional action is necessary. As cited in S.619, Sec. 2, entitled "Findings", Congressional action with regard to antibiotic overuse in human medicine was accomplished by amendments to the Public Health Service Act (42 U.S.C. § 201 et seq.) made by section 102 of the Public Health Threats and Emergencies Act (Public Law 106-505, title I; 114 Stat. 2315). In at least one instance, a Federal agency caused the cessation of antibiotic use in farm animals to which they were administered, as occurred with fluoroquinolones, where the FDA's Center for Veterinary Medicine found that the use of fluoroquinolones in poultry caused the development of fluoroquinolone-resistant Campylobacter, a pathogen to humans, in poultry, and resulting infections were a hazard to human health. 25 However, thus far Congress has not addressed antibiotic overuse in agriculture. Bill supporters, such as the Union of Concerned Scientists, state that Federal legislation relating to farm animals is needed in order to achieve comprehensive reductions in antibiotic use because few private sector producers of meat products have initiated reductions on their own.²⁶

Federal Pre-emption

The importance of this proposed legislation is highlighted by the dismissal of a lawsuit brought by Animal Defense League of Boston v. Provimi Veal Corp., 626 F.

²⁴ H.R. 2932, 108th Congress (2003); S. 1460, 108th Congress (2003).

²⁵ PCIFAP, supra note 2 at 16; see also Goforth & Goforth, supra note 7 at 50-51 (2000) (discussing the FDA's approval in 1995 of the use of fluoroquinolones in farm animals despite vigorous opposition by the CDC because fluoroquinolones are critically important in treating salmonella in humans). Effective September 2005, five years after the FDA's 2000 proposal to withdraw fluoroquinolone (e.g., enrofloxacin) use in poultry, an Administrative Law Judge ordered that enrofloxacin be so withdrawn. www.journals.uchicago.edu/doi/abs/10.1086/512369 (last visited Jan 3, 2010) and www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm042012.htm (last visited Jan 3, 2010).

²⁶ Union of Concerned Scientists Web page,

http://www.ucsusa.org/food and agriculture/solutions/wise antibiotics/pamta.html (last visited on Nov. 28, 2009); see also APAU, FAAIR Scientific Advisory Panel, Select Findings and Conclusions, CLINICAL INFECTIOUS DISEASES S76 (June 2002) (stating the need for legislation in order to implement APAU recommendations), available at http://www.journals.uchicago.edu/toc/cid/34/s3?cookieSet=1 (last visited Nov. 29, 2009).

Supp. 278 (D. Mass 1986), *aff'd no opinion*, 802 F. 2d 440 (1st Cir. 1986). ²⁷ There were several non-Federal grounds for the suit: (1) violation of state consumer protection laws, contending that if consumers knew of the cruel factory farming conditions they would not consume the veal; (2) violation of state anti-cruelty laws; and (3) violation of both state standards and Federal standards applicable to the use of antibiotics in animal feed. The Court found the plaintiff's goal worthy, but dismissed for lack of standing.

The Court, in finding lack of standing, did so on the following grounds:

- 1. anti-cruelty laws could be enforced only by public officials and humane societies deputized to enforce the anti-cruelty laws. (Plaintiff was not so deputized.)
- 2. the area of antibiotics and antibiotic animal feed was not subject to state or local legislation, citing, *inter alia, Capital Cities Cable Inc.* v. *Crisp*, 467 U.S. 691 (1984). The relevant statute, the Food, Drug, and Cosmetics Act, and relevant regulations under the FDA, completely pre-empted the area and no state or locality could attempt to set a standard any higher than the Federal one.
- 3. as a private organization, plaintiff had no standing to enforce any alleged violations of the Federal Food, Drug and Cosmetic Act.

By its nature, farming and farm products are interstate. In many areas where there is interstate activity, *e.g.*, prohibited animal fighting enterprises and wildlife protection, the Federal, state and sometimes even local governments have concurrent jurisdiction. However, Federal pre-emption of the regulation of antibiotic use on farm animals and farm animal feed ²⁸ demonstrates the importance of this proposed legislation inasmuch as states cannot legally set any greater limitation on antibiotic use in farming, irrespective of their respective legislatures' concerns, than the Federal limitations.

U.S. v Vitek Supply Corporation, 144 F.3d 476 (7th Cir. 1998), cert. denied, 525 U.S. 1138 (1999) further reinforces the relevance of Federal law in this area. In Vitek, a corporation and its president were convicted of conspiracy to defraud Customs and the FDA for distributing adulterated or misbranded animal drugs in its premixes for veal calves (mixtures that feed companies and livestock growers add to animal feed), with intent to defraud or mislead. The company's product contained non-FDA-approved substances – e.g., animal feed tainted with clenbuterol, avoparcine (a dilution of an "antibiotic"), or zinc bacitracin (an antibiotic), or blended into premixes and animal feed - which either promote growth and increase meat-to-fat ratios or are used to treat and prevent diarrhea. The Circuit Court described these substances as follows: "Several of the drugs are carcinogens; one may lead to acute poisoning in humans; and another may

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²⁷ The lawsuit was originally brought in Mass. State Ct. alleging only violations of state law, then upon removal to Federal District Court, plaintiff Animal Defense League amended its complaint to allege violations of the Food, Drug & Cosmetic Act – a consumer fraud theory,

²⁸ The approval of "new animal drugs" is regulated under 21 U.S.C. 360b (a) and (d). A drug that is not a "new animal drug" can be marketed without FDA approval if recognized by experts as safe and effective for the purpose for which it was intended. See 21 U.S.C. 321 (w). Animal feeds that contain antibiotics

increase human resistance to antibiotics." Federal law provides the basis for protecting innocent consumers who would otherwise consume the animal meat that had been treated with the company's tainted products. *Id*.

Supporters and Opponents

As of October 26, 2009, over 200 organizations have endorsed the bill, including agricultural/farming, health, animal protection, consumer, environmental, and religious organizations such as the Union of Concerned Scientists, the Consumers Union, and the Humane Society.²⁹ The FDA also supports the bill³⁰, and the American Medical Association, the Centers for Disease Control and Prevention, the WHO and the Institute of Medicine of the National Academies of Science have all called for restrictions of antibiotic use for non-therapeutic purposes in food animals.³¹

The bill is opposed by some agribusiness advocates such as the National Pork Producers Council³² as well as the American Veterinary Medical Association (AVMA) which disputes some of the PCIFAP's findings and recommendations.³³ The AVMA argued that the legislation would increase animal disease and death without assuring improved human health.³⁴ The AVMA cites as support the examples of Denmark and The Netherlands, which instituted a ban on the use of antibiotics as growth promoters in 2000 and 1999, respectively. The AVMA argues that in both countries, there is little evidence that antibiotic resistance in humans decreased and that death and disease in animals increased, along with greater amounts of antibiotics used therapeutically to address the increase in disease.³⁵

The PCIFAP disputes the AVMA's argument, noting that Danish swine production actually increased following the ban, the cost of meat did not increase following the ban, and that there was a decrease in antibiotic-resistant bacteria in food animals and meat.³⁶ The Danish Chief Veterinarian's letter to Congress also contradicts

require FDA approval. See 21 U.S.C. Secs. 360b (m) and 321 (x).

²⁹ Humane Society Veterinary Medical Association Web page, Endorsers List, http://www.hsvma.org/pdf/pamta-endorsers-102609.pdf (last visited).

Testimony of Joshua M. Sharfstein, M.D., Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration, U.S. Dept. of Health and Human Sycs., available at

http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=106468.

Institute for Agriculture and Trade Policy, Press Release, September 9, 2009, *available at www. latp.org/iatp/*press.cfm?refID=106736 (last visited Dec. 29, 2009)

National Pork Producers Council Web page, Kennedy Antibiotics Ban Detrimental to Pigs, http://www.nppc.org/News/DocumentSingle.aspx?DocumentID=24542 (last visited Nov. 29, 2009).

³³ AVMA Response to the Final Report of the Pew Commission on Industrial Farm Animal Production (2009), *available at* http://www.avma.org/advocacy/PEWresponse/PEW_report_response.pdf. ³⁴ *Id* at 5.

³⁵ *Id*.

³⁶Laura Rogers, project director of the Pew Campaign on Human Health and Industrial Farming, *What Can Danish Hogs Teach Us About Antibiotics*, THE HUFFINGTON POST (Oct. 13, 2009), *at* http://www.huffingtonpost.com/laura-rogers/what-can-danish-hogs-teac_b_318478.html (last visited Nov. 29, 2009).

the AVMA's assertions about productivity, animal health, and consumer prices.³⁷

Moreover, numerous animal-welfare groups support the bill because they believe, contrary to the AVMA's position that animal health may be impaired from a reduction in antibiotic use, that such reduction will make it necessary for farmers to keep animals in more humane conditions.³⁸ Farmers may have a strong economic incentive to reduce stress placed on animals in production.³⁹ For example, farmers may reduce the practice of removing weaning piglets prematurely, the movement and transport of animals, and unsanitary housing conditions.⁴⁰ The FAAIR Report found that antimicrobial resistance has an impact on animal health, though little is yet known about the magnitude of the problem. Therefore, reducing the non-therapeutic use of antibiotics in farm animals may result in an improvement of the overall health of farm animals.⁴¹

Summary

The proposed law has the potential to improve the health of both farm animals and humans. It also has the potential to give farmers an economic incentive to reduce stressful practices in IFAPs, improving the inhumane conditions that farm animals endure. Therefore, the ABCNY fully supports these bills.

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³⁷ Letter from Danish Chief Veterinarian, Danish Veterinary and Food Administration, to Congress 3 (Aug. 12, 2009), *available at* http://www.saveantibiotics.org/resources/DanishChiefVet.pdf (last visited Nov. 29, 2009).

³⁸ E.g., ASPCA Web page,

https://secure2.convio.net/aspca/site/Advocacy?cmd=display&page=UserAction&id=2615 (last visited Nov. 29, 2009).

³⁹ Terence J. Centner, *Regulating the Use of Non-Therapeutic Antibiotics in Food Animals*, 21 GEO. INT'L L. REV. 21 (2008).

⁴⁰ Id.

⁴¹ APAU, FAAIR Scientific Advisory Panel, *Select Findings and Conclusions*, CLINICAL INFECTIOUS DISEASES S73 (June 2002), *available at* http://www.journals.uchicago.edu/toc/cid/34/s3?cookieSet=1 (last visited Nov. 29, 2009).