

Antibiotic Resistance Action Center, the George Washington University*Center for Biological Diversity*Center for Foodborne Illness Research & Prevention*Center for Food Safety*Center for Science in the Public Interest*Clinician Champions for Comprehensive Antibiotic Stewardship*Consumer Federation of America*Consumer Reports *Environmental Working Group*Food & Water Watch*Food Animal Concerns Trust*Friends of the Earth*Government Accountability Project*Health Care Without Harm*Humane Society Legislative Fund*Humane Society of the United States*Human Society Veterinary Medical Association*Infectious Diseases Society of America*International Center for Technology Assessment*John Hopkins Center for a Livable Future*National Center for Health Research*National Resources Defense Council*Pediatric Infectious Diseases Society*Society of Infectious Diseases Pharmacists*U.S. PIRG

November 19, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We are writing to express our deep concern about the current draft position of the United States Government at the Codex Alimentarius Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance regarding the use of antibiotics important to human medicine for the purposes of promoting growth in food animals. We urge you to ensure that the U.S. opposes the use of medically important antibiotics in animals for growth promotion without exception when this committee meets in early December. The U.S. position should be consistent with current Food and Drug Administration (FDA) policy as well as your previous statements on this subject.

We were greatly encouraged by your [comments](#) at the Pew Charitable Trusts on September 14, 2018, on FDA's Strategic Approach for Combating Antimicrobial Resistance, where you noted that FDA's "aim was to eliminate production uses of [medically important] antibiotics, such as growth promotion." Antibiotic resistance is a global crisis, which the Centers for Disease Control and Prevention estimates already causes 23,000 deaths a year in the United States. We therefore commend FDA for its success in this area, as a result of which antibiotic products intended for animals that are important to human medicine no longer mention growth promotion on their label indications for use.

As the Codex Task Force on Antimicrobial Resistance negotiates a global Code of Practice on antibiotic use in agriculture, we are surprised and concerned that the U.S. government is not seeking global agreement to eliminate the use of medically important antibiotics for growth promotion worldwide. The current language in the draft Code does not

call for a blanket prohibition on production uses of antibiotics, as is FDA policy. Rather, it includes a significant exception that would allow the use of medically important antimicrobials for growth promotion purposes if a risk analysis is conducted. Principle 5 of the draft Code states, “Responsible and prudent administration in food-producing animals does not include the use for growth promotion of antimicrobial agents that are considered medically important ... in the absence of a risk analysis.” This language creates a large loophole through which other countries could continue to authorize the use of medically important antibiotics for growth promotion--they need only to have analyzed the risk of doing so, regardless of the magnitude of that risk.

FDA and USDA collaborate in developing the U.S. positions at Codex, which should be consistent with established U.S. policy. Given that the U.S. does not allow medically important antimicrobials to be used for growth promotion purposes under any circumstances, the draft U.S. position should oppose the language in Principle 5 that would permit the use of medically important antimicrobials, if there is a risk assessment.

The growth of antibiotic resistance is an urgent worldwide crisis, fueled by the overuse of antibiotics in both human medicine and animal agriculture. Resistant bacteria do not respect national borders. It is extremely likely that multi-drug resistant bacteria that arise as a result of antibiotic overuse in animals in other countries will eventually make their way to our shores, and cause illnesses and deaths here. All countries, not just developed countries like the U.S. and the EU, must end the use of medically important antibiotics for growth promotion in animals if we are to control resistance and preserve their effectiveness for fighting disease in people. While many global experts have called for stronger action to reduce antibiotic use on animals that are not sick, this request is focused solely on aligning the U.S. Codex position with its own regulations on antibiotic use in livestock.

In conclusion, we urge you to work with your colleagues at USDA to ensure that the U.S. position on Principle 5 of the Code of Practice makes it clear that medically important antimicrobials should not be allowed for growth promotion purposes, without exception.

We appreciate your consideration of our views.

Sincerely,

Consumer Reports
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Humane Society Legislative Fund
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National Center for Health Research
National Resources Defense Council
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Society of Infectious Diseases Pharmacists
U.S. Public Interest Research Group

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