

May 16, 2013

Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
White Oak Building One
10903 New Hampshire Avenue, Room 2217
Silver Spring, MD 20993

Dear Commissioner Hamburg,

We are astounded by the U.S. Food and Drug Administration's (FDA) recent action to discredit a public interest group's report about the problem of rising antibiotic resistance. The action sends exactly the wrong message to the pharmaceutical industry and to the public. We urge the FDA to immediately rescind its published statement. At the very least, any FDA statement should be consistent with the Agency's own prior assessment of the science. The statement in question is not.

On April 22, 2013, the FDA published a media release entitled "[FDA Cautions in Interpretation of Antimicrobial Resistance Data](#)," charging that the Environmental Working Group's (EWG) recently [published summary](#) of FDA's [2011 Retail Meat Annual Report of the National Antimicrobial Resistance Monitoring Systems \(NARMS\)](#) data is "alarmist," "inaccurate," and "misleading." FDA staff made similar assertions in a [letter](#) published in the *New York Times* on April 23, 2013.

We are surprised and disappointed that your agency would launch a communications campaign seeking to downplay the risks posed by antibiotic resistant pathogens in the food supply. In 2009, the Principal Deputy Commissioner of Food and Drugs [testified](#) that "antimicrobial use in animals has been shown to contribute to the emergence of resistant microorganisms that can infect people. The inappropriate nontherapeutic use of antimicrobial drugs of human importance in food-producing animals is of particular concern." You yourself edited a [report](#) that stated that "[s]ubstantial efforts must be made to decrease inappropriate overuse of antimicrobials in animals and agriculture as well." Moreover, most of the statements contained in the EWG report are findings that the FDA previously published in the *2011 Retail Meat Annual Report*. In support of its charge that EWG has exaggerated the health risks, the agency published a partial list of selected findings from the *2011 Retail Meat Annual Report* data that are clearly intended to downplay perceived risk. These findings include those where resistant bacteria were not found or found with low frequency. In making this argument, the agency omits mention of the more worrisome findings from its own report. Some examples include:

- There were significant increases in ampicillin resistance among retail chicken and ground turkey [*Salmonella*] isolates from 2002 through 2011.
- A full 44.9% of retail chicken isolates were resistant to 3 antimicrobial classes, as were 50.3% of ground turkey isolates.
- Between 2002 and 2011, the FDA's report shows that the prevalence of *Salmonella* resistant to three or more classes of antibiotics rose from 20.0 percent to 44.9 percent on retail chicken and from 20.3 percent to 50.0 percent on ground turkey.

Further, while the FDA strongly de-emphasizes the importance of the *Enterococcus* figures in EWG's report, the agency fails to stress why it then measures resistance among these bacteria in the first place. According to the FDA's original *2011 Retail Meat Annual Report*, the resistant nature of

Enterococcus is highly relevant to the use of antibiotics in food animal production. The agency noted that the bacteria were resistant to “many antimicrobials used in food animal production” yet “no isolates were resistant” to drugs not used on industrial farms. This correlation struck the FDA as significant in February, yet we are dismayed that it omitted this finding from its response to EWG.

Contrary to the FDA’s assertions in its response to EWG that *Enterococcus* is not a true pathogen, *Enterococcus* is a leading cause of [nosocomial infections](#) in the United States, and is a frequent cause of bacteremia, urinary tract infections, and heart infections. Treatment for all of these requires effective antibiotics. In addition to directly causing illness, there is [also considerable evidence](#) that *Enterococcus* can transfer resistance traits to other bacteria that could then cause illness. Similarly, the FDA’s assertion that *Enterococcus* is not foodborne oversimplifies and misstates the available scientific [evidence](#). While the extent to which food plays a role in the spread of resistant *Enterococcus* is still unclear, there is considerable evidence that *Enterococcus* in food and food animals can be a source of resistant infection in humans. Because of this, the [World Health Organization](#) (WHO) considers *Enterococcus* along with *Escherichia coli*, *Salmonella*, and *Campylobacter* as bacteria “that commonly transfer to people from food animals.”

We urge you to rescind the public statement now published on the FDA’s website in response to EWG’s report and to clarify that the NARMS report does not indicate that there is no problem with resistant pathogens in food including resistant *Enterococcus*. We also hope you will redouble your efforts to collect and report more detailed antibiotic sales and use data pertaining to food animal production, and to thoroughly eliminate antibiotic practices that the agency well knows threaten human health. The FDA should use its bully pulpit to convince industry that antibiotic stewardship is needed and to counter industry misinformation that says antibiotic use in animals is not a matter of concern. It should not attack public interest groups calling for appropriate action.

When several representatives from health and environmental organizations met with you in 2009, you described the problem of antibiotic resistance as similar to having your “hair on fire.” We regret that the agency’s actions to date do not reflect this urgency. That urgency is certainly now felt by clinicians and patients alike as we experience the diminishing effectiveness of life-saving antibiotics.

We thank you for your consideration in reading our comments. If you would like to speak with a representative of any of the undersigned groups, please contact Jonathan Kaplan at jkaplan@nrdc.org.

Sincerely,

Center for Food Safety
FamilyFarmed.org
Food Animal Concerns Trust
Food & Water Watch
Health Care Without Harm
Humane Society of the United States
Institute for Agriculture & Trade Policy
Johns Hopkins Center for a Livable Future

Keep Antibiotics Working
Physicians for Social Responsibility
School Food FOCUS National Office
STOP Foodborne Illness
The Association for Politics and the Life Sciences
Union of Concerned Scientists