Waxman

October 17, 2016

The Honorable Sylvia Mathews Burwell
Secretary, United States Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Room 120 F
Washington, D.C. 20201

Dr. Robert McKinnon Califf
Commissioner, United States Food and Drug Administration
White Oak Building One
10903 New Hampshire Avenue
Room 2217
Silver Spring, Maryland 20993

Dear Secretary Burwell and Commissioner Califf,

Antimicrobial resistance is one of the most serious threats to global health this century. The Food and Drug Administration has taken a leading role in addressing this threat by releasing guidance on judicious use, enhancing surveillance, expanding research and education, and acting as part of a global effort to reduce resistance. The FDA's actions, along with strategy meetings by the White House, the United Nations, and various industry stakeholders, confirm that antimicrobial resistance is an issue that must be taken seriously and addressed quickly. I am writing to commend this work, and to encourage you to take further action on this issue.

One contributor to the AMR crisis has not been adequately examined on a systemic level: pollution from drug manufacturing facilities producing antibiotics, which are predominantly produced in India and China. Recent reports indicate that Indian and Chinese drug makers routinely release untreated waste fluid containing active ingredients into surrounding soil and waterways. One study published in Journal of Hazardous Materials showed antibiotic concentrations downstream of drug manufacturing plants in these countries that exceed those expected in a patient being treated for infection. Researchers from Rice, Nankai and Tianjin universities concluded that for every bacterium that entered a waste treatment plant in northern China, four or five resistant bacteria were released into the water system.

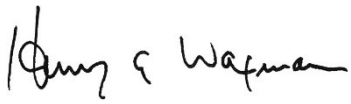
Pollution of active ingredients by antibiotic manufacturers is not mentioned in any plan to address antimicrobial resistance released by the U.S. government. However, 13 pharmaceutical companies have pledged to crack down on the practice, effectively admitting that the problem is real, and is contributing to the AMR crisis. This admission in addition to a growing body of research supports the view that factory pollution of antibiotic active pharmaceutical ingredients creates the perfect conditions for resistance to develop and spread.

The FDA is in the ideal position to encourage others to take action, even though it cannot take direct action itself. First, I ask that you coordinate with your Indian and Chinese counterparts to ensure they have environmental controls in place to eliminate antibiotic pollution. Second, I ask that you work with

all U.S. pharmaceutical companies that import antibiotics to implement all necessary steps to stop antibiotic pollution in their manufacturing supply chains. And last, I would ask you to explore if it is possible for the FDA to spur pharmaceutical company cooperation by making limiting environmental impact part of good manufacturing practices and expanding transparency requirements.

Thank you for all of your hard work on preventing the spread of antimicrobial resistance. It will take a coordinated effort to fight antibiotic pollution as a contributor to AMR, and the FDA has an opportunity to be a leader in that fight. I look forward to hearing back from you on this issue. If you have any questions, or would like to schedule a meeting to discuss this issue further, please contact Casey Farrington at (202) 899-2634 ext. 105 or casey@waxmanstrategies.com.

Sincerely,



Henry Waxman
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