



the campaign for
environmentally responsible
health care

CAMPAIGN HEADQUARTERS

12355 SUNRISE VALLEY DRIVE
SUITE 680
RESTON, VA 20191
T: 703.860.9790
F: 703.860.9795
EMAIL: INFO@HCWH.ORG
WWW.NOHARM.ORG

The Honorable Margaret A. Hamburg, M.D.
Commissioner
C/o Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

July 16, 2014

Dear Commissioner Hamburg:

As representatives of the health care sector, we are writing to respectfully request your continued leadership in addressing the growing crisis of antibiotic resistance.

As health professionals, we ourselves are taking steps to fight this public health crisis in several ways including educating our colleagues, patrons, communities, and patients on when it is appropriate to use antibiotics and, increasingly, by purchasing meat from farms that raise their livestock with little or no antibiotics.

Today, medically-important antibiotics sold for food animals constitute more than 70 percent of total reported sales of these drugs in the United States. This statistic is particularly troubling considering that decades of science prove that antibiotic overuse on the farm directly contributes to antibiotic-resistant infections in people. Antibiotic resistant infections are harder and more expensive to treat and lead to greater rates of hospitalization and even death.

As we work in the health care sector to save the efficacy of antibiotics, we hope to see industrial food producers do the same. We thank you for finalizing Guidance for Industry #213 (Guidance 213) last December and for your transparency in publicly announcing drug sponsor compliance with the voluntary program. At the same time, we remain concerned that the guidance will not do enough to reduce antibiotic use in animal production. In particular, many medical, public health and consumer groups are worried that FDA's choice to not seek reductions in disease prevention uses may still allow significant unnecessary uses of antibiotics. To prevent this, FDA must ensure there is a clear and defensible distinction between effective, targeted prevention uses that are essential to animal health and those prevention uses that could be replaced with effective

alternatives. Antibiotics are not production tools to be wielded wantonly without authentic veterinary involvement; if the animals cannot remain infection-free absent continuous, preventive medication, then better hygiene practices or other measures need to be implemented. We do not turn to antibiotics as a first-resort solution to sanitation issues, and neither should industrial farms.

Importantly, Guidance 213 confers primary responsibility to veterinarians for ensuring preventive uses of antibiotics are judicious. Last December when FDA finalized Guidance 213, it also released a draft Veterinary Feed Directive rule. Unfortunately, this draft rule removed the current requirement for a valid veterinarian-client-patient relationship and put it under the purview of the states to define. States may or may not choose to require familiarity with the animals and farm. FDA should amend the draft rule and require veterinarians to examine the animals or visit the premises where the animals are kept. There is no other way to know whether antibiotics are being used responsibly and judiciously.

We urge FDA to address disease prevention and require meaningful veterinary oversight on the farm as expeditiously as possible. We strongly believe that FDA can help save antibiotics and lives by adopting these suggestions.

Thank you for your consideration.

Sincerely,

The undersigned 805 health professionals:

(Signatures removed for public pdf)