

John P. Holdren, Ph.D.
Eric Lander, Ph.D.
Co-Chairs
President's Council of Advisors on Science and Technology
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

Dear Dr. Holdren and Dr. Lander:

Good morning and thank you to the President's Council of Advisors on Science and Technology for inviting me to give comments this morning. As you complete your report on antibiotic resistance for President Obama, I would like to note a few recent developments for your consideration.

On July 1st, the CDC released a report on resistant, foodborne bacteria as part of the National Antimicrobial Resistance Monitoring System. It stated that "antibiotic resistance in foodborne germs is an ongoing threat," adding that such resistant foodborne pathogens sicken at least 430,000 people every year. This resistance can be mitigated.

Second, on June 30, FDA issued its first report on the progress of Guidance for Industry #213. While all of the pharmaceutical companies that sell antibiotics for growth promotion ensured FDA they will stop doing so within three years, several of the largest companies will continue to sell antibiotics for "the maintenance of weight gains" so that subtherapeutic use will not change. The marketing materials of these companies, and their sales practices, must change for the voluntary guidances to be impactful.

Earlier this year, this council heard testimony as to how, in theory, drug companies and livestock producers could exploit loopholes in Guidance #213 to continue using antibiotics to boost production. And we have several real-life, real-time examples that demonstrate just how they will carry this out. The public health goal of the FDA policy to reduce antibiotic resistance, while laudable, can only be achieved through significant reductions in the use of antibiotics in food animals.

FDA relies on veterinarians to ensure appropriate use, and they use this onus of responsibility to justify why the agency doesn't do more to curb disease prevention. Yet in FDA's attempt to put veterinarians in the driver's seat, FDA has taken one step forward and two steps back. Requiring veterinarians to prescribe or order antibiotics for use in animal feed and water is an important step, but in its draft rule, the agency proposes to roll back federal standards for veterinary oversight. Of greatest public health concern, FDA would eliminate the current federal definition of a veterinarian-client-patient relationship (VCPR) with respect to animal

antibiotics and instead would defer to a patchwork of state policies. However, there are four states have no such definitions, and in the 34 states that do, their definitions do not apply to the addition of drugs to animal feed. FDA envisions state policies as a safety net, but that is only accurate in the sense that nets are full of holes.

I respectfully urge this council to consider the clear and overwhelming scientific weight of evidence that antibiotic overuse in livestock threatens human health, as well as the equally clear practical evidence that drug companies and industrial livestock producers will continue to protect their bottom line and misuse antibiotics unless FDA takes steps to close the disease prevention loopholes in Guidance #213 and require meaningful veterinary oversight.

Please advise President Obama to: (1) strengthen Guidance #213 so that FDA can eliminate wanton uses of antibiotics for disease prevention; (2) uphold existing federal standards that will ensure meaningful veterinary oversight of antibiotic use; and (3) restrict pharmaceutical marketing claims that emphasize the growth promoting benefits of antibiotics.

Thank you.

If you have any questions, feel free to contact me, sgrooters@keepantibioticsworking.com.

Sincerely,

A handwritten signature in black ink that reads "Susan V. Grooters". The signature is written in a cursive, flowing style.

Susan Vaughn Grooters, MPH, DrPH (c)
Policy Analyst
Keep Antibiotics Workin