



**UNIVERSITY OF
PENNSYLVANIA
MEDICAL CENTER**

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Bernard Schwetz, D.V.M., Ph.D.
Acting Lead Deputy Commissioner
Food and Drug Administration
Rockville, MD 20857

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Dear Dr. Schwetz:

We, as concerned scientists and academic physicians, are writing about a crucial issue that demands urgent attention. Two years ago, the Center for Science in the Public Interest filed a petition ("Petition to Rescind Approvals of the Subtherapeutic Uses in Livestock of Antibiotics Used in (or Related to Those Used In) Human Medicine," Docket #99P-0485) with the Food and Drug Administration. The petition called for the ban of medically important antibiotics used as growth promoters in livestock. We recognize the strides the FDA has made towards addressing a framework for new drug approvals. This framework would consider antibiotic resistance and the public health standard of reasonable certainty of no harm in the criteria for approval. However, almost no activity has taken place regarding growth promoters.

Antibiotic resistance is a growing crisis in medicine. We are seeing patients infected with bacteria resistant to the best antibiotic treatments. Occasionally, no antibiotic therapy is available. We recognize the important role that medical practice plays in this problem. However, that is not a reason for inaction on the agricultural side.

Growth promotion is not essential for the welfare of the animals. It is solely used to fatten the animals more rapidly to bring them to market quickly. Other management practices can be used along with other medications that pose no risk to human health. Instead, millions of pounds of antibiotics like tetracycline, penicillin, and virginiamycin are added to feed and water. These antibiotics create a reservoir of resistant bacteria that pose a real human health threat. An environmental impact also exists, and needs to be further quantified.

Without evidence that this use is safe, the FDA must protect the public health and ban medically important antibiotics from nontherapeutic uses in agriculture. We urge you to act on the CSPI petition expeditiously.

Thank you for your consideration.

Sincerely,

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Brian L. Strom, M.D., M.P.H.

99P-0485



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UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

