Congress of the United States
Washington, DC 20510

January 16, 2014

The Honorable Gene Dodaro
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Dodaro:

We write to request that the U.S. Government Accountability Office (GAO) conduct a study on the compounding of drugs for use in animals. Congress recently passed the Drug Quality and Security Act (DQSA), which helps resolve the legal uncertainty surrounding compounded drugs for humans that contributed to the fungal meningitis outbreak that began last year. The DQSA amends section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) by striking its unconstitutional provisions so that it will have clear legal effect throughout the country.

There is no counterpart provision to section 503A in the FDCA that explicitly addresses animal drug compounding. The FDA recognizes certain compounding of animal drugs from approved products in regulation, however, and FDA exercises enforcement discretion regarding the compounding of specified animal drugs from bulk ingredients.

Although we did not change the laws governing compounding of animal drugs in the DQSA, during our deliberations on the bill we recognized the need for further study of the issue. While we heard that compounded drugs play an important role in animal health, we also heard disturbing reports about animals receiving unproven or unsafe compounded drugs and about the compounding of copies of approved animal drugs discouraging companies from manufacturing these approved drugs and from undertaking the approval process for new animal drugs. We also found that there is widespread confusion about the regulatory landscape for animal drug compounding, not unlike that which existed for human drug compounding before the DQSA.

Therefore, to inform Congress' future consideration of animal drug compounding policy and oversight, we request GAO work with federal and state authorities, veterinarians, animal drug manufacturers, animal drug compounders, and other relevant stakeholders to examine the following issues with respect to compounding drugs for food animals and non-food major and minor species:

(1) current state and federal laws and policies regarding compounding of drugs for animals, including how state and federal litigation has affected the enforcement and implementation of such laws and policies ;
(2) the safety and effectiveness of compounded animal drugs and adverse events associated with such drugs;
(3) the extent to which compounding of animal drugs, including compounding copies or near-copies of approved animal drugs, affects the drug approval process;
(4) the standards and practices used by animal drug compounders to assure the quality and potency of bulk ingredients;
(5) promotion and marketing of drugs compounded for animal use; and,
(6) the extent to which compounded animal drugs fill clinical needs that cannot be met through approved animal or human drugs.

Thank you for your careful consideration of our request. If you have any questions about this request, please have your staff contact Nathan Brown with Chairman Harkin at 202-224-7465, Grace Stuntz with Ranking Member Alexander at 202-224-0623, Carly McWilliams with Chairman Upton at 202-225-2927, and Eric Flamm with Ranking Member Waxman at 202-225-5056.

Sincerely,

Tom Harkin
Chairman
HELP Committee

Lamar Alexander
Ranking Member
HELP Committee

Fred Upton
Chairman
Energy and Commerce Committee

Henry Waxman
Ranking Member
Energy and Commerce Committee