

Why GAO Did This Study

Drug compounding for animals involves combining, mixing, or altering ingredients to create drugs tailored to the medical needs of individual animals. While states have primarily exercised responsibility for oversight of drug compounding, FDA is responsible for ensuring the safety and effectiveness of drugs marketed in the United States, including animal drugs. FDA regulations generally allow for drug compounding for animals from approved animal or human drugs but not from bulk active pharmaceutical ingredients—the raw ingredients that make up finished drug products. Mistakes in compounding drugs for animals can result in injuries to or deaths of animals.

GAO was asked to review drug compounding for animals. This report examines (1) the benefits and risks of drug compounding for animals, (2) the extent of drug compounding for animals, and (3) FDA's approach to regulating these drugs. GAO reviewed federal regulations and guidance, FDA documents, and 18 peer-reviewed and other studies assessing drugs compounded for animals. GAO also interviewed federal and state regulatory officials, and a range of stakeholders in the animal health industry.

What GAO Recommends

GAO recommends that FDA modify its reporting form, develop guidance for agency staff regulating compounding for animals, and document consistently the bases for its regulatory actions. FDA generally agreed with GAO's recommendations.

View [GAO-15-671](#). For more information, contact Steve D. Morris at (202) 512-3841 or morris@gao.gov.

DRUG COMPOUNDING FOR ANIMALS

FDA Could Improve Oversight with Better Information and Guidance

What GAO Found

Drugs compounded for animals offer certain medical benefits but also pose risks of causing harm or being ineffective. Specifically, drugs compounded for animals can serve as treatment options when no suitable drug approved by the Food and Drug Administration (FDA) is available. For example, no FDA-approved drugs exist to treat megacolon—a potentially lethal form of constipation—in cats, so veterinarians rely on a compounded drug for treatment. Drugs compounded for animals can also pose risks of serious harm or may be ineffective if they contain too much or too little of an active ingredient, according to scientific studies and veterinary experts. However, FDA has acknowledged that it is not practical for the agency to approve each drug compounded for every animal that requires one; as a result these drugs are not reviewed for safety and effectiveness. In addition, because states have primarily exercised responsibility for pharmacies that compound drugs for animals, the states and not FDA generally review pharmacy compounding processes.

The extent to which drugs are compounded for animals is unknown because the information FDA and states collect is not aggregated or comprehensive for various reasons. First, unlike animal drug manufacturers, drug compounding pharmacies do not have to register with FDA. Second, although FDA and states try to share information about drug compounding pharmacies with each other, due to some states' privacy and confidentiality laws this information sharing is impacted. For example, FDA officials told GAO that some states are unable to share information about the results of their pharmacy inspections with FDA because of their states' privacy laws. Finally, FDA does not know the extent to which compounded drugs are associated with adverse events, in part because the form used to voluntarily report such events does not ask if a compounded drug was involved. Federal standards for internal control state that agencies are to obtain information from stakeholders that may have a significant impact on achieving its goals. By not asking for compounded drug information on its reporting form, FDA is missing an opportunity to inform its enforcement actions regarding animal drug compounding.

FDA does not currently have final guidance directing its regulatory approach on drug compounding for animals and has not consistently documented the bases for the actions it has taken to regulate such compounding in the past. Until May 2015, FDA had guidance to direct its regulation of drug compounding for animals. In May 2015, FDA withdrew the guidance because it did not reflect FDA's current thinking on the issues and has not yet replaced it. This lack of guidance is inconsistent with federal internal control standards and raises concerns as to how FDA staff will make consistent decisions on enforcing animal drug compounding regulations in the future. Moreover, with regard to the actions FDA has taken against pharmacies compounding drugs for animals from bulk active pharmaceutical ingredients, the agency has not consistently documented how or whether it followed up on these actions. This lack of consistent documentation is also not in accordance with federal internal control standards, and without complete and consistent documentation of its actions, FDA cannot ensure that its regulatory approach is being applied consistently.