



Alliance for a Stronger FDA Budget Priorities Webinar Series
Summary of Webinar with Dr. Steven Solomon, Director of the Center for
Veterinary Medicines (CVM)
April 22, 2022 | Moderated by Peter Lurie and Allison Phibbs

The Alliance for a Stronger FDA on April 22 continued its FY 23 FDA budget webinar series with Dr. Steven Solomon, DVM, Director of FDA's Center for Veterinary Medicine. Dr. Solomon provided an overview of CVM's work. It is the smallest of the various FDA Centers, representing just 4% of FDA's budget. They have 700 FTEs, overseeing a \$560 billion industry. Two-thirds of all households have pets. Food producing animals are particularly important both for nutrition and for human health.

FY 23. With respect to the President's FY 23 budget request for CVM, the budget is proposing increases of \$22.9 million and 47 FTEs across multiple areas including \$10.1 million for data management enhanced technology building on work started in FY 22; \$5 million for premarket animal drug review, noting a big increase in workload and the need to hire additional personnel; \$.8 million for medical product supply chain data gaps; \$.7 million for reducing animal testing through alternate testing methods; \$4.6 million for New Era Smarter Food Safety; and \$1.8 million to help cover increased pay costs.

FY 22. As part of the final FY 22 appropriations action, he said CVM will receive a total of \$181 million (\$129 million in budget authority and \$52 million in user fees). Both the House and Senate had proposed more for CVM in their respective bills, but available funding was reduced in the final agreement. Specific items provided include \$6.2 million for human and animal health; \$2.3 million for animal food safety; \$1 million for animal food ingredients; \$1.5 million for medical supply chain; \$.5 million for data modernization; and \$.9 million to help cover some of the FY 22 cost of living adjustments. With respect to animal food safety Dr. Solomon emphasized that this is an issue that people "really care about." He noted past experiences of contaminations coming from pig ear pet treats and aflatoxin as examples. CVM is partnering with states which conduct 80% of inspections in this area.

Pandemic. Dr. Solomon said the only positive note coming from the pandemic was the increased adoption of pets from animal shelters. CVM did provide a number of flexibilities for the duration of the public health event, and they will have to determine how to deal with them in the future. He noted remote regulatory inspections and remote record analysis as two examples. CVM plans to review its overall inspection program looking to move to comprehensive inspections. They also want to improve inventory and risk models.

Data Modernization. Data modernization and enhanced technology were identified as major infrastructure needs. He suggested that Ukraine being the largest supplier of sunflower oil and the Russian production of Cobalt 60 demonstrate the need to modernize systems to provide better assessment of supply issues. FDA systems need to be able to talk to each other. Significant investment is needed in lab assessments, including FDA's aquaculture facility.

One Health. The One Health approach is being used to better understand the interconnection between human, animal, and plant health. There is a desire to better link local, regional, national, and global levels for the better exchange of information. He used Mad Cow Disease, Creutzfeldt-Jakob, Monkey Pox, and melamine in pet food which was later found in infant formula in China as examples of the need for the One Health approach. They are working with the Office of the Chief Scientist and looking to create a Center for One Health Excellence. Some resources may be provided as part of pandemic preparedness.

Anti-microbial resistance. Regarding anti-microbial resistance, Dr. Solomon said CVM has been very active for decades. They have a five-year plan for anti-microbials, have developed various guidance documents, ranking criteria, and stewardship projects. They are collaborating with stakeholders as to how to measure progress.

Dr. Solomon responded to several questions:

- ***CVM in the context of the pandemic*** – CVM has followed transmission to and from animals, finding mild illnesses in dogs and cats. No evidence that companion animals transmit COVID back to humans. There has been evidence of transmission from minks in Europe. There is also concern that the deer population could be an animal reservoir for the virus.
- ***Goals for CVM over the next five years*** - Very active on antimicrobial resistance, seeing challenges increasing exponentially. The development of more innovative products will require more people, technology enhancements, and strategies for dealing with emergency issues. More oversight of animal food will be needed, looking at pet food safety and enhancing mutual reliance with states. Post market surveillance on the drug side is needed. While there are 100,000 adverse event reports each year only 25% are looked at. The animal food industry is increasingly innovative, and FDA needs to be prepared.
- ***CVM's hiring priorities*** – CVM has a fairly low attrition rate. While lots of people would like to work at CVM, they do not have the resources to hire them. They are doing horizon scanning to determine what skills they will need in the future. He mentioned geneticists, bioinformaticists, and statisticians.
- ***Compounding Guidance*** – Compounding is a need for animal drugs but should be done in a way that does not undermine safety. CVM has delayed inspectional activities to provide time for education actions until the beginning of the next fiscal year.
- ***Most exciting areas of innovation*** – He suggested veterinary regenerative medicine; animal cell and tissue production; the need for good high-quality data from scientific studies; animal genetic information; investment in research infrastructure; veterinary innovation program; and new guidance on the use of biomarkers.

- ***Supply chain delays for veterinary food or medicines*** – There have been significant challenges, with staffing, manufacturing, ingredients, and packaging. CVM has worked hard to mitigate shortages. There are significant challenges with animal food, now seeing that fuel ethanol is having a ripple effect with the diversion of fats and oils to green energy. More time needs to be spent looking at the issue.