The Center for Veterinary Medicine at FDLI's Annual Conference

By Katie Gates Calderon

The Center for Veterinary Medicine (CVM) breakout session provided participants and attendees with an insightful update regarding CVM's recent undertakings, as well as a forward-looking preview outlining its short- and long-term focus points.

Director Steven Solomon, D.V.M., M.P.H, delivered introductory remarks detailing the Center's recent actions and accomplishments since he was appointed in January 2017. His remarks were followed by those of Jesse Sevcik, the Senior Director of Global Government Affairs for Elanco Animal Health, and Peter Tabor, Vice President of Regulatory and International Affairs, Pet Food Institute (PFI). Madeleine McDonough, Chair of Shook, Hardy & Bacon LLP, asked the panelists several questions about recent trends following their introductory remarks. Below I detail a few topics covered at the breakout session.

User Fees

Dr. Solomon indicated that one area where CVM remains focused is on premarket animal drug reviews, and he discussed the successes and forthcoming reauthorizations of the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA). The fees collected through these programs allow FDA to enhance the timeliness and predictability of drug application reviews. Dr. Solomon reiterated how the programs have benefitted industry. According to him, CVM's focus is to encourage innovation by ensuring that these programs are well-funded and efficient to facilitate getting animal drugs safely but efficiently to market.

Notably, Mr. Sevcik agreed and provided industry's viewpoint on these particular issues, including that the U.S. is on the forefront of animal health developments due, in part, to ADUFA and AGDUFA. Before these programs (and enhancements to the same over the years), the timelines for animal drug approvals were twice as long, and it was hard for industry to get feedback from or engagement with CVM. The net effect of this prolonged process was that the ultimate products brought to market were not necessarily innovative or novel because getting approval was simply too difficult.

Because of ADUFA and AGDUFA, Mr. Sevcik relayed that industry research and development resources directed towards the formulation of new drugs has increased because companies have confidence that they can work with CVM to identify innovative products, bring novel candidates forward, and ultimately work with CVM to get approval. From Mr. Sevcik's perspective, Dr. Solomon and CVM's openness and transparency about both ADUFA and AGDUFA have further played a positive role in this outcome. In particular, Mr. Sevcik credits CVM's presubmission and feedback process because it allows industry to get early feedback and implement it into the clinical development process.

Mr. Tabor also reiterated that he encourages his clients to engage with FDA because the result is generally productive dialogue. That said, both panelists encouraged CVM to keep looking to improve ADUFA and AGDUFA with the goal of encouraging and incentivizing companies to continue to engage in identifying new products and bringing them to market. FDA's authorization to collect fees under both programs is set to expire in September 2018. All in all, Dr. Solomon, who detailed a few notable changes in proposed ADUFA IV and AGDUFA III provisions, believes that both programs will be reauthorized because the history of CVM and industry, as well as the success of user fees, is largely positive.

Biotechnology

Biotechnology and regulation of the same were also discussed both in introductory comments and further in response to a panel question by Ms. McDonough. Dr. Solomon noted that technology continues to advance in this area, specifically mentioning gene editing techniques like CRISPR. CVM's approach to regulation will focus on potential positive uses or outcomes for biotechnology, as well as potential issues and effective regulation using a risk-based approach. Dr. Solomon broadly discussed CVM's risk-based approach, and—in response to questions—noted the difference, from his viewpoint, between using gene-editing technology for academic versus commercial purposes, particularly if a person or group uses the technology irresponsibly. Dr. Solomon expressed his hope that scientists and academics will continue to work in this area for purposes

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other than financial gain. Conversely, if people or companies are utilizing gene-editing technology for commercial gain, the public needs regulatory assurance that the animal or ultimate end product has been reviewed and deemed safe for its intended purpose.

Food Safety Modernization Act (FSMA)

Not surprisingly, another hot topic at the CVM breakout was FSMA implementation and progress. Dr. Solomon views concurrent FSMA requirements and changes in the pet food industry as presenting "unique" opportunities. After walking through a FSMA compliance timeline, Dr. Solomon briefly discussed that FDA is already doing GMP inspections (for which guidance has been issued) but has postponed preventative control inspections (for which draft guidance has been issued) until September 2018. On the same note, Mr. Tabor, who noted that PFI was heavily involved in the FSMA rulemaking process—a process he viewed as a thoughtful approach to stakeholder input—suggested that, from PFI's perspective, guidance from FDA is critical, even in draft form. The biggest challenge for both FDA and industry is having clear expectations on both sides, whether on policy issues or field operations. Mr. Tabor also suggested that training for field inspectors continues to be another critical enforcement factor. On that front, Dr. Solomon reiterated CVM's commitment to stakeholder outreach, especially as to FSMA implementation, CVM's education and communications activities, and industry's generally positive view of CVM.

Issues to Watch

Going forward, the panelists identified several key areas to watch in addition to those discussed above. For example, both Dr. Solomon and Mr. Tabor focused on the process for getting animal feed ingredients, including ingredients for pet food, approved. Dr. Solomon noted there had been a 300% increase in GRAS notices, as well as a significant increase in food additive petitions. Indeed, Mr. Tabor agreed that having ingredients considered and approved continues to take more time than industry would like. Dr. Solomon reiterated that FDA intends to apply ingredient rules uniformly across the pet food industry. Dr. Solomon further noted that pet food safety has been challenging, and he expects that CVM will continue to see such challenges, specifically noting recent reported raw food incidents.

Finally, the panelists discussed the reality that humans and animals, as well as their respective food supplies, may be susceptible to a pandemic. Dr. Solomon relayed the story of the 2003 monkeypox outbreak in the U.S. that was caused by a shipment of rodents from Ghana. He reiterated that this outbreak could have become a pandemic, and that the risk or potential for risk for a pandemic still exists today. Dr. Solomon assured the attendees that CVM spends a lot of time considering these scenarios and identifying solutions, in addition to its other important work.