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Maria Serpa, Pharm D
Chair, Enforcement and Compounding Committee
California Board of Pharmacy
2720 Gateway Oaks Dr, Ste. 100
Sacramento, CA 95833

Dear Dr. Serpa:

I write today in my role as regulatory and legislative counsel for the Alliance for Pharmacy Compounding (APC), formerly the International Academy of Compounding Pharmacists (IACP). APC is the voice for pharmacy compounding, advocating for thousands of pharmacists, technicians, students, researchers and suppliers. The organization is driven by pharmacy compounders' passion for their patients and the medications they provide, and focused on strategies to assure patients can continue to access those medications. APC's commitment to the entire pharmacy compounding profession is to lead, to influence, to speak, and to serve so that the practice of pharmacy compounding is not merely preserved, but is publicly recognized as a key component of health care delivery for millions of patients across America.

APC shares concerns that have recently been expressed to the Board by the California Pharmacists Association (CPhA) regarding "orders of correction" issued to a number of pharmacists from Board inspectors stating that licensees are to "update the practice", "please state how pharmacy will comply with this law", "please find a path for compliance" and "PIC educated on 21 CFR 530.13(a)." 21 CFR 530.13(a) states in full that "This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs."

APC strongly agrees with the legal opinion asserted by CPhA in the letter submitted to the Board on August 26, 2020, that 21 CFR 530.13(a) is in no way a prohibition on compounding animal drugs from bulk substances. As the CPhA letter points out, this regulation was promulgated pursuant to the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), which does not speak directly to animal drug compounding. AMDUCA simply allows vets to prescribe certain FDA- approved human or animal drugs for extra-label use when certain conditions are met. (*see* USC §§ 360b(a)4 and (a)5). The implementing regulations (21 CFR § 530 *et. seq.*) neither authorize nor prohibit bulk ingredient compounding for animals, and simply establish the requirements that must be met for prescribing extra-label use of FDA approved drugs, including drugs compounded from FDA-approved drugs for extra-label use.

Those same regulations also point parties to non-binding FDA guidance for information on compounding (*see* 21 CFR § 530.13). As referenced in the CPhA letter, FDA has indeed issued draft Guidance for Industry #256 establishing the circumstances under which animal drugs can be compounded from bulk substances.

Extra-label use is not bulk substance compounding. They are two completely unrelated activities that have nothing to do with each other- and it is not plausible that Congress would have intended to give FDA broad regulatory authority to regulate, much less prohibit animal drug compounding in a section of the law related to a completely different subject. It would be a gross misinterpretation of federal law for the Board of Pharmacy to enforce a blanket prohibition on the compounding of animal drugs from bulk substances, a critical component of veterinary medicine and pharmacy law that has traditionally been handled by state law and state boards of pharmacy, not the FDA under federal law.

Veterinary medicine involves the treatment of many different species of animals that come in many different sizes and have many different health conditions that require varying types of medications in varying dosages and strengths and routes of administration. This is why FDA-approved products often do not meet the needs of a particular animal patient and why animal drug compounding from bulk substances is such an integral part of the treatment of animal patients.

For these reasons, we respectfully request that Board inspectors better educate themselves on the status of state and federal laws and regulations related to veterinary medicine and animal drug compounding and cease misinforming California pharmacies about the status of the federal law as it relates to compounding animal drugs from bulk substances. Thank you in advance for your consideration of this request.

Sincerely

R. David Pore