CALIFORNIA® VETERINARY MEDICAL ASSOCIATION

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February 6, 2023

Maria D. Serpa, PharmD
Chair, Enforcement and Compounding Committee
California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

RE: Comments on Board of Pharmacy Discussion, Consideration and Possible Action on Proposed Changes to Regulations Related to Pharmaceutical Compounding of Nonsterile Preparations

Dear Dr. Serpa:

The California Veterinary Medical Association (CVMA), representing over 7,800 veterinarians, registered veterinary technicians, and veterinary students, would like to ensure that potential changes to California Code of Regulations, Title 16 (16 CCR), section 1735.2(c)(3) do not further harm California's pets, consumers, or the veterinarians who are trying to provide vitally needed medications to their patients.

Now, more than ever, veterinarians are experiencing difficulties in finding and obtaining sources of medications needed to treat patients immediately. The CVMA notified your Board of this growing issue in a letter dated January 19, 2022 (see attached). As stated in that letter, in many instances the pharmaceutical industry falls short of providing FDA-approved medications commonly utilized in veterinary practice. As a result, the veterinary industry relies on compounding pharmacies to provide such medications in order to effectively treat animal patients to alleviate suffering, illness and death. While the recent emergence of 503B outsourcing facilities in California has helped to some degree, only two outsourcers in California currently carry appreciable lines of veterinary products. While some outsourcers advertise sterile compounds for veterinary practice, most of those are chemotherapeutics, which represent a small subset of medications used by veterinarians. Thus, the 503B route is not a complete solution to veterinarians finding medications that they need on hand to help animals in need.

Veterinarians must rely on 503A pharmacies to fill gaps in medication availability, including for medications needed in-house to treat patients. Unlike humans, animals instinctively hide their pain or illness, which results in many of them needing immediate treatment when they come to a veterinary practice. Because so few 503A compounding pharmacies offer veterinary products in California, consumers must often wait several days for a patient-specific prescription to be filled. This is due not only to stringent compounding mandates, but also to delays experienced when trying to locate a pharmacy willing to compound a veterinary medication. It is not uncommon for veterinarians and consumers to wait weeks for an animal patient to receive the medication that it needs pursuant to a patient-specific prescription. And, despite the CVMA's

multiple communications to the Board of Pharmacy over the past decade, this problem has grown worse as a result of regulatory changes that have resulted in an industry shift.

CCR 16 section 1735.2(c)(3) indicates that a 503A compounding pharmacist can prepare in advance, in anticipation of a veterinarian's needs, a supply that is "sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing." At the time that this regulation was instituted, the CVMA met with then BOP Executive Officer Ginny Herold and DAG Joshua Room to discuss the significance of this requirement. At that time, Mr. Room explained that this regulation applied to compounding pharmacists in the amount of medication that they could prepare in advance, but did not apply to veterinarians in the amount that they could furnish on a patient-by-patient basis. While the concept is for the veterinarian to furnish an average of a 120-hour supply to each patient, Section 1735.2(c)(3) does not dictate or limit the professional decisions that a veterinarian makes in the course of patient treatment. Therefore, if a veterinarian feels that they must provide more than a 120-hour supply of a medication to a given patient, they are free to do so.

At the time that Section 1735.2(c)(3) was passed, it was anticipated that a compounding pharmacist could provide medication pursuant to receipt of a patient-specific prescription in four days time. The CVMA positively attests that more often than not, this is not the case. To that end, the CVMA would like to request that the Board of Pharmacy increase the average supply of medication that a pharmacy can prepare in advance to a seven day average supply per patient, based on anticipated needs as identified by the veterinarian. The CVMA proposes the following specific wording change to CCR 16 section 1735.2(c)(3):

> *Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a ~~120-hour~~ seven day supply per animal patient for veterinarian prescribers ~~veterinary medical practices~~, solely to the veterinarian prescriber's own ~~veterinary~~ patients ~~seen as part of regular treatment in the prescriber's office~~, as fairly estimated by the veterinarian prescriber in anticipation of their patient needs and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing.*

Thank you for your consideration.

Dan Baxter
Executive Director

Enclosure

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January 19, 2022

California Board of Pharmacy c/o
Anne Sodergren, Executive Officer
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

RE: Lack of Crucial Veterinary Medications in California

Dear Ms. Sodergren,

The California Veterinary Medical Association (CVMA), representing over 7,800 veterinarians, registered veterinary technicians, and veterinary students, would like to inform the Board of Pharmacy (BOP) of a critical issue facing veterinarians due to a combination of changes to state compounding regulations and BOP enforcement action (also being termed "pharmacist education.")

Several times in the past, including most recently on October 23, 2020, the CVMA has communicated to the BOP that enforcement activities which discourage and inhibit the work of compounding pharmacists would result in California veterinarians losing access to important medications that may only be obtained from compounding pharmacies that compound from active pharmaceutical ingredients. During public comment at BOP meetings, including those of the Compounding and Enforcement Committees, BOP members encouraged the CVMA to report back any issues that we become aware of relating to drug availability or lack thereof. Those issues are summarized below.

Veterinary Drugs Now Currently Unavailable in California

CVMA members have reported that the following drugs are currently unavailable in California:

- **Tolazoline:** this alpha-2 receptor antagonist is used in veterinary medicine on an emergency basis to reverse sedation by alpha-2 agonists such as xylazine or detomidine. California Code of Regulations, title 16, section 2030(f)(12) requires that all registered veterinary premises have appropriate drugs readily available to treat an animal emergency. Tolazoline can be included as one of those drugs. Veterinarians need this drug and others to be able to provide life-saving medical care to animal patients. While alternatives such as yohimbine and atipamezole are available, they are less preferable than tolazoline primarily because of the more reliable, consistent and effective nature of

tolazoline, and the impracticality of using yohimbine and atipamezole in equine and livestock patients due to the high volumes needed to achieve an effect.

- **Thyrotropin-Releasing Hormone:** Thyrotropin-releasing hormone (TRH; protirelin) is most commonly used in veterinary medicine as a diagnostic agent (TRH stimulation test) for diagnosing pituitary pars intermedia dysfunction (PPID) in horses. While other test methods exist, such as a dexamethasone suppression test or an endogenous adrenocorticotropic hormone test, the TRH stimulation test is supported in current literature as being an important component in accurate testing, especially for detection of early cases.

- **Tissue Plasminogen Activase:** Alteplase (tPA) is an enzyme (serine protease) that binds to fibrin in clots, converting the plasminogen component of the clot to plasmin. In veterinary practice, it is most commonly injected intracamerally to lyse intraocular fibrin and blood clots following cataract surgery. No effective alternatives exist.

Because no equivalent products approved by the United States Food and Drug Administration (FDA) exist, the only available supply of these critical medications must be derived through compounding from active pharmaceutical ingredients (bulk drug substances). Indeed, the FDA itself has demonstrated sensitivity to this need, as reflected in a statement made in its draft Guidance for Industry #256:

> FDA has generally exercised enforcement discretion with regard to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment options exist. This guidance, a continuation of this practice, is intended to provide additional information and clarity to veterinarians and pharmacists about FDA's current thinking with respect to animal drug compounding from bulk drug substances.
>
> At this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action for violations of the FD&C Act's requirements for approval, adequate directions for use, and cGMP requirements, for these products that meet the circumstances described below. The policies described in this document aim to protect human and animal health by limiting the use of animal drugs compounded from bulk drug substances primarily to situations in which a veterinarian is acting within a valid veterinarian-client-patient relationship (VCPR) 3 and there is no medically appropriate drug that is FDA approved, conditionally approved, or on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (indexed) to treat the animal.

The FDA's statement reflects its recognition of the clinical importance of bulk drug compounding.

Status of 503b Outsourcing Facilities Providing Veterinary Drugs in California

Currently, out of the small number of registered 503b facilities in California, only two provide appreciable lines of veterinary products. They are: Wedgewood Connect, LLC, formerly registered as Leiter's Compounding, San Jose, CA; and Stokes Pharmacy dba Epicur Pharma, in Mt. Laurel Township, NJ. The CVMA has researched all of the registered 503b facilities that we know of in California,[1] including the "veterinary" ones mentioned above, and has determined that none of them offer tolazoline, thyrotropin releasing hormone, or tissue plasminogen activase in California. If the BOP is aware of other veterinary outsourcing facilities in California, the CVMA would welcome their identification. The CVMA would also like to request that the BOP post all California-registered 503b facilities on its website here: https://www.pharmacy.ca.gov/applicants/outsrc.shtml

In the meantime, the CVMA has contacted both Wedgewood and Epicur and have been told that, other than Wedgewood researching the prospect of adding tPA to its product line, those entities will not be pursuing approval to add these drugs to their catalogues. Accordingly, we would like the BOP to be aware of the harm that is resulting from the collective changes to California compounding regulations and from BOP enforcement policy which has resulted in 503a pharmacies discontinuing product lines in California.

Please share this letter with the members of the Board of Pharmacy. If you or any of them care to discuss these matters further, the CVMA is available to meet or to appear at a Board or committee meeting in the future.

Thank you for your consideration.

Dan Baxter
Executive Director

cc: Jessica Sieferman, Executive Officer, California Veterinary Medical Board

[1] The CVMA's research was conducted based on this FDA list: https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities.