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Ryan M. Arnold

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## **Clarifying Authority: Closing the Loophole on Dangerous Drugs**

*Ryan M. Arnold*

### *Code Sections Affected*

Business and Professions Code §§ 4022, 4067, 4170, 4171, 4175  
(amended).  
SB 175 (Kuehl); 2003 STAT. Ch. 250.

### I. INTRODUCTION

In 2002, two veterinarians approached the California Board of Pharmacy with complaints about potential inappropriate dispensing of dangerous drugs through Internet pharmacy websites.<sup>1</sup> They received an alarming response.<sup>2</sup> The Board of Pharmacy contended that it had no authority to regulate any substances labeled for veterinary use.<sup>3</sup>

Veterinarians estimate that some three hundred drugs approved for human use have also been approved for use in domestic animals.<sup>4</sup> These drugs contain the same active ingredients as the drugs intended for humans but often have different labels and/or brand names.<sup>5</sup> The statutory loophole uncovered by the veterinary community meant that unlicensed individuals, possibly those in animal feed stores or grooming salons, could potentially procure and dispense dangerous drugs simply because they were labeled for animal use.<sup>6</sup>

Prominent among these drugs is the anesthetic, ketamine.<sup>7</sup> An important anesthetic used by veterinarians to treat cats and dogs,<sup>8</sup> ketamine has developed a following among recreational drug users who refer to the substance as “vitamin

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1. ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 2 (July 1, 2003); California Veterinary Medical Association, SB 175 Fact Sheet, at 1 [hereinafter CVMA Fact Sheet] (copy on file with the *McGeorge Law Review*).

2. See CVMA Fact Sheet, *supra* note 1, at 1-2 (stating that the CVMA contended that the Board of Pharmacy’s position left many dangerous drugs and devices totally unregulated).

3. ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 3 (July 1, 2003).

4. Benedict Carey, *Not Above Popping Pills Meant for Pets*, L.A. TIMES, July 29, 2002, at S1.

5. *Id.*

6. ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 3 (July 1, 2003); CVMA Fact Sheet, *supra* note 1.

7. CVMA Fact Sheet, *supra* note 1.

8. Marisa Taylor & Sandra Dibble, *Ketamine Smuggling Ring Is Broken Up*, SAN DIEGO UNION-TRIB., Oct. 3, 2002, at B-1.

K” and “special K.”<sup>9</sup> The drug has become popular among teenagers at dance clubs and raves because of its hallucinogenic effects and has been used as a date rape drug.<sup>10</sup> Recently, authorities broke up a large ketamine smuggling ring involving a veterinarian and veterinary supply company in Mexico.<sup>11</sup> In California, veterinarians have been advised to keep only a small stock of ketamine and to keep it securely locked up.<sup>12</sup>

Recently, some people have attempted to treat their own illnesses by using drugs intended for animals.<sup>13</sup> With rising costs and difficulties in obtaining prescription drugs, easy-to-obtain pet medications containing similar or identical ingredients have proved to be an unorthodox alternative.<sup>14</sup> Last year, a Pentagon doctor surveyed products available at pet stores and over the Internet, and found about a dozen antibiotics commonly used by humans in clearly labeled doses.<sup>15</sup>

The potential for abuse caused by this gap in the regulation of dangerous drugs was the impetus for the California Veterinary Medical Association (CVMA) to sponsor Chapter 250.<sup>16</sup> The new law amends the Business and Professions Code to include veterinarians and drugs labeled for animal use within the scope of the Board of Pharmacy’s authority.<sup>17</sup>

## II. EXISTING PHARMACY LAW

The Pharmacy Law provisions of the Business and Professions Code define the term “dangerous drug” and govern the prescribing, dispensing and furnishing of such drugs by licensed individuals.<sup>18</sup> The law defines a “dangerous drug” or “dangerous device” as any drug or device that is unsafe for self-use, including

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9. *Id.*; Carey, *supra* note 4.

10. California Veterinary Medical Association, *Keeping Ketamine off the Street*, CAL. VETERINARIAN, Nov.-Dec. 2002, at 7.

11. Taylor & Dibble, *supra* note 8.

12. See California Veterinary Medical Association, *supra* note 10 (describing dangers related to the theft of ketamine and listing guidelines for the safe storage and record-keeping of the drug).

13. Carey, *supra* note 4.

14. See *id.* (stating that factors such as time-consuming doctor visits, expensive prescription drugs and lack of insurance have spurred people to buy easily obtainable pet medications that contain the same active ingredients).

15. *Id.* (describing the case of a Special Forces soldier who was discovered to have been treating his sinus infection with antibiotics intended for fish that he had obtained at a pet store).

16. See CVMA Fact Sheet, *supra* note 1 (stating that veterinarians had for years operated under the assumption that all dangerous drugs were covered by the Board of Pharmacy, but that the new law was needed when the Board recognized “a statutory void where the dispensing of drugs for veterinary use [was] concerned”).

17. See ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF SB 175, at 1 (July 16, 2003) (summarizing the changes made by Chapter 250).

18. ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 1 (July 1, 2003).

drugs that are available by a prescription only.<sup>19</sup> Prior to Chapter 250, drugs labeled for veterinary use were specifically exempted from this legal definition.<sup>20</sup>

The law also defines the term “prescriber.”<sup>21</sup> Prescribers may dispense dangerous drugs directly to their patients if they meet certain requirements.<sup>22</sup> Certain exceptions to these requirements exist, and prior to Chapter 250, the dispensing of drugs for use on animals by veterinarians was among them.<sup>23</sup> Dangerous drugs may also be dispensed over the Internet, but only by those who “knew or reasonably should have known” of a prescription that was “issued pursuant to a good faith prior examination.”<sup>24</sup>

The Pharmacy Law also requires that the Board of Pharmacy forward any complaints regarding dangerous drugs dispensed by a prescriber to the licensing agency responsible for that prescriber.<sup>25</sup>

### III. CHAPTER 250

Chapter 250 makes clarifying changes to the Business and Professions Code to ensure that dangerous drugs intended for veterinary use are regulated in the same manner as drugs used in human medicine.<sup>26</sup> The new law creates an expanded definition of “dangerous drug” or “dangerous device” to include “any drug or device unsafe for self-use in humans or animals,” deleting the old exemption of veterinary drugs from this definition.<sup>27</sup> Chapter 250 amends regulations relating to the dispensing of dangerous drugs directly to patients to include licensed veterinarians within the definition of “prescriber.”<sup>28</sup> Additionally, Chapter 250 gives the Veterinary Medical Board and other licensing agencies<sup>29</sup> the responsibility, along with the Board of Pharmacy, to “ensure compliance.”<sup>30</sup>

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19. CAL. BUS. & PROF. CODE § 4022 (West 2003). The term “dangerous drugs” will also include dangerous devices throughout the rest of this article.

20. *Id.*

21. *Id.* § 4170(c).

22. *See id.* § 4170(a) (listing the requirements for prescribers dispensing dangerous drugs directly to their patients, which include meeting labeling, record-keeping, and disclosure standards).

23. *Id.* § 4171.

24. *Id.* § 4067.

25. *Id.* § 4175.

26. *See* SENATE COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 1 (Mar. 24, 2003) (summarizing the new law as clarifying the Board of Pharmacy’s authority to regulate all dangerous drugs).

27. CAL. BUS. & PROF. CODE § 4022 (amended by Chapter 250); ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175 at 1 (July 1, 2003).

28. ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 1 (July 1, 2003); CAL. BUS. & PROF. CODE § 4170(c) (amended by Chapter 250).

29. *See* CAL. BUS. & PROF. CODE § 4170(b) (amended by Chapter 250) (listing, in addition to the Veterinary Medical Board, the Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, and the Physician Assistant Committee as licensing agencies which must “ensure compliance” along with the Board of Pharmacy and enforce the law “with respect to their respective licensees”).

30. ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 1 (July 1, 2003); CAL. BUS. & PROF. CODE § 4170(b) (amended by Chapter 250).

Chapter 250 also removes the statutory exclusion of veterinarians from prescriber dispensing regulations,<sup>31</sup> and adds the Veterinary Medical Board to the list of licensing agencies to which the Board of Pharmacy must forward appropriate complaints relating to dangerous drugs or devices.<sup>32</sup>

Finally, Chapter 250 amends the Business and Professions Code regarding the regulation of dispensing dangerous drugs over the Internet.<sup>33</sup> The requirement that any drug dispensed over the Internet be “pursuant to a good faith prior examination” of the patient is extended to humans and animals alike.<sup>34</sup> Moreover, for clarification of this standard, the new law includes the statutory provisions defining “good faith prior examination” for both physicians and veterinarians.<sup>35</sup>

#### IV. ANALYSIS

The Board of Pharmacy’s interpretation of existing law prior to the enactment of Chapter 250 surprised the veterinary community.<sup>36</sup> For years, veterinarians operated under the assumption that all dangerous drugs fell under the regulation of the Board of Pharmacy.<sup>37</sup> In 1995, a successful effort was made by the veterinary community to create tighter regulation of dangerous drugs for use in food-producing animals, putting regulatory control with the Pharmacy Board.<sup>38</sup> Further, the exception of “veterinary drugs labeled as such,” which Chapter 250 removes from the definition of dangerous drugs, has been interpreted in the past as referring only to certain drugs used in the food-producing animal industry.<sup>39</sup>

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31. CAL. BUS. & PROF. CODE § 4171 (amended by Chapter 250).

32. *Id.* § 4175.

33. ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 1 (July 1, 2003); CAL. BUS. & PROF. CODE § 4067 (amended by Chapter 250).

34. CAL. BUS. & PROF. CODE § 4067(a) (amended by Chapter 250) (referencing California business and Professions Code section 2242 which, with respect to physicians, states that prescribing, dispensing, or furnishing dangerous drugs without a good faith prior examination constitutes unprofessional conduct, and CAL. CODE REGS. tit. 16, § 2032.1 (2003) which requires a veterinarian-client-patient relationship before a veterinarian may prescribe, dispense or furnish a dangerous drug).

35. CAL. BUS. & PROF. CODE § 4067(f) (amended by Chapter 250).

36. See Telephone Interview with Donald J. Klingborg, Associate Dean of Public Programs, UC Davis School of Veterinary Medicine and Chairman, House of Delegates, California Veterinary Medical Association (Aug. 15, 2003) [hereinafter Klingborg Interview] (notes on file with the *McGeorge Law Review*) (describing the surprise felt by the veterinary community when the Board of Pharmacy took the position that existing law gave them no authority over veterinary drugs).

37. *Id.*; ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 2 (July 1, 2003).

38. See Klingborg Interview, *supra* note 36 (discussing AB 611 from 1995 (1995 Stat. Ch. 350) which created regulations governing the prescription, labeling and distribution of drugs used in the food-producing animal industry).

39. See CVMA Fact Sheet, *supra* note 1, at 1-2 (stating that the language of “veterinary drugs labeled as such” in Business and Professions Code section 4022 was originally intended only as a narrow exception for specific drugs used in the food animal and poultry industries).

The Board of Pharmacy's position, however, indicated that statutory language still exempted veterinarians and veterinary drugs, dispensed either by the prescriber or over the Internet, from regulation.<sup>40</sup> With the clarifications made by Chapter 250, all dangerous drugs fall under the same regulatory standards without any further confusion or possible loopholes.<sup>41</sup>

Chapter 250 deals with curbing potential risk rather than with solving a particular problem.<sup>42</sup> While not focusing on any particular abuse, the supporters of the new law focus on what could conceivably occur if veterinary drugs were left unregulated.<sup>43</sup> However, since dangerous drugs are also regulated at the wholesale level, fears of pet stores and grooming salons dispensing drugs may be unfounded.<sup>44</sup> As a result of clarifications made in Chapter 250, the Board of Pharmacy now has unambiguous authority to enforce the Pharmacy Law with respect to all drugs.<sup>45</sup>

Additional enforcement efforts as a result of Chapter 250 should not have a significant fiscal impact on either the Pharmacy Board or the Veterinary Medical Board.<sup>46</sup> Although early in the legislative process leading to the enactment of Chapter 250 the Pharmacy Board indicated it would require additional funding to accommodate the added responsibility, the Pharmacy Board ultimately decided that the anticipated workload increase was minimal and would fit within existing resources.<sup>47</sup>

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40. ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 3 (July 1, 2003).

41. *See id.* at 2 (stating that the CVMA "states that [the new law] essentially ensures that the [Pharmacy] Board will have a role in regulating veterinary pharmaceuticals and Internet sales of all prescription drugs and devices regardless of whether or not they are labeled for human or animal use").

42. Klingborg Interview, *supra* note 36.

43. *See* CVMA Fact Sheet, *supra* note 1, at 1-2 (discussing the response of creating the legislation as a result of determining the Pharmacy Board's position on existing law and the potential ramifications veterinary drug non-regulation).

44. *See* Klingborg Interview, *supra* note 36 (stating that because of regulation at the wholesaler level, pet stores should never obtain prescription-only medications to begin with).

45. SENATE FLOOR, COMMITTEE ANALYSIS OF SB 175, at 1 (July 21, 2003).

46. *See* ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF SB 175, at 2 (July 16, 2003) (showing no fiscal impact to the Veterinary Medical Board and the ability for the Board of Pharmacy to implement the new law within existing resources).

47. *Compare* SENATE COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF SB 175, at 1 (Apr. 7, 2003) (stating that the Board of Pharmacy estimated the cost of enforcing the new law at \$200,000 for the first year and \$230,000 for each subsequent year, which would have to come from existing funds), *with* ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF SB 175, at 2 (July 16, 2003) (stating a low number of anticipated complaints due to the new law and the Board of Pharmacy's intention to implement the law to the extent possible within existing resources).

## V. CONCLUSION

The risk of leaving any dangerous drugs unregulated is too dangerous to ignore. Chapter 250 responds to a realization by the California veterinary community that no agency was statutorily authorized to regulate the dispensing of any dangerous drugs labeled for animal use.<sup>48</sup> The new law eliminates old exemptions for veterinarians and veterinary drugs from the Pharmacy Law, putting the Board of Pharmacy in charge of regulating all dangerous drugs, regardless of the species the drugs are designed to treat.<sup>49</sup> Although veterinarians were surprised by the Board of Pharmacy's interpretation of prior law,<sup>50</sup> all are agreed that with the enactment of Chapter 250, there will be a closure of any possible loophole that might have existed with minimal impact to the regulatory agencies involved.<sup>51</sup>

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48. ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 2-3 (July 1, 2003).

49. *Id.* at 1.

50. Klingborg Interview, *supra* note 36.

51. See ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 175, at 3-4 (July 1, 2003) (discussing the closure of the statutory loophole that existed for drugs labeled for animal use and showing the lack of any registered opposition to the legislation).