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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 S. Norwalk** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about October 2, 1995, the Board of Pharmacy issued Wholesale Permit Number WLS 3076 to McKesson Corporation, dba McKesson Drug Company (Respondent

McKesson). The Wholesale Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2021, unless renewed.

3. On or about January 21, 2004, the Board of Pharmacy issued Original Certificate Number EXC 17318 to John F. Bohlinger (Respondent Bohlinger) to act as a Designated Representative. The certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2021, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
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> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
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> (1) Suspending judgment.
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> (2) Placing him or her upon probation.
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> (3) Suspending his or her right to practice for a period not exceeding one year.
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> (4) Revoking his or her license.
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> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4307 of the Code states:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

…

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

…

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

…

(*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

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8. California Health and Safety Code section 11153.5 states, in pertinent part:

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes."

…

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

9. Section 4169.1 of the Code (effective January 1, 2018), states:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

10. Section 4059.5, subsection (a), of the Code states:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

REGULATORY PROVISIONS

11. Code of Federal Regulations, title 21, section 1301.74, subsection (b), states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

12. California Code of Regulations, title 16, section 1783, states, in pertinent part:

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

COST RECOVERY

13. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

14. Section 4021 of the Code states: "'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

15. Section 4022 of the Code states: "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.

…

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

16. Phenergan with Codeine Syrup 6.25 mg – 10 mg / 5 ml is the brand name for promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C), a Schedule V controlled substance designated by California Health and Safety Code section 11058(c)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat coughing.

17. Xanax is the brand name for alprazolam, a Schedule IV controlled substance designated by California Health and Safety Code section 11057(d)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat anxiety.

FACTUAL ALLEGATIONS – CHILDREN'S MEDICAL CENTER PHARMACY

18. At all times relevant herein, the Children's Medical Center Pharmacy, also known as the Rady Children's Outpatient Pharmacy (Rady Pharmacy), was part of the Rady Children's Hospital of San Diego. According to its website, it is the only hospital in the San Diego area dedicated exclusively to pediatric healthcare.

19. Between May 7, 2017 and June 26, 2018, the Rady Pharmacy could not account for an inventory shortage of approximately 119 pints of P/C and 5,300 tablets of alprazolam 2mg. A pharmacy technician at the Rady Pharmacy had stolen these dangerous drugs and controlled substances for herself and her friends.

Promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C)

20. Based on Lexicomp Online, a collection of clinical database and clinical decision support tools, P/C is not recommended in pediatrics due to risk of adverse effects, such as slowed or difficult breathing, misuse, abuse, addiction, overdose, and death.

21. According to the pharmacy manager, the Rady Pharmacy did not use or dispense P/C because pediatric doctors did not prescribe P/C to children. On the rare occasion the doctor prescribed P/C, it would be during the winter season according to the pharmacy manager.

22. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, less than two 16-ounce bottles of P/C **per year** to the Rady Pharmacy between January 2014 and August 2017. Beginning in September 2017, the sales of P/C displayed an irregular pattern compared to the previous ordering pattern:

P/C Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (16oz) of P/C Sold**
September 2017	11
October 2017	7
November 2017	7
December 2017	10
January 2018	14
February 2018	10
March 2018	15
April 2018	10
May 2018	18
June 2018	17

23. When calculating the monthly percentage change in sales, there were sales of P/C which varied from 40% to 80% more than the sale from the previous month.

24. The orders for P/C beginning in September 2017 were significantly larger and were shipped in consecutive months from September 2017 to June 2018, which totaled approximately 119 pints or 56,287 ml of P/C.

Alprazolam 2mg

25. Alprazolam is available in dosages of 0.25 mg, 0.5 mg, 1 mg, and 2mg.

26. According to Lexicomp Online, alprazolam should be titrated and used at the lowest effective dose. Lexicomp provided the following dosing information: "*Children ≥ 7 years and Adolescents < 18 years: Limited data available… Initial: 0.005 to 0.02 mg/kg/dose 3 times daily… maximum of 0.02 mg/kg/dose.*" For example, if a child is 40 kg (about 88 pounds), the dosing range is from 0.2 to 0.8 mg per dose.

27. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, one bottle of 100-count alprazolam 2mg **per year** between January 2014 and September 2017. Beginning in October 2017, the sales of alprazolam 2mg displayed an irregular pattern compared to the previous ordering pattern:

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Alprazolam 2mg Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (100-count) of alprazolam 2mg Sold**
October 2017	7
November 2017	9
December 2017	8
January 2018	4
February 2018	4
March 2018	4
April 2018	0
May 2018	15

28. When calculating the monthly percentage change in sales, there were sales of alprazolam 2mg which varied from 250% to 275% more than the sale from the previous month.

29. The orders for alprazolam 2mg beginning in October 2017 were significantly larger and were shipped in consecutive months (except April 2018) from October 2017 to May 2018, which totaled approximately 5,100 tablets of alprazolam 2 mg.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Excessive Furnishing of Controlled Substances)

30. Respondents are subject to disciplinary action under Code section 4301, subsection (e), in that Respondents clearly and excessively furnished controlled substances in violation of California Health and Safety Code section 11153.5, subsection (a), as follows:

a. Respondents furnished the Rady Pharmacy one to two pints of P/C in non-consecutive months from January 2014 to August 2017. Sales increased to seven to 18 pints ordered in consecutive months from September 2017 to June 2018.

b. Respondents furnished the Rady Pharmacy 100 to 200 tablets of alprazolam 2mg in non-consecutive months from January 2014 to September 2017. Sales increased to 400 to 1,500 tablets ordered in consecutive months from October 2017 to May 2018 (except April 2018).

c. Respondents furnished the Rady Pharmacy large quantities of controlled substances (P/C and alprazolam 2mg) that are not typically distributed to pediatric patients.

d. The P/C and alprazolam 2mg furnished by Respondents were not dispensed to patients for legitimate medical purposes but were diverted by a pharmacy technician.

Paragraphs 18 to 29 are re-alleged as if fully set forth herein.

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FACTUAL ALLEGATIONS – CARING PHARMACY

31. On January 7, 2020, a Board inspector conducted an inspection of Caring Pharmacy (Caring Pharmacy), located at 25802 Hemingway Avenue #103, Stevenson Ranch, CA 91381. K.F. is a licensed pharmacist and the owner of Caring Pharmacy. S.F. is K.F's wife and is an unlicensed individual.

32. During this inspection at approximately 9:30 a.m., the Board inspector observed Respondent McKesson's delivery driver bring a drug tote (Drug Tote) to S.F.'s car in front of Caring Pharmacy. S.F. signed for the delivery, and the delivery driver left. S.F. subsequently brought the Drug Tote into Caring Pharmacy.

33. Shortly thereafter, the Board inspector entered Caring Pharmacy, and S.F. stated that no pharmacist was present at Caring Pharmacy at that time. The invoice that accompanied the Drug Tote revealed that the Drug Tote consisted of Emgality and Repatha, both of which are dangerous drugs under California Business and Professions Code section 4022.

SECOND CAUSE FOR DISCIPLINE

(Violation of Statute Regulating Dangerous Drugs)

34. Respondents are subject to disciplinary action under Code section 4301, subsection (j), in that Respondents committed unprofessional conduct by violating California Business and Professions Code section 4059.5, subsection (a). Specifically, on or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for or received by a pharmacist. The drugs were signed for by an unlicensed individual.

THIRD CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law)

35. Respondents are subject to disciplinary action under Code section 4301, subsection (o), in that Respondents committed unprofessional conduct by violating the following Pharmacy Law and regulations:

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a. California Business and Professions Code section 4059.5, subsection (a): On or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for and received by a pharmacist. The drugs were signed for by an unlicensed individual.

b. California Code of Regulations, title 16, section 1783: On or about January 7, 2020, Respondents delivered dangerous drugs to an unlicensed person at Caring Pharmacy who was not an "authorized person" under California Code of Regulations, title 16, section 1783, subsection (b).

DISCIPLINARY CONSIDERATIONS

36. On April 5, 2018, the Board issued Citation No. CI 2014 63111 to Respondent McKesson for violating California Health and Safety Code section 11153.5 [wholesaler furnishing controlled substance other than for legitimate medical purposes] and assessed a fine of $5,000.00. Respondent McKesson has paid the fine.

37. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

38. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

39. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

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40. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Wholesale Permit Number WLS 3076 issued to McKesson Corporation, McKesson Corporation shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Wholesale Permit Number WLS 3076, issued to McKesson Corporation, dba McKesson Drug Company;

2. Revoking or suspending Designated Representative Number EXC 17318, issued to John F. Bohlinger;

3. Prohibiting McKesson Corporation from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if Wholesale Permit Number WLS 3076 issued to McKesson Corporation is revoked;

4. Ordering McKesson Corporation and John F. Bohlinger to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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5. Taking such other and further action as deemed necessary and proper.

DATED: 11/16/2020

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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