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

In the Matter of the Accusation Against**:** **CAREMARK, LLC DBA CVS/SPECIALTY** **1127 Bryn Mawr Avenue Suite A** **Redlands, CA 92374** **Pharmacy Permit No. PHY 39314,** **and** **GREGORY OTTO HARRINGTON** **Pharmacist in Charge** **1204 W. Palm Ave.** **Redlands, CA 92373** **Pharmacist License No. RPH 63139,** Respondents.	Case No. 6527 **ACCUSATION**

PARTIES

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

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2. On or about July 22, 1993, the Board of Pharmacy issued Pharmacy Permit Number PHY 39314 to Caremark, LLC dba CVS/Specialty (Respondent Caremark). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2022, unless renewed.

3. On or about September 28, 2009, the Board of Pharmacy issued Pharmacist License Number RPH 63139 to Gregory Otto Harrington (Respondent Harrington). Between May 20, 2016 to September 26, 2016 and April 21, 2017 to June 22, 2018, Harrington was the Pharmacist in Charge for Respondent Caremark. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2023, 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 unless otherwise indicated.

5. Section 4169 of the Code states in pertinent part:

"(a) A person or entity shall not do any of the following:

. . . .

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

"(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

. . . . .

6. Section 4301 of the Code states:

"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:

. . . .

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

. . . . .

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

7. Section 4306.5 of the Code states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

8. 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:
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> (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.
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> (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.

9. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, 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.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(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.

HEALTH AND SAFETY CODE

10. Section 111260 of the Health and Safety Code states:

Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

11. Section 111295 of the Health and Safety Code states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

12. Section 111300 of the Health and Safety Code states:

It is unlawful for any person to adulterate any drug or device.

13. Section 111305 of the Health and Safety Code states:

It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device.

14. Section 111330 of the Health and Safety Code states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

15. Section 111335 of the Health and Safety Code states:

Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

16. Section 111380 of the Health and Safety Code states:

Any drug is misbranded if it purports to be a drug that is recognized in an official compendium and it is not packaged and labeled as prescribed in the official compendium. The method of packaging, however, may be modified with the consent of the department.

17. Section 111440 of the Health and Safety Code states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

18. Section 111445 of the Health and Safety Code states:

It is unlawful for any person to misbrand any drug or device.

19. Section 111450 of the Health and Safety Code states:

It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

COST RECOVERY

20. 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.

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DEFINITIONS

21. Enbrel (etanercept) is typically used to treat arthritis. The FDA approved temperature range requires that the product be kept between 36°F and 46°F. When the approved temperature is not maintained, the expiration date becomes shortened to 14 days according to the FDA-approved manufacturer labeling. It is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL SUMMARY

22. Respondent Caremark is a closed-door[1] pharmacy located at 1127 Bryn Mawr Avenue, Suite A, Redlands, California 92374.

23. Respondent Caremark dispenses medications designated as specialty medication due to the high cost of the medication, the use of the medication for rare diseases, and/or requirement of special instructions or side effect monitoring.

24. Respondent Caremark is organized into two areas: (a) the "front end" that performed processing, billing and pharmacist verification of the prescriptions (PV1); and (b) the "back end" that was responsible for receiving, handling, storage, “picking” (filling), pharmacist verification of the medication (name, lot, expiration and quantity, PV2), and packing shipments.

25. On February 12, 2018, Board inspectors conducted an inspection of Respondent Caremark. During the inspection, Respondent Harrington was the Pharmacist-in-Charge and present at the time of the inspection.

26. During the inspection, Board inspectors examined the “back end" of the pharmacy, which contained thermometer monitored refrigerators with medications inside and thermometer monitored freezers with gel packs. Also present was a UPS “air conditioned trailer” for storage of medications for shipping.

27. During the time of the inspection, Respondent Caremark, through Respondent Harrington, represented that it was dispensing an average of 10,000 to 11,000 prescriptions per week (around 2,000 prescriptions a day), of which, 80% of the prescriptions were refrigerated.

[1] All prescriptions were either delivered directly to the consumer or to retail CVS pharmacies. A closed-door pharmacy fills prescriptions remotely and is not a storefront open to the public.

28. Employees of Respondent Caremark explained to Board inspectors the medication receiving procedures, medication picking (filling)/verifying procedures and packing/shipping procedures.

29. During the February 12, 2018 inspection, Board inspectors observed large quantities of filled medications located outside of the refrigerators on a conveyer belt waiting to be verified by the pharmacist and eventually packed by the packer. Many of the medications on the conveyer belt were required to be maintained at FDA-approved temperatures that were below room temperature.

30. After the inspection, Respondent Caremark provided records that showed that prescriptions for the drug Enbrel were removed from refrigerated storage and placed on a non-refrigerated conveyor belt for an extended period of time resulting in its exceeding its FDA-approved refrigerated temperature of 46 degree Fahrenheit.

31. Specifically, records showed the following gaps between filling, verifying and packing prescriptions where Enbrel was kept on the conveyer belt at room temperature and not in a refrigerated environment:

Date	**Prescription Number/PT**	**Time Filled**	**Time Verified**	**Time Packed**	**Duration Out of Refrigeration before Packing**
6/08/2017	2729342/DT	2:14:30 PM	2:33:21 PM	3:57:07 PM	Approx. 103 min.
09/11/2017	2773086/DM	7:54:58 AM	9:34:47 AM	9:53:54 AM	Approx. 119 min.
09/12/2017	2832036/JP	8:37:05 AM	10:15:44 AM	11:25:47 AM	Approx. 168 min.
06/13/2017	2746654/SB	9:29:57 AM	11:39:12 AM	1:13:19 PM	Approx. 224 min.
02/06/2018	2844851/AL	9:59:22 AM	10:25:11 AM	12:14:47 PM	Approx. 135 min.
08/16-17/2017	2743898/MF	7:16:19 PM	7:40:05 PM	7:59:46 AM	Approx. 763 min.
08/18-20/2017	2726650/KR	12:08:27 PM	12:49:46 PM	9:39:12 AM	Approx. 2,731 min.

32. Once the Enbrel product achieves a temperature above the FDA approved temperature, the expiration date of the product is permanently shortened to 14 days.

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FIRST CAUSE FOR DISCIPLINE

(Prohibited Acts: Purchase, Trade, Sell, or Transfer of Adulterated Drugs)

33. Respondents Caremark and Harrington are subject to disciplinary action under Code sections 4022 and 4169 subdivision (a)(2) and Health and Safety Code sections 111260, 111295, 111300, 111305 in that on February 12, 2018, during an inspection of Respondent Caremark located in Redlands, California, Respondents were observed to have left large quantities of filled medications, such as Tobramycin inhalation solution, on a conveyor belt. The medications on the conveyor belt were not maintained within FDA approved temperature ranges between 36°F and 46°F.

34. Respondents records for the period June to August 2017 demonstrated that filled Embrel prescriptions had also been left outside the temperature controlled environment so that the medication was exposed to temperatures above the FDA approved temperature range for an extended period of time. Such exposure caused the drug to become adulterated.

35. Respondents did not disclose to patients that their prescriptions of Embrel had improperly been kept at room temperature for an excessive period of time when Respondents sold, shipped and delivered the adulterated drugs to the patients.

36. Respondents did not use shipping practices that ensured that Enbrel, and other medications, would be maintained at FDA approved temperatures. The prescriptions include, but are not limited to the following: 2729342, 2773086, 2832036, 2746654, 2844851, 2743898 and 2726650.

37. By this reference, paragraphs 22 through 32 are incorporated as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Prohibited Acts: Purchase, Trade, Sell, or Transfer of Misbranded Drugs)

38. Respondents Caremark and Harrington are subject to disciplinary action under Code section 4169 subdivision (a)(3) and Health and Safety Code sections 111440 and 111445 as defined by section 111335 in that on February 12, 2018, during an inspection of Respondent Caremark located in Redlands, California, Respondents were observed to have left large

quantities of filled medications, such as Tobramycin inhalation solution, on a conveyor belt where the medications were not maintained within the FDA approved temperature ranges.

39. Between June and August 2017, Embrel prescriptions that had been filled were maintained outside of a temperature regulated environment for an excessive period of time so that the drug exceeded the FDA approved temperature of 46°F. As a result, the expiration date was shortened to 14 days. The dispensed prescriptions were misbranded in that the medication label contained the original expiration date as if proper temperature control had been maintained.

40. The misbranded Embrel prescription labels include, but are not limited to, prescription numbers: 2729342, 2773086, 2832036, 2746654, 2844851, 2743898 and 2726650.

41. Respondents' packing and shipping practices failed to ensure that Enbrel was maintained within the FDA-approved temperature range during the processing and shipping of prescriptions. The Embrel prescriptions include, but are not limited to, prescription numbers: 2729342, 2773086, 2832036, 2746654, 2844851, 2743898 and 2726650.

42. By this reference, paragraphs 22 through 32 are incorporated as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct- Dishonesty, Fraud and/or Deceit)

43. Respondents Caremark and Harrington are subject to disciplinary action under Code sections 4301 subdivision (f) for engaging in for engaging in any act involving moral turpitude dishonesty, fraud, deceit, or corruption, in that Respondents allowed the medication Enbrel to become adulterated by failing to maintain it within FDA approved temperature ranges. Respondents then processed, sold and shipped the adulterated and misbranded Enbrel to consumers and falsely showed the original expiration date, even though expiration date was shortened to fourteen (14) days. By this reference, paragraphs 22 through 32 are incorporated as if fully set forth herein.

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FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

44. Respondent Harrington, as PIC of Respondent Caremark is subject to disciplinary action under Code section 4306.5 for inappropriately exercising his education, training, or experience as a pharmacist by allowing the medication Enbrel to become adulterated by failing to maintain it within FDA approved temperature ranges while prescriptions were being filled and processed for shipping to customers. Respondent Harrington then sold and shipped the adulterated Embrel with its original expiration label, causing it to be misbranded when sold and delivered to customers. By this reference, paragraphs 22 through 32 are incorporated by reference as if fully set forth herein.

OTHER MATTERS

45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 39314 issued to Caremark, LLC dba CVS/Specialty, then Respondent Gregory Otto Harrington shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 39314 is placed on probation or until Pharmacy Permit Number PHY 39314 is reinstated if it is revoked.

46. Pursuant to Code section 4307, if disciplined is imposed on License Number RPH 63139, issued to Gregory Otto Harrington, then he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 63139 is placed on probation or until Pharmacist License Number RPH 63139 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 Pharmacy Permit Number PHY 39314, issued to Caremark, LLC dba CVS/Specialty;

2. Revoking or suspending Pharmacist License Number RPH 63139, issued to Gregory Otto Harrington;

3. Prohibiting Gregory Otto Harrington from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 39314 is placed on probation or until Pharmacy Permit Number PHY 39314 is reinstated if Pharmacy Permit Number PHY 39314 is revoked;

4. Ordering CVS/Specialty and Gregory Otto Harrington 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,

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

DATED: 2/21/2022

Signature on File

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

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