

WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

| | | |
|-------------------------------|---|--------------------------|
| IN THE MATTER OF DISCIPLINARY | : | |
| PROCEEDINGS AGAINST | : | |
| | : | FINAL DECISION AND ORDER |
| MCKESSON DRUG COMPANY, | : | |
| RESPONDENT. | : | 0006082 |

Division of Legal Services and Compliance Case No. 17 PHM 014

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

McKesson Drug Company
3000 Kenskill Ave.
Washington Court House, OH 43160

Wisconsin Pharmacy Examining Board
P.O. Box 8366
Madison, WI 53708-8366

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

1. Respondent, McKesson Drug Company, is licensed in the state of Wisconsin as a wholesale distributor of prescription drugs, having license number 889-45, first issued on January 8, 1997, and current through May 31, 2020 (This wholesale distribution license, through its owner, McKesson Drug Company, is hereinafter referred to as "Respondent"). Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services ("Department") is 3000 Kenskill Ave., Washington Court House, Ohio 43160.
2. At all times relevant to this proceeding, Respondent was a wholesale distributor of prescription drugs, located in Washington Court House, Ohio.

3. In 2008, McKesson Corporation (“McKesson”) entered into a Settlement and Release Agreement and an Administrative Memorandum of Agreement with the United States Department of Justice, Drug Enforcement Administration (“DEA”) (“the 2008 Agreement”). The 2008 Agreement arose out of, among other things, allegations regarding McKesson’s failure to report suspicious orders of controlled substances, as required by 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As part of the 2008 Agreement, McKesson paid a \$13.25 million civil penalty and created a Controlled Substance Monitoring Program (“CSMP”).
4. On January 17, 2017, Respondent self-reported to the Board that McKesson entered into a Settlement Agreement and Release and an Administrative Memorandum of Agreement with the DEA (“the 2017 Agreement”), based on allegations that McKesson, including Respondent, had failed to adequately monitor and or report suspicious orders of controlled substances.
5. In the 2017 Agreement, the DEA alleged the following:
 - a. McKesson failed to properly monitor its sales of controlled substances, including:
 - i. failure to follow the procedures and policies set forth in the CSMP;
 - ii. failure to conduct adequate due diligence of its customers;
 - iii. failure to keep complete and accurate records in the CSMP files maintained for many of its customers;
 - iv. bypassing suspicious order reporting procedures set forth in the CSMP; and
 - v. failure to report suspicious orders—including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency.
 - b. Certain McKesson distribution centers distributed controlled substances to pharmacies even though those distribution centers should have known that the pharmacists practicing at those pharmacies had failed to fulfill their corresponding responsibility to ensure that the controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes.
 - c. McKesson violated the 2008 Agreement and federal law.
6. The DEA’s allegations were limited to certain of McKesson’s distribution centers, including Respondent.
7. The DEA’s allegations were also against the following distribution centers licensed in Wisconsin: Aurora, Illinois (License No. 2230-45, Current, Active from June 3, 2009 to May 31, 2020); West Sacramento, California (License No. 1366-45, Current, Active from February 13, 2002 to May 31, 2020); LaCrosse, Wisconsin (License No. 868-45, Not Current, Active from November 12, 1996 to May 31, 2018); LaVista, Nebraska (License No. 2572-45, Not Current, Active from November 11, 2013 to May 31, 2018). The DEA took no action against these facilities and these distribution centers are not subject to this Final Decision and Order.

8. Pursuant to the 2017 Agreement, McKesson acknowledged that, at various times from January 1, 2009, through January 17, 2017, it did not identify or report to the DEA certain orders placed by certain pharmacies which McKesson should have detected as suspicious in a manner fully consistent with the requirements set forth in the 2008 Agreement.
9. The 2017 Agreement required McKesson to pay a settlement payment of \$150 million and provided for a time-limited suspension of the DEA Certification of Registrations of four (4) of McKesson's distribution centers, including Respondent.
10. The suspension included an exception that permits, but does not require, Respondent, during the period of suspension, to continue to distribute controlled substances to federal customers that purchase controlled substances from Respondent under McKesson's exclusive contract with the United States Department of Veteran Affairs. The suspensions also do not apply or limit McKesson's authority to distribute, or operations involving, List 1 Chemical products from any of its distribution centers.
11. Respondent neither admits nor denies wrong-doing. In resolution of this matter, and to avoid the expense and uncertainty of litigation, Respondent consents to the entry of the following Conclusions of Law and Order.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).
2. By the conduct described in the Findings of Fact, Respondent, license no. 889-45, engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(17), by having been subject to disciplinary action by another licensing authority.
3. As a result of the above violations, Respondent, license no. 889-45, is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.
4. Pursuant to Wis. Stat. § 450.10(2), in addition to a limitation or suspension, the Board may, for violations of Wis. Stat. § 450.10(1), assess a forfeiture of not more than \$1,000.00 for each separate offense, with each day of violation constituting a separate offense.

ORDER

1. The attached Stipulation is accepted.
2. Except as provided in paragraph 3 of this Order, the ability to distribute controlled substances under the license to practice as a wholesale distributor of prescription drugs in the state of Wisconsin issued to Respondent, license no. 889-45, is **SUSPENDED** for a period of two (2) years, effective from January 17, 2019, to January 17, 2021, or for the same effective dates as the suspension of the DEA Certificate of Registration for this distribution center under the 2017 Agreement. The suspension will terminate

automatically on either January 17, 2021, or upon the date the suspension of the DEA Certificate of Registration for this facility terminates. In the event that Respondent's DEA Certificate of Registration will remain suspended beyond January 17, 2021, Respondent shall notify the Board prior to January 17, 2021, of the continued suspension of its DEA Certificate of Registration and the date that the suspension of its DEA Certification of Registration will terminate.

3. This suspension shall not apply to or limit Respondent's authority to distribute, or Respondent's operations involving, List 1 chemical products at or from Respondent which are authorized under Respondent's DEA Certificate of Registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the United States Department of Veterans Affairs.
4. The license to practice as a wholesale distributor of prescription drugs in the state of Wisconsin, issued to Respondent, license no. 889-45, is further LIMITED to require Respondent to fully comply with Administrative Memorandum of Agreement and any amendments or modifications thereto, entered into by Respondent and the United States Department of Justice, Drug Enforcement Administration and effective on January 17, 2017.
5. Within one-hundred and twenty (120) days from the date of this Order, Respondent, license no. 889-45, shall pay a FORFEITURE in the amount of fifty thousand dollars (\$50,000.00).
6. Within one-hundred and twenty (120) days from the date of this Order, Respondent, license no. 889-45, shall pay costs in the amount of 1,959.00.
7. Any payments, requests, petitions, reports, and other information required by this Order may be mailed, faxed, or emailed to:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190
Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

You may also submit this information online via DSPS' Monitoring Case Management System, here:


<https://app.wi.gov/DSPSMonitoring>

8. In the event that Respondent violates any term of this Order, Respondent's license, license no. 889-45, to practice as a wholesale distributor in the state of Wisconsin may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order. The Board may, in addition and/or in the alternative, refer any violation of this Order to the Division of Legal Services and Compliance for further investigation and action.

9. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by:


A Member of the Board

2/27/2019
Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

MCKESSON DRUG COMPANY,
RESPONDENT.

:
:
:
:
:

STIPULATION

0006082

Division of Legal Services and Compliance Case No. 17 PHM 014

Respondent McKesson Drug Company, license no. 889-45, and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:


1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.
2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:
 - the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
 - the right to confront and cross-examine the witnesses against Respondent;
 - the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
 - the right to testify on Respondent's own behalf;
 - the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
 - the right to petition for rehearing; and
 - all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.
3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation. Respondent is represented by Attorney Roger N. Morris and Attorney Susan Brichler Trujillo.
4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining Board ("Board"). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

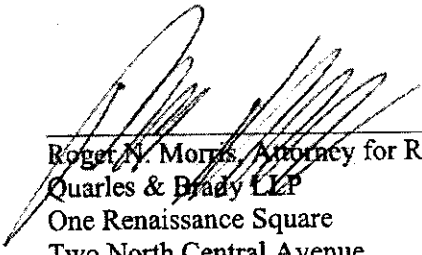
6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent or Respondent's attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.


8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.


McKesson Drug Company, Respondent
3000 Kenskill Ave.
Washington Court House, OH 43160
License no. 889-45

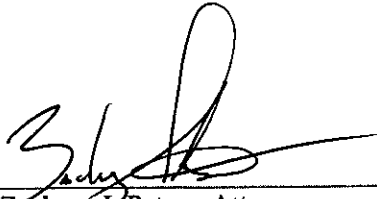
1-16-2019
Date


Roger N. Morris, Attorney for Respondent
Quarles & Brady LLP
One Renaissance Square
Two North Central Avenue
Phoenix, AZ 85004

1-18-19
Date


Susan Brichler Trujillo, Attorney for Respondent
Quarles & Brady LLP
One Renaissance Square
Two North Central Avenue
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1/22/2019
Date



Zachary J. Peters, Attorney
Wisconsin Department of Safety and Professional Services
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P.O. Box 7190
Madison, WI 53707-7190

1/23/19
Date