

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
GUARANTEED RETURNS, :
RESPONDENT. :

ORDER 0006823

Division of Legal Services and Compliance Case No. 19 PHM 155

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

Guaranteed Returns
Holbrook, NY 11741

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 Guaranteed Returns is licensed in the state of Wisconsin as a wholesale distributor of prescription drugs, having license number 2478-45, first issued on June 22, 2012, and current through May 31, 2020. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is in Holbrook, New York, 11741.

2. At all relevant times, Respondent was a pharmaceutical returns company managing pharmaceutical product returns for healthcare providers (Clients) in exchange for a fee.

3. Pharmaceutical product manufacturers allow refunds for the return of recently expired drugs, but not for the return of saleable, unexpired drugs.

4. Clients contracted with Respondent to hold drugs in storage on their behalf until the drugs expired, return the drugs to the manufacturers for a refund, take a percentage of the refund as its fee, and send the remainder of the refund to the Client.

5. Under the direction of Respondent's owner and its vice president, Respondent modified its own computerized inventory control system to divert its Clients' drugs.

6. Respondent returned the Clients' drugs to the manufacturers as if they were Respondent's own drugs and kept the full refunds.

7. Between 1999 and 2014, Respondent diverted approximately \$179,907,751 in Client refunds.

8. On July 26, 2019, Respondent self-reported that the U.S. District Court for the Eastern District of Pennsylvania (Court) had issued a judgment and sentencing in *U.S. v. Devos Ltd. d/b/a Guaranteed Returns, et al.*

9. Respondent was found guilty by the Court of 64 counts of various federal crimes, including wire fraud, mail fraud, theft of government property, conspiracy to launder money, conspiracy to obstruct justice, obstruction of justice, aiding and abetting, and making false statements, and sentenced to five (5) years of probation ("Criminal Probation Term"), payment of fines and restitution, and monitoring by a Court-appointed monitor and probation officer. The Court imposed several conditions on Respondent's probation.

10. Since 2014, Respondent has taken steps to reform its policies and procedures so that it can continue to conduct business in a more transparent and ethical manner, including the following:

- a) The owner and vice president were removed along with all their voting and management rights.
- b) Respondent's new CEO put protections and precautions in place to ensure against the practices in the indictment, including hiring outside counsel to act as compliance officer.
- c) Respondent hired an independent monitor to review its compliance programs, internal controls, and their implementation.
- d) Respondent established an escrow account into which all funds received from manufacturers are deposited and analyzed by an independent accounting firm before they are released to Respondent for distribution to Clients.

11. In resolution of this matter, 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 violated Wis. Stat. § 450.10(1)(a)2., by violating this chapter or, subject to s. 961.38(4r), ch. 961 or any federal or state statute or rule which substantially relates to the practice of the licensee.
3. By the conduct described in the Findings of Fact, Respondent violated Wis. Stat. § 450.10(1)(a)7., by obtaining or attempting to obtain compensation by fraud or deceit.
4. By the conduct described in the Findings of Fact, Respondent engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(1), by administering, dispensing, supplying or obtaining a drug other than in legitimate practice, or as prohibited by law.
5. As a result of the above violations, Respondent is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)1. and 3.

ORDER

1. The attached Stipulation is accepted.
2. The license to engage in the wholesale distribution of prescription drugs issued to Respondent is **SUSPENDED** for the duration of the Criminal Probation Term.
3. The suspension is hereby **STAYED**.
4. The Board or its designee may, without hearing, remove the stay upon receipt of information that Respondent is in violation of any provision of this Order. The suspension becomes reinstated immediately upon notice of the removal of the stay being provided to Respondent either by:
 - a) Mailing to Respondent's last known address provided to the Department, pursuant to Wis. Stat. § 440.11; or
 - b) Actual notice to Respondent or Respondent's attorney.
5. The Board or its designee may reinstate the stay, if provided with sufficient information that Respondent is in compliance with the Order and that it is appropriate for the stay to be reinstated. Whether to reinstate the stay shall be wholly in the discretion of the Board or its designee.
6. Respondent shall comply with all the conditions of probation ordered by the Court in *U.S. v. Devos Ltd. d/b/a Guaranteed Returns, et al.* The August 1, 2019 Amended Judgment of the Court is attached hereto and incorporated into this Final Decision and Order. Any violations of the terms of probation shall be considered violations of this Order.

7. Respondent shall, within 14 days, report any modification by the Court to its August 1, 2019 Amended Judgment to the Department Monitor at the address below.

8. Respondent shall submit self-reports to the Department Monitor on a quarterly basis, as directed by the Department Monitor. The reports shall include a summary of Respondent's compliance with the terms and conditions of this Order in the previous quarter.

9. Respondent may petition the Board for termination of this Order upon termination of the Criminal Probation Term. Whether or not to terminate this Order is solely within the discretion of the Board or its designee. Denial of a petition in whole or in part shall not be considered a denial of a license within the meaning of Wis. Stat. § 227.01(3)(a), and Respondent shall not have a right to any further hearings or proceedings on the denial. The Board may, on its own motion, grant full Wisconsin licensure at any time.

10. Within 120 days from the date of this Order, Guaranteed Returns (License No. 2478-45) shall pay COSTS of this matter in the amount of \$625.00.

11. All reports and payment of costs (made payable to the Wisconsin Department of Safety and Professional Services) shall be sent by Respondent to the Department Monitor at the address below:

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:

www.dpsmonitoring.wi.gov

12. In addition to any other action authorized by this Order or law, the Board, in its discretion, may impose additional limitations or pursue separate disciplinary action for violation of any term of this Order. Notwithstanding the foregoing, the parties agree that disciplinary action taken by another state or jurisdiction that is based on the same underlying factual circumstances upon which this Order is based shall not form the basis for new grounds for disciplinary action against Respondent by the Board.

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

WISCONSIN PHARMACY EXAMINING BOARD

By: Phillip Trapshin, M.D.
A Member of the Board

6/4/2020
Date

UNITED STATES DISTRICT COURT

Eastern District of Pennsylvania

UNITED STATES OF AMERICA
 V.

AMENDED JUDGMENT IN A CRIMINAL CASE
 (For Organizational Defendants)

DEVOS LTD. d/b/a GUARANTEED RETURNS

CASE NUMBER: DPAA2:14CR000574-001

Date of Original Judgment: 7/16/2019
 (or Date of Last Amended Judgment)

Douglas Grover, Esq.
 Defendant Organization's Attorney

Reason for Amendment:

- Correction of Sentence on Remand (18 U.S.C. § 3742(f)(1) and (2))
- Reduction of Sentence for Changed Circumstances (Fed. R. Crim. P. 35(b))
- Correction of Sentence by Sentencing Court (Fed. R. Crim. P. 35(a))
- Correction of Sentence for Clerical Mistake (Fed. R. Crim. P. 36)
- Modification of Supervision Conditions (18 U.S.C. §§ 3563(c) or 3583(e))
- Modification of Restitution Order (18 U.S.C. § 3664)

THE DEFENDANT ORGANIZATION:

FILED

- pleaded guilty to count(s) _____
- pleaded nolo contendere to count(s) _____
 which was accepted by the court.
- was found guilty on count(s) 1-64
 after a plea of not guilty.

AUG 01 2019

By KATE BARKMAN, Clerk
 Dep. Cl.

The organizational defendant is adjudicated guilty of these offenses:

| Title & Section | Nature of Offense | Offense Ended | Count |
|-----------------|---|---------------|-------|
| 18:1343 | Mail Fraud | 7/28/2019 | 1-23 |
| 18:1341, 1349 | Mail Fraud | 10/18/2014 | 24-52 |
| 18:641, 18:2 | Theft of Government Property; Aiding & Abetting | 10/28/2014 | 53 |

The defendant organization is sentenced as provided in pages 2 through 6 of this judgment.

- The defendant organization has been found not guilty on count(s) _____
- Count(s) _____ is are dismissed on the motion of the United States.

It is ordered that the defendant organization must notify the United States attorney for this district within 30 days of any change of name, principal business address, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant organization must notify the court and United States attorney of material changes in economic circumstances.

Defendant Organization's Federal Employer ID No 11-2946549

7/1/2019
 Date of Imposition of Judgment

Defendant Organization's Principal Business Address
 100 Collin Drive
 Holbrook, NY 11741

Petrese B. Tucker
 Signature of Judge

Petrese B. Tucker, EDPA District Court Judge
 Name of Judge Title of Judge

8/1/2019
 Date

Defendant Organization's Mailing Address

100 Collin Drive
 Holbrook, NY 11741

DEFENDANT ORGANIZATION: DEVOS LTD. d/b/a GUARANTEED RETURNS
CASE NUMBER: DPAE2:14CR000574-001

Judgment - Page 3 of 6

PROBATION

The defendant organization is hereby sentenced to probation for a term of:

5 years Probation

The defendant organization shall not commit another federal, state or local crime.

If this judgment imposes a fine or a restitution obligation, it is be a condition of probation that the defendant organization pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant organization must comply with the standard conditions that have been adopted by this court as well as with any additional conditions below or on the attached page (if indicated below).

Guaranteed Returns not commit another federal, state or local crime during the term of probation. Until the restitution has been paid in full, No person should be paid a salary or other compensation greater than the salary of the CEO without the express written permission of the probation officer. Guaranteed Returns should not make any payments to or on behalf of Dean Volkes, Donna Fallon or their relatives without express permission of the probation officer. Guaranteed returns should not hire any relatives of Volkes or Fallon with the express permission of the probation officer. No one should be paid who does not show up for work, without the express permission of the probation department. That includes not only the category of the Volkesses and Fallons, but anyone who is being paid and does not show up. Guaranteed Returns shall request a refund of all prepaid expenses currently listed on the financial statements unless an exception is obtained from the Probation office. Probation should be notified immediately of any material or adverse change in the business or financial condition or prospects, or the commencement of any bankruptcy proceedings, major civil litigation, criminal prosecution or administrative proceeding against the company or any investigation or formal inquiry by governmental authorities regarding the organization. Mr. Howard will be retained as monitor and liaison between the company and the probation office.

STANDARD CONDITIONS OF SUPERVISION

- 1) within thirty days from the date of this judgment, the defendant organization shall designate an official of the organization to act as the organizations's representative and to be the primary contact with the probation officer;
- 2) the defendant organization shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
- 3) the defendant organization shall notify the probation officer at least ten days prior to any change in principal business or mailing address;
- 4) the defendant organization shall permit a probation officer to visit the organization at any of its operating business sites;
- 5) the defendant organization shall notify the probation officer within seventy-two hours of any criminal prosecution, major civil litigation, or administrative proceeding against the organization;
- 6) the defendant organization shall not dissolve, change its name, or change the name under which it does business unless this judgment and all criminal monetary penalties imposed by this court are either fully satisfied or are equally enforceable against the defendant's successors or assignees; and
- 7) the defendant organization shall not waste, nor without permission of the probation officer, sell, assign, or transfer its assets.

DEFENDANT ORGANIZATION: DEVOS LTD. d/b/a GUARANTEED RETURNS
 CASE NUMBER: DPAAE2:14CR000574-001

Judgment - Page 4 of 6

CRIMINAL MONETARY PENALTIES

The defendant organization must pay the following total criminal monetary penalties under the schedule of payments on Sheet 4.

| | | | |
|---------------|-------------------|------------------|--------------------|
| | <u>Assessment</u> | <u>Fine</u> | <u>Restitution</u> |
| TOTALS | \$ 25,600.00 | \$ 15,000,000.00 | \$ 95,253,090.05 |

- The determination of restitution is deferred until _____. An Amended Judgment in a Criminal Case (AO 245C) will be entered after such determination.
- The defendant organization shall make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant organization makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

| <u>Name of Payee</u> | <u>Total Loss*</u> | <u>Restitution Ordered</u> | <u>Priority or Percentage</u> |
|----------------------|--------------------|----------------------------|-------------------------------|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| TOTALS | \$ 0.00 | \$ 0.00 | |

- Restitution amount ordered pursuant to plea agreement \$ _____
- The defendant organization shall pay interest on restitution or a fine of more than \$2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 4 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).
- The court determined that the defendant organization does not have the ability to pay interest, and it is ordered that:
 - the interest requirement is waived for the fine restitution.
 - the interest requirement for the fine restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT ORGANIZATION: DEVOS LTD. d/b/a GUARANTEED RETURNS
CASE NUMBER: DP AE2:14CR000574-001

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SCHEDULE OF PAYMENTS

Having assessed the organization's ability to pay, payment of the total criminal monetary penalties are be due as follows:

- A Lump sum payment of \$ 5,000.00 due immediately, balance due
 - not later than _____, or
 - in accordance with C or D below; or
- B Payment to begin immediately (may be combined with C or D below; or
- C Payment in _____ (e.g., equal, weekly, monthly, quarterly) installments of \$ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after the date of this judgment; or
- D Special instructions regarding the payment of criminal monetary penalties:
 - Restitution to be paid every month in the amount of \$5000.00
 - Guaranteed Returns is ordered to pay a special assessment in the amount of \$25,600 to begin in 90 days

All criminal monetary penalties are made to the clerk of the court.

The defendant organization shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

Joint and Several

Defendant and Co-Defendant Names and Case Numbers (including defendant numbers), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate:

Guaranteed Returns (14-cr-574-1) and Dean Volkes defendant (14-cr-574-2) to pay restitution in the amount of \$95,253,090.05 to be paid at \$5000.00 per month, subject to being changed up or down, and to be paid first.

- The defendant organization shall pay the cost of prosecution.
- The defendant organization shall pay the following court cost(s):
- The defendant organization shall forfeit the defendant organization's interest in the following property to the United States:

Forfeiture amount, not to exceed \$114,832,445.62. All funds held in Merrill Lynch account number 843-38521 in the name of Dean Volkes; and All funds held in Merrill Lynch account number 843-14166, titled "Donna Fallon TTEE U/A DTD 5/31/12 by Dean Volkes Ashley Judson Irrev Trust"

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

GUARANTEED RETURNS,
RESPONDENT.

:
:
:
:
:
:

STIPULATION
ORDER 0006823

Division of Legal Services and Compliance Case No. 19 PHM 155

Respondent Guaranteed Returns 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 in this matter by Attorney Nick Meza.

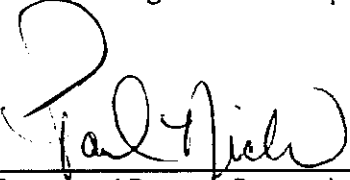
4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining (Board). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives 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, 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.

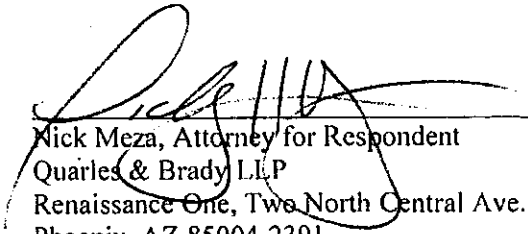
8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.



Guaranteed Returns, Respondent
License No. 2478-45
By: Paul Nick, President and CEO

5/19/2020


Date



Nick Meza, Attorney for Respondent
Quarles & Brady LLP
Renaissance One, Two North Central Ave.
Phoenix, AZ 85004-2391

5/19/20

Date



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

5/20/20

Date