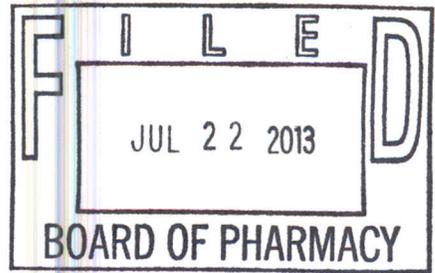


# 95566



JOHN J. HOFFMAN  
ACTING ATTORNEY GENERAL OF NEW JERSEY  
Division of Law  
124 Halsey Street - 5th Floor  
P.O. Box 45029  
Newark, New Jersey 07101

By: Kim D. Ringler  
Deputy Attorney General  
Tel. No. (973) 648-4741

STATE BOARD OF NEW JERSEY  
DEPARTMENT OF LAW & PUBLIC SAFETY  
DIVISION OF CONSUMER AFFAIRS  
STATE BOARD OF PHARMACY

---

IN THE MATTER OF THE SUSPENSION  
OR REVOCATION OF

THE PERMIT OF  
MEDPREP CONSULTING INC.  
Permit No. 28RS00615400

Administrative Action

TO OPERATE AS A PHARMACY  
IN THE STATE OF NEW JERSEY

---

FINAL CONSENT ORDER

This matter was opened to the New Jersey State Board of Pharmacy (hereinafter the "Board") on March 15, 2013, upon receipt of information from MedPrep Consulting, Inc., a pharmacy located at 1540 West Park Avenue, Suite 5, Tinton Falls (hereinafter "MedPrep"), that it voluntarily recalled all magnesium sulfate products compounded at its facility. It subsequently expanded the recall to include

all of its products. The recall resulted from MedPrep being notified by Yale New Haven Hospital that it observed visible particulate contaminants in 50 ml bags of magnesium sulfate intravenous solution belonging to unique and distinct lots compounded and dispensed by MedPrep only to Yale New Haven Hospital. As of this date, there are no known injuries or illnesses attributable to the contamination.

At all relevant times Stephen W. Kalinoski, R.PH. ("Kalinoski") was the Registered Pharmacist in Charge ("RPIC") of MedPrep. Gerald Tighe ("Tighe") was the sole shareholder and President of MedPrep.

MedPrep and the Board entered into a Voluntary Interim Consent Order filed March 15, 2013 in which MedPrep agreed to refrain from and stop all pharmacy operations through the close of business on Friday, March 22, 2013. Said Order was then extended to April 5, 2013 and again to April 12, 2013.

MedPrep has voluntarily refrained from engaging in compounding activities from March 15, 2013 to the present, and it cooperated with an investigation and physical inspection by the Board.

That investigation revealed alleged deficiencies in the labeling of compounded sterile products; product

testing; sterility of the cleanroom; assignment of beyond use dates; compounding recordkeeping (audit trail) and documentation; the ratio of pharmacists to pharmacy technicians; and the filing of joint centralized prescription handling agreements.

MedPrep provided to the Board reports from experts in the field, laboratory data, a summary of corrective measures taken since the recall, and other pertinent information.

On or about April 10, 2013, MedPrep applied for immediate relief from the shutdown order. On April 12, 2013 and April 15, 2013, a Committee of the Board held a hearing on MedPrep's application. The Attorney General opposed the application and cross-moved for the continued closure of the facility. The Attorney General submitted a Certification from Enforcement Bureau Investigator Tony Qi with numerous attachments; a Certification from EB Investigator Leida Martinez with statements from MedPrep personnel attached; a Certification from Executive Director Anthony Rubinaccio; and a Certification from DAG Jodi Krugman with numerous attachments. MedPrep submitted voluminous documentation of its plan for remediation, compliance with all regulations and standards applicable to sterile compounding in New Jersey, and the expert reports

of consultants who provided guidance for implementing best practices. The Committee of the Board heard testimony from Tighe; Louis Diorio, R.Ph., principal of LDT Health Solutions, Inc., the expert/consultant hired by MedPrep; FDA Investigator Barbara Wilimczyk-Macri; David Newton, Ph.D., the expert for the State; and Enforcement Bureau Investigators Qi and Martinez.

The Committee of the Board heard argument from counsel and deliberated before issuing a verbal Order on April 15, 2013 denying the Attorney General's cross motion and identifying numerous conditions and prerequisites for a graduated, limited re-opening.

The Attorney General moved for reconsideration based on newly acquired information. The Committee of the Board granted the motion in part, modifying its Interim Order to require prior to re-opening, among other things, a report from the monitor advising of the training of all employees and testing performed at the facility, subject to further order of the full Board. The Order was memorialized in an Interim Order and Report of Hearing Committee ("Interim Order") filed April 19, 2013. The Interim Order permitted MedPrep, subject to approval of the Board after submission of a monitor's report, to gradually re-open with numerous protections, conditions and requirements including

additional training, reduced personnel, enhanced oversight by a dedicated cleanroom supervisory pharmacist, an on-site independent outside monitor, and increased reporting and notification procedures, among other reforms.

The Attorney General submitted an application filed April 22, 2013, for supplementation of the Interim Order proposing fourteen additional protections for inclusion. Also on April 22, 2013, the Attorney General filed an eight count Administrative Complaint against MedPrep and Kalinoski.

At its monthly meeting on April 24, 2013, the Board issued an oral Order, placed on the record, ratifying the Interim Committee Order with clarifications and supplemental conditions. On April 25, 2013, the Attorney General filed a First Amended Complaint against both MedPrep and Kalinoski which added a ninth count alleging violations of the Board's central fill regulation.

On May 2, 2013, the Board filed an Order requiring MedPrep to satisfy enumerated conditions prior to re-opening. On May 7, 2013, the Board advised MedPrep that it could re-open on a limited basis subject to the conditions set forth in its May 2, 2013 Order.

The Office of the Attorney General contends that the permit holder's alleged failure to adequately oversee the

operations of MedPrep and its employees which occurred while Kalinoski served as the RPIC created potential risks to the public as set forth in the Amended Complaint. The Amended Complaint alleges inter alia deficiencies in the labeling of compounded sterile product; product testing; the sterility of the cleanroom; the assignment of beyond use dates; compounding recordkeeping (audit trail) and documentation; the ratio of pharmacists to pharmacy technicians; and the filing of joint centralized prescription handling agreements.

N.J.A.C. 13:39-4.17 defines the responsibilities of permit holders:

(a) All permit holders shall be responsible for compliance with all the rules, regulations and laws governing the practice of pharmacy.

(b) Any permit holder may be held liable for violations of the Pharmacy Practice Act, N.J.S.A. 45:14-1 et seq., and the rules in this chapter and may be subject to disciplinary action.

The Attorney General's allegations, if established, provide grounds to take disciplinary action against Respondent=s permit to operate a pharmacy in New Jersey.

MedPrep and Tighe, being desirous of resolving this matter without the necessity of further formal proceedings, and having waived any right to same, and having agreed and given their voluntary consent to the within Order, without admission of liability or wrongdoing, and the Board finding

the within disposition adequately protective of the public health, safety, and welfare, and other good cause having been shown;

IT IS THEREFORE on this 22<sup>nd</sup> day of July, 2013,

ORDERED AND AGREED that

1. MedPrep shall surrender its permit to operate MedPrep Consulting, Inc., permit number 28RS00615400, to be deemed a revocation with prejudice in the State of New Jersey. MedPrep agrees not to seek to reinstate its permit to operate a pharmacy in the State of New Jersey.

2. MedPrep shall return its most recent permit to the Executive Director of the Board upon receipt of this filed Order, by mailing same to Anthony Rubinaccio, Executive Director, Board of Pharmacy, P.O. Box 45013, Newark, New Jersey 07101.

3. MedPrep shall pay civil penalties pursuant to N.J.S.A. 45:1-25(a) in the amount of \$100,000.

4. MedPrep shall pay investigative costs in the amount of \$55,000 and attorneys fees in the amount of \$35,000 pursuant to N.J.S.A. 45:1-25(d), for a total of \$90,000.

5. Payment of civil penalties and costs shall be made by check or money order made payable to the New Jersey Board of Pharmacy and mailed to the New Jersey State

Board of Pharmacy, ATTN: Anthony Rubinaccio, Executive Director, 124 Halsey Street, P.O. Box 45013, Newark, New Jersey 07101.

6. A Certificate of Debt shall be filed in the amount of \$190,000 against MedPrep after the date of the filing of this Consent Order.

7. Upon submission to the Board of a current financial statement demonstrating that MedPrep is unable to pay any portion of the \$190,000 in civil penalties and costs imposed by this Consent Order, payment shall be stayed. In the event that MedPrep's financial condition changes, due to receipt of insurance proceeds or otherwise, so that it becomes able to pay some or all of the \$190,000 at any point in the future, Tighe must timely notify the Board, the stay shall be lifted and immediate payment due.

8. Tighe shall not seek a permit to operate a pharmacy involved in sterile compounding in the State of New Jersey for a minimum period of five years. During that five-year period, Tighe shall refrain from any ownership in, serving as an officer of, operation of, or employment by any registered pharmacy in the State of New Jersey involved in sterile compounding. Tighe shall not seek a permit to operate a pharmacy involved in any other pharmaceutical operations for a period of three years. During that three-year period, Tighe shall refrain from

ownership in, operation of, or employment by any registered pharmacy in the State of New Jersey

9. Prior to applying for a permit to operate a pharmacy, if requested by the Board, Tighe shall appear before the Board or a committee thereof to discuss his plan for the operation of the pharmacy in New Jersey.

10. As a pre-requisite to Tighe receiving a permit to operate a pharmacy individually, or as a sole or partial owner of a company, Tighe shall pay in full any outstanding unpaid balance of the \$190,000 in fines and costs imposed against MedPrep in paragraphs 3 and 4 above.

11. The entry of the within Order is without prejudice to the further investigation and/or prosecution by any regulatory or law enforcement agency, including the Division of Consumer Affairs for the State of New Jersey or other State agency, of any violations by MedPrep, its principal or employees, whether or not currently under investigation

NEW JERSEY STATE BOARD OF PHARMACY

By: \_\_\_\_\_  
Thomas F. X. Bender, R.Ph.  
President

ownership in, operation of, or employment by any registered pharmacy in the State of New Jersey

9. Prior to applying for a permit to operate a pharmacy, if requested by the Board, Tighe shall appear before the Board or a committee thereof to discuss his plan for the operation of the pharmacy in New Jersey.

10. As a pre-requisite to Tighe receiving a permit to operate a pharmacy individually, or as a sole or partial owner of a company, Tighe shall pay in full any outstanding unpaid balance of the \$190,000 in fines and costs imposed against MedPrep in paragraphs 3 and 4 above.

11. The entry of the within Order is without prejudice to the further investigation and/or prosecution by any regulatory or law enforcement agency, including the Division of Consumer Affairs for the State of New Jersey or other State agency, of any violations by MedPrep, its principal or employees, whether or not currently under investigation

NEW JERSEY STATE BOARD OF PHARMACY

By: Thomas F. X. Bender, Jr., R.Ph.  
Thomas F. X. Bender, R.Ph.  
President

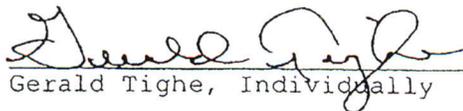
I have read the within Order,  
understand its terms and agree  
to be bound by them. I  
consent to entry of the Order  
by the Board of Pharmacy.

MEDPREP CONSULTING, INC.

  
BY: Gerald Tighe, President

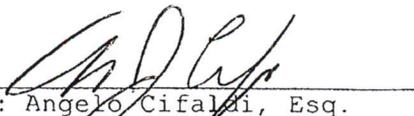
Dated: 7/11/2013

I have read the within Order,  
understand its terms and agree  
to be bound by them. I  
consent to entry of the Order  
by the Board of Pharmacy.

  
Gerald Tighe, Individually

Dated: 7/11/2013

Consent as to Form and Content  
WILENTZ, GOLDMAN & SPITZER, P.A.

  
BY: Angelo Cifaldi, Esq.  
Attorneys for MedPrep Consulting, Inc. and Gerald Tighe

Dated: 7/22/13