STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

Kenny R. Walkup, Jr., R.Ph.
License Nos. 53-02-028789
_____/ Complaint No. 53-13-130506

ORDER OF SUMMARY SUSPENSION

An administrative complaint has been issued against Respondent under the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 *et seq*, promulgated rules, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 *et seq*.

After consideration of the documentation filed in this case and consultation with the Chairperson of the Board of Pharmacy, the Department concludes that the public health, safety or welfare requires emergency action, as allowed by sections 16233(5) and 17768(1) of the Public Health Code and section 92(2) of the Administrative Procedures Act. Pursuant to section 7311(6) upon suspension of the pharmacist license the controlled substance license becomes automatically void.

THEREFORE, IT IS ORDERED that Respondent's pharmacist and controlled substance licenses shall be summarily suspended commencing on the date this order is served.

Under 1996 AACS, R 338.1610, Respondent has the right to petition for the dissolution of this order of summary suspension. This petition shall clearly state that it is a Petition for Dissolution of Summary Suspension and shall be filed with the Department of Licensing and Regulatory Affairs, Bureau of Health Care Services, P.O. Box 30670, Lansing, Michigan 48909, with a copy served upon the Department of Attorney General, Licensing & Regulation Division, Cadillac Place, 10th Floor, 3030 W. Grand Blvd., Detroit, MI 48202.

Questions concerning the Order of Summary Suspension may be directed to (517) 373-1146. Upon receipt of such a petition, an administrative hearing will immediately be scheduled before an administrative law judge, who shall dissolve the order of summary suspension unless sufficient evidence is produced to support a finding that the public health, safety, or welfare requires emergency action and a continuation of the suspension order.

DEPARTMENT OF LICENSING AND
REGULATORY AFFAIRS

By:_____
Carole H. Engle, Director
Department of Licensing and
Regulatory Affairs
Bureau of Health Care Services

Dated:_____

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ADMINISTRATIVE COMPLAINT

Attorney General Bill Schuette, through Assistant Attorney General Wanda M. Stokes and Assistant Attorney General Kelly K. Elizondo, on behalf of the Department of Licensing and Regulatory Affairs, Bureau of Health Care Services (Complainant), files this complaint against Kenny Walkup, Jr, R.Ph. (Respondent), alleging upon information and belief as follows:

1. The Board of Pharmacy (Board), an administrative agency established by the Public Health Code (Code),1978 PA 368, as amended, MCL 333.1101 *et seq*, is empowered to discipline licensees under the Code through its Disciplinary Subcommittee.

2 The Board of Pharmacy has been designated the administrator of the controlled substance provisions in Article 7 of the Code and is empowered to

discipline licensees under the controlled substance provisions of the Code through its DSC.

3. Respondent is currently licensed by the Board as a pharmacist and holds a controlled substance license issued by the administrator pursuant to the Code. Respondent is the owner and pharmacist in charge of Specialty Medicine Compounding Pharmacy.

4. Section 16233(5) of the Public Health Code provides for the summary suspension of a license, reading in pertinent part, as follows:

> After consultation with the chair of the appropriate board or task force or his or her designee, the department may summarily suspend a license or registration if the public health, safety, or welfare requires emergency action in accordance with section 92 of the administrative procedures act of 1969, MCL 24.292. If a licensee or registrant is convicted of a felony; a misdemeanor punishable by imprisonment for a maximum term of two years; or a misdemeanor involving the illegal delivery, possession, or use of a controlled substance, the department shall find that the public health, safety, or welfare requires emergency action and, in accordance with section 92 of the administrative procedures act of 1969, MCL 24.292, shall summarily suspend the licensee's license or the registrant's registration.

5. Section 7311(6) of the Code provides that a license under section 7306 to manufacture, distribute, prescribe, or dispense a controlled substance is automatically void if the licensee's license to practice is suspended or revoked under article 15.

6. Section 17768(1) of the Code provides that: "In a manner consistent with part 161, the board may fine, reprimand, or place on probation a person licensed under this part (part 177), or deny, limit, suspend, or revoke a person's license or order restitution or community service for a violation of this part or rules promulgated under this part."

7. Section 17706(1) of the Code defines a manufacturer as: "a person who prepares, produces, derives, propagates, compounds, processes, packages, or repackages a drug or device salable on prescription only, or otherwise changes the container or the labeling of a drug or device salable on prescription only, and who supplies, distributes, sells, offers for sale, barters, or otherwise disposes of that drug or device and any other drug or device salable on prescription only, to another person for resale, compounding, or dispensing."

8. Section 17748 of the Code provides: "a pharmacy, manufacturer, or wholesale distributor of prescription drugs, whether or not located in this state but doing business in this state, shall be licensed by the board in accordance with this part."

9. Section 17751(1) provides in pertinent part: "A pharmacist shall not dispense a drug requiring a prescription under the federal act or a law of this state

except under the authority of an original prescription or an equivalent record of an original prescription approved by the board."

10. Section 17756(1) provides in pertinent part: "A prescription dispensed by a pharmacist shall bear upon the label the name of the medication in the container, unless the prescriber writes "do not label" on the prescription. The prescription shall also bear upon the label the following statement: "Discard this medication 1 year after the date it is dispensed", unless the medication expires on another date under applicable state or federal law or rules or regulations or other state or federal standards." If the medication expires on another date, the pharmacist dispensing the prescription shall strike or omit the statement required under this subsection and shall specify on the label the actual expiration date of the medication.

11. 1980 AACS, R 338.479(2) provides in pertinent part: "All containers in which prescription medication is dispensed shall bear a label which contains, at a minimum, all of the following information:

(a) Pharmacy name and address.
(b) Prescription number.
(c) Patient's name.
(d) Date the prescription was most recently dispensed.
(e) Prescriber's name.
(f) Directions for use.
(g) The name of the medication, unless the prescriber indicates "do not label."

12. 1998-2000 AACS, R 338.481(3) provides that "a pharmacy shall have the necessary technical equipment to compound and dispense prescription drugs."

13. 1980 AACS, R 338.482(1) provides that "all professional and technical equipment and supplies and prescription drugs shall be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings."

14. 1998-2000 AACS, R 338.490(1) provides that "a pharmacist has a professional responsibility for the strength, quality, purity, and the labeling of all drugs and devices dispensed under a prescription. In discharging this responsibility, a pharmacist shall utilize only those drugs and devices that are obtained from manufacturers and wholesale distributors licensed under section 17748 of the code or from other lawful channels of distribution."

15. Section 17764(2) of the Code provides: "a person shall not knowingly or recklessly do either of the following:

> (a) Adulterate, misbrand, remove, or substitute a drug or device knowing or intending that the drug or device shall be used.
>
> (b) Sell, offer for sale, cause to be sold, or manufacture for sale an adulterated or misbranded drug."

16. Section 17764 provides the following penalties for a violation of section 17764(2)(b):

(3) Except as otherwise provided in this section, a person who violates subsection (2) is guilty of a felony punishable by imprisonment for not more than 2 years or a fine of not more than $1,000.00, or both.

(4) A person who violates subsection (2), which violation results in personal injury, is guilty of a felony punishable by imprisonment for not more than 4 years or a fine of not more than $4,000.00, or both.

(5) A person who violates subsection (2), which violation results in serious impairment of a body function, is guilty of a felony punishable by imprisonment for not more than 5 years or a fine of not more than $5,000.00, or both. As used in this subsection, "serious impairment of a body function" means that term as defined in section 58c of the Michigan vehicle code, 1949 PA 300, MCL 257.58c.

(6) A person who violates subsection (2), which violation results in death, is guilty of a felony punishable by imprisonment for not more than 15 years or a fine of not more than $20,000.00, or both.

(7) A person who violates subsection (2) with the intent to kill or to cause serious impairment of a body function of 2 or more individuals, which violation results in death, is guilty of a felony punishable by imprisonment for life without the possibility of parole or life without the possibility of parole and a fine of not more than $40,000.00. It is not a defense to a charge under this subsection that the person did not intend to kill a specific individual, or did not intend to cause serious impairment of a body function of 2 or more specific individuals.

(8) This section does not prohibit an individual from being charged with, convicted of, or punished for any other violation of law that is committed by that individual while violating this section.

17. Section 1106 defines person to mean "an individual, partnership, cooperative, association, private corporation, personal representative, receiver, trustee, assignee, or other legal entity. Person does not include a governmental entity unless specifically provided."

18. 1979 AC, R 338.478 defines the word person: "the word 'person,' as used in all statutes, and regulations relating to the profession of pharmacy, shall be construed to include individuals, partnerships, firms, corporations, associations, and governmental institutions."

FACTUAL ALLEGATIONS

19. Respondent is a pharmacist licensed in the State of Michigan. Respondent holds both a Michigan pharmacist license and controlled substance license, which allow Respondent to prepare a medication for a single patient pursuant to a prescription. Respondent applied for a manufacturer's license for his pharmacy but does not currently possess such a license.

20. On October 17, 2013 the Food and Drug Administration (FDA) was notified that a local hospital had received multiple vials of an unexpired sterile product, specifically Dextrose injection 50%, 50 ml vials, compounded by Respondent which contained significant amounts of a material which was a green/brown color. Involved lot numbers were identified as: 07232013@5; 07222013@24; 07302013@32; 07252013@5.

21. A local microbiology department performed a wet mount of the product from the contaminated vials and confirmed the presence of two types of mold/fungus. Final cultures are pending at this time.

22. On October 19, 2013, Respondent issued a voluntary recall of "certain unexpired human and veterinary sterile products to the consumer level due to particulate matter found in vials of a compounded dextrose injection product dispensed to a local hospital." The recalled products were distributed to hospitals and consumers located within the State of Michigan from July 1, 2013 through October 19, 2013. A list of all recalled products is published on the FDA website.

23. Based on information and belief none of the compounded drugs were prepared pursuant to an individual patient prescription and the volume of compounded products suggests that Respondent began manufacturing products before his application for a manufacturer's license was processed. It appears medications were prepared in bulk without appropriate labeling. Furthermore, the sterility of Respondent's facility is called into question based on the contaminated product produced.

24. Based on the information currently available there is the potential that products received by Michigan facilities have been contaminated. Respondent allowed an adulterated product to be shipped to Michigan health facilities leading to an imminent public health threat in the State of Michigan as it is unknown how many products were contaminated and administered to patients.

25. In order to protect the public health, safety & welfare Respondent's pharmacist and controlled substance licenses must be summarily suspended pursuant to the Board's authority under sections 16233(5), 7311(6) and 17768(1).

COUNT I

Respondent's conduct as set forth above constitutes a violation of section 17748 of the Code, contrary to section 17768(1) of the Code.

COUNT II

Respondent's conduct as set forth above constitutes a violation of section 17751(1) of the Code, contrary to section 17768(1) of the Code.

COUNT III

Respondent's conduct as set forth above constitutes a violation of section 17756(1) of the Code, contrary to section 17768(1) of the Code.

COUNT IV

Respondent's conduct as set forth above constitutes a violation of 1980 AACS, R 338.479(2) in violation of section 17768(1) of the Code.

COUNT V

Respondent's conduct as set forth above constitutes a violation of 1998-2000 AACS, R 338.481(3) in violation of section 17768(1) of the Code.

COUNT VI

Respondent's conduct as set forth above constitutes a violation of 1980 AACS, R 338.482(1) in violation of section 17768(1) of the Code.

COUNT VII

Respondent's conduct as set forth above constitutes a violation of 1998-2000 AACS, R 338.490(1) in violation of section 17768(1) of the Code.

COUNT VIII

Respondent's conduct as set forth above constitutes a violation of section 17764(2)(b) of the Code, contrary to section 17768(1) of the Code.

WHEREFORE, Complainant requests that a hearing be scheduled pursuant to the Administrative Procedures Act of 1969, MCL 24.201 et. seq; the Public Health Code, and the rules promulgated thereunder, to determine whether disciplinary action should be taken against Respondent for the reasons set forth above.

FURTHER, pending a hearing and final determination in the within cause, and pursuant to sections 16233(5), 7311(6) and 17768(1) of the Public Health Code

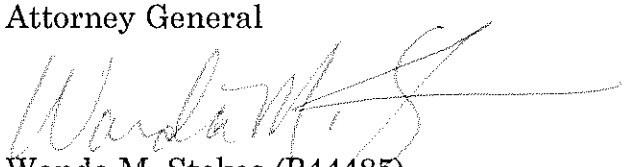
Complainant states that the public health, safety and welfare requires emergency action and Respondent's pharmacist and controlled substance licenses should be summarily suspended.

THEREFORE, Complainant requests that this complaint be served upon Respondent and that Respondent be offered an opportunity to show compliance with all lawful requirements for retention of the aforesaid licenses. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated pursuant to it, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 *et seq.*

RESPONDENT IS HEREBY NOTIFIED that, pursuant to section 16231(7) of the Public Health Code, Respondent has 30 days from receipt of this Administrative Complaint to submit a written response to the allegations contained in it. The written response shall be submitted to the Bureau of Health Care Services, Department of Licensing & Regulatory Affairs, P.O. Box 30670, Lansing, Michigan, 48909, with a copy to the undersigned assistant attorney general. Further, pursuant to section 16231(8) of the Public Health Code, failure to submit a written response within 30 days shall be treated as an admission of the allegations

contained in the Administrative Complaint and shall result in transmittal of the Administrative Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

BILL SCHUETTE
Attorney General



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