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The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy

239 Causeway Street, Suite 200, 2nd Floor
Boston, MA 02114
617-973-0954

January 12, 2010

VIA FIRST CLASS AND CERTIFIED MAIL RETURN
RECEIPT REQUESTED NO. 7009 1680 0001 1520 1412
Gerald L. Liberfarb
[redacted]

RE: In the Matters of **Gerald L. Liberfarb, R.Ph.** - Docket No. PH-06-011
Bourne Pharmacy – Docket No. DS-06-074

Dear Mr. Liberfarb:

Enclosed is the *Final Decision and Order* issued by the Board of Registration in Pharmacy regarding the above-referenced matters.

Please be advised of your appeal rights noted on page 25 of the *Final Decision and Order*.

Sincerely,

Joanne M. Trifone

Joanne Trifone, R.Ph.
President

Encl.

cc: James. L. Lavery, Prosecuting Counsel w/Encl.

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matters of	)	
BOURNE PHARMACY	)	DOCKET NO. DS-06-074
131 Main Street	)	
Buzzards Bay, Massachusetts	)	
Pharmacy Registration No. 3078	)	
	)	
GERALD L. LIBERFARB, R.Ph.	)	DOCKET NO. PH-06-011
Pharmacist License No. 15152	)	
	)	

FINAL DECISION AND ORDER

I. Introduction

These matters came before the Board of Registration in Pharmacy (Board) for determination of why the Board should not suspend, revoke or otherwise take action against: (a) the pharmacy license of Bourne Pharmacy, previously operating at 131 Main Street in Buzzards Bay, Massachusetts, License No. 3078 (Pharmacy); and (b) the pharmacist license of Gerald L. Liberfarb (Respondent), License No. 15152, owner and manager of record of the Pharmacy at all times relevant to Board Complaint Docket Nos. DS-06-074 and PH-06-011 (the Complaints), and any right to renew either license, pursuant to Massachusetts General Laws (G. L.) c. 112, §§ 27, 28, 32, 42A and 61, and Board regulations 247 CMR 9.00 and 10.00, based on the record in these matters, including written submissions presented to the Board, exhibits introduced into evidence, and testimony provided at a hearing conducted over multiple dates and in accordance with G.L. c. 30A and 801 CMR 1.01 *et seq.*

II. Procedural Background

On September 27, 2005, the Board conducted an investigative conference regarding the Complaints, which was attended by Respondent and prior counsel. Respondent declined to answer questions at the conference on advice of counsel. Following the conference, the Board voted to initiate summary suspension proceedings regarding the licenses of Respondent and the Pharmacy.

On October 12, 2005, Beryl W. Cohen, Esq. entered an appearance on behalf of Respondent and the Pharmacy.

On October 17, 2005, the Board issued a *Temporary Order of Suspension* (Exhibit 4) summarily suspending the Pharmacy license and Respondent's pharmacist license. Following Respondent's October 20, 2005 waiver of his rights to a hearing on the necessity of the summary suspensions, the Board issued a *Final Order of Summary Suspension* on October 23, 2005 (Exhibit 5), continuing the suspensions of the respective licenses of Respondent and the Pharmacy pending a hearing on the merits of the allegations in the Complaints.

On November 10, 2005, the Board issued respective *Orders to Show Cause* (Show Cause Order) regarding Respondent (Exhibit 6) and the Pharmacy (Exhibit 8).

On November 23, 2005, Respondent filed an *Answer* to each Show Cause Order (Exhibits 7 and 9), which Answers: (a) admitted certain allegations in the respective Show Cause Order, including that Respondent was present in the Pharmacy on September 21, 2005 when Board investigators were on the premises; (b) denied other Show Cause Order allegations; and (c) stated Respondent "lacks knowledge or information sufficient to form a belief as to the truth of the allegations" regarding other Show Cause Order allegations.

Administrative Hearings Counsel Mitchell Goldstein (Hearings Counsel Goldstein) conducted an adjudicatory hearing regarding these matters over six days (January 10, 11, 12, 23, 24 and 25, 2007). Atty. Cohen represented Respondent on all hearing dates. James G. Lavery was Prosecuting Counsel.

By letter dated July 2, 2007, Hearings Counsel Goldstein advised Respondent "At the conclusion of the last hearing, the parties agreed to explore the possibility of settlement and your attorney was to request further hearing dates for the sanction phase of the hearing if the case did not settle" and inquired if Respondent was still represented by Atty. Cohen, who had been suspended from the practice of law for a 90 day period commencing May 31, 2007. Respondent's response to Hearings Counsel Goldstein (Letter dated July 13, 2007) requested a sanction hearing be scheduled after the receipt of hearing transcripts and stated "[a]t that time I will be represented by Attorney Cohen." After several continuances, a hearing on sanctions (Sanction Hearing) was held on December 20, 2007. Atty. Cohen represented Respondent at the Sanction Hearing. Respondent and [redacted] of Respondent, provided testimony and Atty. Cohen reviewed prior Board decisions at the Sanction Hearing.

Neither party filed post-hearing memoranda. Communications between the parties continued thereafter, including the July 30, 2008 letter from Atty. Cohen to Prosecuting Counsel referenced below.

As of April 24, 2009, Hearings Counsel Goldstein discontinued employment at the Department of Public Health, Division of Health Professions Licensure. On April 14, 2009, the Board voted to designate Hearings Counsel Goldstein to continue to act as presiding officer in these matters to present a proposed final decision to the Board, in accordance with G.L. c. 30A, s. 11, subsection (8) and 801 CMR 1.01(11).

In accordance with 801 CMR 1.01 (11) (c), Hearings Counsel Goldstein issued a *Tentative Decision* in this matter to Prosecuting Counsel Lavery and Respondent on November 2, 2009, with specific notice to Respondent to advise counsel and referencing

the currently suspended attorney registration of Atty. Cohen. Any outstanding motion made by Respondent relating to the inspection of the Pharmacy or other matter relating to these proceedings that was taken under advisement or otherwise not previously ruled on; specifically, *Respondent's Motion to Dismiss Based Upon Warrantless Search* which was filed and argued by Respondent on January 25, 2007 and taken under advisement by Hearings Counsel Goldstein, was DENIED, in accordance with the ruling of Hearings Counsel Goldstein in the previously issued *Tentative Decision*. (Vol. VI: 46) All other motions Respondent filed and argued on various dates have been previously ruled on by Hearings Counsel Goldstein. (Vol. I: 30-54; Ex. 1)

Respondent filed his *pro se Objections to Tentative Decision* on December 2, 2009. Prosecuting Counsel filed *Prosecuting Counsel's Response to Respondent's Objections to Tentative Decision* with attached Exhibit 1 (*Ruling on Respondent's Motion to Suppress* dated June 8, 2006 and Letter dated June 28, 2006 from Hearings Counsel Goldstein to Beryl Cohen, Esq.) and Exhibit 2 (Letter dated July 30, 2008 from Beryl Cohen, Esq. to Prosecuting Counsel) on December 9, 2009. On December 31, 2009, the Board received "*Respondent Gerald L. Liberfarb's Objections to Chief Board Prosecutor's Objections to Tentative Decision.*" Although such further objections are not provided for 810 CMR 1.01 (11) (c) (1), the Board has reviewed and considered Respondent's additional filing.

After review of the filings by both parties after the issuance of the *Tentative Decision,* Hearings Counsel Goldstein revised certain portions of the *Tentative Decision* and issued his *Proposed Final Decision* consideration by the Board. Arthurs v. Board of Registration in Medicine, 383 Mass. 299, 315-316 (1981) (Board is not required to respond specifically to objections to the Recommended Decision).

At the Board meeting on January 12, 2010, the Board reviewed the *Proposed Final Decision* of Hearings Counsel Goldstein. As set forth below, the Board voted to adopt the *Proposed Final Decision* in its entirety and issue this *Final Decision and Order*, effective as of January 12, 2010.

III. **Witnesses**

A. For the Prosecution

1. Kurtis Roth, Diversion Investigator, U.S. Dept. of Justice, Drug Enforcement Administration (DEA)
2. Samuel J. Penta, R.Ph., Supervising Investigator, Department of Public Health, Division of Health Professions Licensure, Office of Public Protection, Investigative Unit

B. For Respondent

1. Respondent
2. [redacted] of Respondent
3. [redacted]
4. [redacted] (Sanction Hearing)

IV. **Exhibits**

Exhibit 1: Records of Standing - Respondent and Pharmacy (12/12/06)

Exhibit 2: Complaint Docket No. PH-06-011 (Respondent)

Exhibit 3: Complaint Docket No. DS-06-074 (Pharmacy)

Exhibit 4: Temporary Order of Suspension (October 17, 2005)

Exhibit 5: Final Order of Summary Suspension (October 23, 2005)

Exhibit 6: Order to Show Cause (October 10, 2005) regarding Respondent

Exhibit 7: Respondent's Answer (November 23, 2005)

Exhibit 8: Order to Show Cause (October 10, 2005) regarding the Pharmacy

Exhibit 9: Pharmacy Answer (November 23, 2005)

Exhibit 10: Declaration of Samuel J. Penta, R.Ph. (October 14, 2005)

Exhibit 11: MDPH – Division of Health Professions Licensure, Investigation Report (19 pages), Samuel J. Penta, R.Ph., Investigator (September 27, 2005)

Exhibit 12: Massachusetts Department of Public Health, Board of Registration in Pharmacy, "Control Substance Inspection Report", Bourne Pharmacy, Samuel J. Penta, R.Ph., Investigator (undated)

Exhibit 13: FOR ID Affidavit of Kurtis Roth, Diversion Investigator, U.S. Dept. of Justice, DEA, U.S. District Court, District of Massachusetts (September 19, 2005)

Exhibit 14: FOR ID Report of Investigation, U.S. Dept. of Justice, DEA (October 2005)

Exhibit 15: Copies of prescriptions (26) dated March 2, 2005 though May 27, 2005 – 19 written by Michael R. Brown, M.D.; two written by Larry J. Price, M.D.; one each written by Harriet Johnson, R.N., C.S.; Renato C. Mandoza, M.D.; Linda F. Habeeb, M.D.; Mary L. Meleski, R.N.C.S.; and Richard W. Marquis, M.D.

Exhibit 16: AmerisourceBergen Corp. "U.S. Official Order Forms - Schedules I & II" (August 29, 2003 though September 6, 2005) and one form from the Pharmacy to Universal Rx Solutions of GA (March 24, 2004)

Exhibit 17: AmerisourceBergen Corp. forms "Monthly Customer Record of Controlled Substances" for the Pharmacy (December 31, 2002 through August 31, 2005)

Exhibit 18: Pharmacy notebook, handwritten, entry dates: September 13, 2003 - August 13, 2004 (AVINZA)

Exhibit 19: "Patient Profile Cards" (12) - last names beginning with "A", handwritten (37 pages)

Exhibit 20: Pharmacy notebook, handwritten, entry dates: August 14, 2004 - September 17, 2005 (Oxycodone + APAP 5/325)

Exhibit 21: Electronic Data Transfer Transmittal Forms (8), Massachusetts Department of Public Health - four dated January 26, 2002; three dated April 15, 2002; one dated June 15, 2002

Exhibit 22: Atlantic Associates, Inc./Sonia Cormier October 20, 2006 facsimile to James Lavery, including: (a) Atlantic Associates, Inc. June 22, 2006 letter to James Lavery; (b) Atlantic Associates, Inc. list of data received from Respondent from November 2004

through September 2005 (dated 10/20/06 and signed by "Sonia"); and (c) Atlantic Associates, Inc. June 23, 2006 letter to Respondent

Exhibit 23: United States Pharmacopeia (USP) - National Formulary (NF) 2004, "The Official Compendia of Standards", Page 10, General Notices, Storage Temperature and Humidity

Exhibit 24: Resume - Samuel J. Penta, R.Ph.

Exhibit 25: Resume - [redacted]

Exhibit 26: Certified Mail receipts (2) dated December 1, 2005 – Pharmacy to Atlantic Associates, Inc.

Exhibit 27: U.S. Dept. of Justice, DEA forms (2), "Receipt for Cash or Other Items" to: (1) Respondent dated September 21, 2005, received by Kurtis Roth, DEA, Diversion Investigator; and (2) Kurtis Roth, DEA, Diversion Investigator, dated September 1, 2006, received by James G. Lavery

Exhibit 28: 105 CMR 720.200 Department of Public Health, Appendix A, Massachusetts List of Interchangeable Drugs

Exhibit 29: 105 CMR 720.200 Department of Public Health, Appendix A (continued), Massachusetts Additional List of Interchangeable Drugs

Exhibit 30: "Drug Facts and Comparisons", Volume Cover, Table of Contents and Update Record, copy of check ($ 606.80) dated December 22, 2004 – Pharmacy to "Facts + Comparisons"

Exhibit 31: "Approved Bioequivalency Codes", Facts and Comparisons – Volume Cover, Update Record with months January - May 2006 checked

Exhibit 32: "Patient Profile Card" form (blank)

Exhibit 33: Five pages (handwritten), undated, with cover: "Biennial Inventory Not Available During Inspection CII-V Aug 14 04 Required every 2 Yrs. FED REC"

Exhibit 34: "Controlled Premises Inspection (G.L. c. 94C Section 11)" Form, Bourne Pharmacy, Inc., Board Investigator Charles Young, dated June 2, 1997

Exhibit 35: Atlantic Associates, Inc. documents – (a) June 23, 2006 letter to Respondent stating: "We did verbally tell you that we could no longer accept your paper submissions to the 'Electronic Data Transmission System' schedule II reporting" (Exhibit 22); (b) June 26, 2006 cover sheet to Bert Cohen; (c) October 14 and 18, 2004 letters to Respondent stating Pharmacy "Controlled Substances prescription data" is "invalid" with copies of handwritten pages (8) for prescriptions dated June 11, 2004 through September 14, 2004 for information Respondent had submitted; and (d) December 6, 2005 letter to Respondent stating diskette data was not acceptable because "it is not in the specified ASAP format"

Exhibit 36: Notebook pages, handwritten, labeled: (a) "Ritalin 5mg 6.10.97-7.26.99" (two pages); and (b) "Oxycontin 40mg 5.19.00-7.6.00" (one page)

Exhibit 37: Notebook pages, handwritten, labeled: (a) "Oxycontin 80mg 5.19.00-12.26.00" (two pages); and (b) "Oxycodone + APAP 5/325 9.4.03-9.5.03" (one page)

Exhibit 38: *Stipulations of Fact* dated January 10, 2007

Exhibit 39: Photographs of the Pharmacy (53), numbered 1 - 54 (no # 42), taken by Kurtis Roth on September 21, 2005

Exhibit 40: Commonwealth of Massachusetts, County of Barnstable, Superior Court, *Commonwealth v. Gerald L. Lieberfarb* Redact "Distributing a controlled substance, Class 'C' 94C/32B", Indictment dated January 20, 1982, Guilty Plea accepted April 15, 1982

Exhibit 41: Data List (multiples pages) that Respondent created from Exhibit 42 and provided to Atlantic Associates, Inc. on December 19, 2005

Exhibit 42: Data Lists (33 pages/computer screen format) dated November 2004 through September 22, 2005 that Respondent used to create Exhibit 41

Exhibit 43: *Warrant* in the Matter of the Administrative Inspection in Re: Bourne Pharmacy Inc., issued September 19, 2005 (Collings, J., U.S. District Court, District of Massachusetts Redact Redac to U.S. Department of Justice, DEA

Exhibit 44: Department of Weights and Measures, Sealing and Adjustment Record No. 2005-043 dated September 12, 2005, Ray Bowman, Sealer of Weights and Measures

V. Findings of Fact[1]

Based on its consideration of all the evidence, the Board finds the following facts established by a preponderance of the evidence:

1. On or about June 18, 1969, the Board issued Pharmacist License No. 15152 to Respondent. (Vol. VI: 48; Exhibits 1 and 38)

2. On or about April 15, 1982, Respondent plead guilty to "knowingly or intentionally distributing a Class 'C' controlled substance, to wit: valium," in violation of G. L. c. 94C, s. 32B. In 1982, the Board suspended Respondent's pharmacist license based on his conviction for violation of G.L. c. 94C, s. 32B. The Board reinstated Respondent's pharmacist license in 1985. (Exhibits 6, 7, 11, 38 and 40)

3. Respondent was owner and Manager of Record of the Pharmacy at all times relevant to the Show Cause Orders issued related to the Complaints. (Vol. VI: 49; Exhibits 1, 6, 8 and 38)

4. As manager of record of the Pharmacy, Respondent was required to comply with the duties and responsibilities of a pharmacist Manager of Record, as outlined in Board regulations 247 CMR 6.07 et seq. (Exhibit 38)

[1] The hearing was recorded on audio tape. Transcripts were prepared of all hearing dates except January 24, 2007 and the sanction portion of the hearing on December 20, 2007. References to testimony provided during the days when a transcript was prepared cite the volume and page number of the transcript where the citation is found. For the two hearing dates when no transcript was prepared, references to the date of the testimony of the particular hearing date from the audio tape of that hearing date are cited.

5. From on or about three years prior to January 2007, Kurtis Roth (Roth) has been employed by the U. S. Department of Justice, Drug Enforcement Administration (DEA), including the prior approximately 16 months as a Diversion Investigator. Roth testified as an expert for the Prosecution. (Vol. I: 83, 113; Vol. II: 113)

6. From on or about a three year two month period prior to January 2007, Samuel J. Penta (Penta), a registered pharmacist, has been employed by the Commonwealth of Massachusetts, Department of Public Health, Division of Health Professions Licensure, Office of Public Protection, as an investigator or supervising investigator, with duties that include conducting inspections for the Board. Penta testified as an expert for the Prosecution. (Vol. II: 140 - 142, 148)

7. On September 21, 2005, at approximately 9:30 a.m., DEA Investigator Roth and other DEA investigators (Mark Rubbins, Group Supervisor; George Haley, Diversion Investigator; Ida Grasso, Diversion Investigator; and Thomas Cook, Diversion Investigator), and Board Investigators Penta and James Emery conducted inspections of the Pharmacy (Inspection) for their respective agencies. The DEA inspected the Pharmacy pursuant to a September 19, 2005 *Warrant* issued by U.S. Magistrate Robert B. Collings on based on an *Affidavit of Kurtis Roth* of same date (Exhibit 13 for ID). The Board inspection was conducted pursuant to authority of G.L. c. 13, s. 25 and Board regulation 247 CMR 11.12.[3] (Vol. I: 101, 114, 165, 169 - 172, 177 - 178; Vol. II: 149 -151; Vol. III: 180 -181; Exhibits 10 and 11)

8. Respondent and Pharmacy employee Redact were present during the Inspection. (Vol. I - 115; Vol. II 152, 232; Vol. VI: 49, 51, 53; Testimony of Red t 1/24/07; Exhibit 11)

9. The Pharmacy included a "front store," which included health and beauty products and other non-prescription items (greeting cards, magazines), and a "Pharmacy area" of approximately 300 square feet, including a passing aisle of

[3] The Board notes that G.L. c. 94C, s. 11 also grants authority for Board inspections of pharmacy premises.

approximately 15 to 20 feet. (Vol. II: 227; Vol. III: 201; Vol. IV: 75, 89; Testimony of Red 1/24/07)

10. Based on the testimony of Roth and Penta, witnesses whom the Board found credible as consistent with Penta's Investigation Report (Exhibit 11) and Inspection Report (Exhibit 12) and consistent with photographs (53) of the Pharmacy premises taken by Roth during the Inspection (Exhibit 39), the Board finds that the following conditions existed in the Pharmacy area at the time of the Inspection:

a. Floors and walls were dirty and dusty;

b. Trash and non-pharmacy items were stored haphazardly on shelves with pharmaceutical inventory;

c. Water damage from overhead sewage pipes was observed on several ceiling times; some ceiling tiles had been removed, exposing ventilation and pipes;

d. Vents were covered with dust and grime;

e. Evidence of prior water leakage and damage appeared on certain drugs (labels) on shelves and on a pipe running through the Pharmacy area;

f. Multiple boxes blocked passage in the Pharmacy area; some boxes were stacked on others with other items placed on top of the boxes, some were filled with outdated medications; some contained papers, notebooks and other miscellaneous items, some boxes were empty. One box included outdated Controlled Substance Schedule II medications, including Dilaudid 2mg and meperidine tablets dated September 2001, intermingled with Schedule III-VI medications dated October 2004 and October 1994. Other items on the floor, including a large cash register, also obstructed passage in the Pharmacy area;

g. The sink had residue and did not drain properly;

h. The refrigerator had food spillage evident, emanated an odor and contained various food products. Medication in the refrigerator (insulin and Miacalcin) was dirty and evidenced food spillage. There was no thermometer (to determine actual temperature) in the refrigerator;

i. The Pharmacy facsimile machine was located outside of the pharmacy area, with a sign advertising a "FAX Center" evident in the front window of the Pharmacy facing the street;

j. There was no patient counseling dedicated area in the Pharmacy; no signage offering counseling to patients; and no patient log regarding offers made to patients for counsel;

k. The balance, although recently sealed, was missing weights;

l. A large see-through several gallon size trash bag, open and filled with trash, was attached to a counter in the Pharmacy area;

m. Medication vials, papers and other items were scattered across the top of the Pharmacy area front counter; and

n. The pharmacist workbench was cluttered and disorganized with files overflowing with papers, loose envelopes and papers on shelves and in drawers. Pharmacy workbench drawers contained an array of prescription medication vials that were loose in the drawers;

o. Respondent had no written policies or manuals regarding pharmacy related practices;

p. Pharmacy reference materials, including the drug interchange book utilized in the Commonwealth of Massachusetts, were not current or readily available; and

q. Handwritten "patient profile cards" were incomplete, inaccurate and indecipherable and stored in a manner that was not conducive to retrieval on prescription fill. Information for a husband and wife was entered on one card without notation as to

which prescription for which patient. Entries on patient profile cards were difficult to read and did not include complete, updated or legible basic necessary information such as address, date of birth, allergies, refill history, prescriber data, insurance coverage, and drug utilization review (DUR) results.

(Vol. I: 180; Vol. II: 87; Vol. VI: 54, 59 - 61, 70, 75, 81, 135, 166 - 172, 175, 188 - 190, 221-223; Exhibits 7, 10, 11, 12, 19 and 39)

11. Pharmacy records, including "Patient Profile Cards" admitted into evidence and other records reviewed at the Pharmacy during the Inspection, included incomplete or illegible handwritten entries, some identifying a patient by first and last name on the first page of a multi-page list only, with various numerical notations on the card without specific identification of the data as referencing either insurance, telephone, prescriber, social security or other number. Patient address or other contact information was not evident or incomplete on the cards. Where two patient names (for example, husband and wife) were listed on a card, identification of which prescription listed was for which patient was not evident. There was no documentation or other evidence of the performance of **appropriate and effective** DUR on any patient or any prescription, or any evidence of a Pharmacy policy or procedure requiring the performance of comprehensive DUR. In his testimony, Respondent stated that he "did a DUR thing" when a patient's [redacted] insurance card indicated she needed a prior authorization and described the "DUR" he performed as calling [redacted] doctor and that a prior authorization was not provided. (Vol. II: 224; Vol. VI: 195 -197; Exhibit 19)

12. Respondent had moved or stored certain outdated medications (controlled substance Schedules II-V) and Pharmacy records, including prescriptions for April 2005, to his residence, a premises not registered by the DEA. Respondent explained the movement of medications and other materials to his home as necessitated by the closure of the prior Pharmacy location in 2000 and that trash is picked up from his home address

or he brings it to the local waste facility. (Vol. II: 87 - 88, 216-217; Vol. VI: 186 -187; Testimony of Red 1/24/07; Exhibit 11)

13. During the Inspection, Respondent failed to provide a compliant biennial inventory of Schedule II controlled substances; which inventory is required to be completed, signed and dated every two years, as an accurate listing of the amount of each controlled substance in the Pharmacy. (Vol. II: 75 - 76, 98-99, 202 -203, 207; VI: 176; Exhibit 33)

14. During the Inspection, Respondent failed to demonstrate he maintained a compliant perpetual inventory that accurately reconciled Schedule II controlled substance inventories every ten days. After the Inspection, Respondent provided several handwritten notebook pages labeled "Perpetual Inventory Biannual 6/97-00" for "Ritalin 5 mg" and "Oxycontin 40mg" and "Perpetual Inventory 00-03" for "Oxycontin 80 mg" and "Oxycodone + APAP 5/325." The pages provided as evidence of a perpetual inventory are non-complaint as not provided at the time of Inspection and incomplete, unreadable and not demonstrative of the required ten day continual tally of all Schedule II controlled substances in the Pharmacy. (Vol. II: 206-211; Exhibits 18, 36 and 37)

15. Pharmacy DEA 222 forms, required to be maintained in an organized manner, were located in various places in the Pharmacy, including in several boxes, on Pharmacy area shelves and on the Pharmacy workbench. (Vol. II: 213; Exhibit 46)

16. During the Inspection, Respondent was not able to provide copies of controlled substance prescription records for the month of April 2005. Several days after the Inspection (on or about September 26, 2005), Respondent provided copies of four prescriptions dated April 4, 2005 (two for patient [redacted] and two for patient [redacted]) to the DEA. The Board notes the large quantities of Schedule II controlled substances that Respondent ordered from AmerisourceBergen on three dates in April 2005 (April 5, 15, and 27), which orders collectively included large amounts methadone 10mg; methylphenidate 10mg; oxycontin 20, 40 and 80 mg; fentanyl patches 50, 75 and 100mg;

mixed amphetamine salts 20 mg; combunox; roxicodone 30mg; oxycodone 15, 30 and 40 mg; endocet 7.5/500; adderall XR 20mg; percocet 5/325; oxycodone +APAP 10/325; roxicet 5/325; actiq 1200mcg; and concerta 36mg. AmerisourceBergen records of deliveries to the Pharmacy in April 2005 also list other controlled substances delivered to the Pharmacy in addition to the controlled substances noted on the orders the Pharmacy placed on April 5, 15, and 27, 2005. (Vol. II: 113-114; 213 - 215; Exhibits 11, 15, 16 and 17)

17. In Roth's opinion, Respondent dispensed controlled substances; in particular, Oxycontin, in a manner that circumvented federal law. (Vol. I: 144-146; Vol. II: 84)

18. In Penta's opinion, Respondent's conduct, as owner and manager of record of the Pharmacy, and the Pharmacy's practices with respect to patient profile card system, DUR, offers to counsel, labeling and tracking refills, patient confidentiality, and compliance with the Code of Professional Conduct for Pharmacists (247 CMR 9.00 et seq.) fell below accepted standards of practice. (Vol. II: 228, 231)

19. During the two year period from August 29, 2003 through August 29, 2005, and as similarly noted in Finding of Fact No. 16 regarding April 2005, Respondent ordered very large quantities of Schedule II controlled substances from wholesale drug distributor AmerisourceBergen. Commencing in early 2004, Respondent typically placed three orders per month (or close to that time period) for significant amounts of Schedule II controlled substances. For example, after placing a large order on April 27, 2005, Respondent also placed large orders on May 4, 11, 17 and 31, 2005. In each of four of those five orders, 30 packages of Oxycodone 30mg 100 units was ordered for a total order of 15,000 units of Oxycodone 30mg in just over a four week period. Large quantities of other strengths of oxycodone as well as other Schedule II controlled substances (Oxycontin, roxicet, percocet, actiq, concerta, fentanyl, endocet, methadone, roxanol) were also included in Respondent's Pharmacy orders for the period from April 27 - May 31, 2005. Respondent placed similarly large wholesale orders for Schedule II

controlled substances either three times (11 months) or two times (9 months) per month during the period from December 2003 through August 2005. (Exhibits16 and 17)

20. In September 2004, Atlantic Associates, Inc., the entity that receives prescription information from Massachusetts pharmacies in accordance with the "Massachusetts Department of Public Health Electronic Data Transmission System (EDTS)," notified Respondent that paper submissions would no longer be accepted for the reporting of EDTS Schedule II reporting. In October 2004, Atlantic Associates advised Respondent that he was unsuccessful in his effort to convert, collect and communicate Schedule II information electronically. Several months after the Inspection, in December 2005 at Respondent's request, [redacted] of Respondent, visited the Pharmacy to assist Respondent in electronically transmitting Schedule II data to Atlantic Associates for approximately 1381 prescriptions dated September 2004 through December 2005. (Vol. VI: 8, 9, 18 27-28, 90 – 93; Exhibit 22)

21. From at least September 2004 to the September 21, 2005 Inspection date, Respondent failed to report Schedule II controlled substance information in a timely manner in accordance with EDTS requirements. (Vol. VI: 8, 9, 18 27-28, 90 - 93,175-176; Exhibit 22)

22. Commencing in 2004, on some date after the February 2004 break-in that Respondent had experienced at the Pharmacy, Respondent employed [redacted] as a cashier and clerk who primarily worked in the "front store" of the Pharmacy but also rang up prescriptions on occasion, when the pharmacy was busy. [redacted] testified that Respondent was a "family friend for years," that she had helped him clean up after the Pharmacy break-in and attended court with him regarding that matter; that Respondent had recommended she see Dr. Michael Brown (Dr. Brown), a local physician (Sandwich, Massachusetts office) whose name appears on prescriptions filled by Respondent; and that she and a family member had visited Dr. Brown. (Vol. VI: 175; Testimony of [redacted]

23. During the Inspection, [redacted] stated to Penta that Respondent had payment arrangements with certain patients she described as "like a credit" in which Respondent provided prescription medications in advance of payment to patients who returned to pay several days later, some patients returning to pay "$5 to $900 in cash." Penta's notes of the conversation with [redacted] state she reported that patient [redacted] "pays for Rx (prescription) in installments" and that Pharmacy customers came from all over the state. [redacted] testified that [redacted] had spoken to her in May 2005 seeking to speak with Respondent about a prescription. (Vol. II: 232 – 234, 236-238; Vol. III: 154, 157 and 165; Vol. IV: 65; Exhibits 11 and 12; Testimony of Red 1/24/07)

24. The Board did not find [redacted] to be a reliable witness at hearing regarding her Pharmacy job duties or her conversations with Penta during the Inspection. Her memory of conversations she had and with whom on the date of the Inspection was selective and her testimony was evasive and contradictory in certain areas. [redacted] initially claimed no personal knowledge of Dr. Brown, and later confirmed she and a family member had appointments with him on separate occasions. She denied knowledge of or making certain statements to Penta regarding patient [redacted] yet later admitted she had conversations with both [redacted] and Respondent regarding [redacted] Respondent's testimony contradicted portions of [redacted] testimony as to her knowledge of patient [redacted] in several respects; specifically as to whether he had spoken with [redacted] about [redacted] (Respondent testified he had) and also that [redacted] had "befriended" him and [redacted] After stating her function were limited to the "front store," she admitted she did "ring up" prescriptions for pharmacy customers at certain times and spent time in the pharmacy area. (Vol. VI: 152, 192 -193; Testimony of Red 1/24/07; Exhibit 15)

25. During the Inspection, Respondent used the terms "credit" and "front" when speaking with Roth. According to Roth, Respondent stated "he'll front the money – he'll front some prescriptions to people that they can pay partially and then come back later, like a day or two later when they're able and pay the rest." Respondent stated that [redacted] had once been arrested in front of the Pharmacy and owed him $720 for two prescriptions from the end of May 2005. Respondent testified that he spoke to Roth or another DEA

agent about [redacted] during the Inspection and that he told them he has "charge accounts" for "some people who charge their prescriptions because they don't have any money on their person at the time they're filling their prescriptions." Respondent acknowledged that some Pharmacy patients traveled from long distances. (Vol. I: 136 -137; Vol. II: 120, 121, 236 – 238; Vol. VI: 152)

26. During the Inspection, Respondent stated to Penta that he provided medication to [redacted] because she could not afford the prescription and that she came back several days later to pay in cash. (Vol. II: 12, 64-65, 237 – 238; Vol. IV: 70; Vol. VI: 145 -146)

27. Respondent testified that [redacted] had filled 12 prescriptions at the Pharmacy during six visits to the Pharmacy over an approximately one year period ending in May 2005; he also noted that [redacted] did not have her prescriptions filled at the Pharmacy "consistently" during that period. [redacted] always paid in cash, although initially she presented an insurance card that did not provide coverage. Respondent testified that he "probably" only provided two prescriptions to [redacted] without receiving payment (value of prescriptions = $620.00) on one date in May 2005. Copies of prescriptions admitted into the record show Respondent dispensed two prescriptions to [redacted] on each of three dates; specifically, on March 7, April 4 and May 26, 2005, Respondent dispensed 80 units of roxicodone (oxycodone) 15 mg and 90 units of Oxycontin 40 mg to [redacted] on each date pursuant to prescriptions of same dates written by Dr. Brown. Respondent testified that [redacted] "was acting in kind of an uncontrollable manner the last time I waited on her, and I didn't understand why she was acting this way." Respondent stated [redacted] had to pay in cash, "usually cash that day" and paid several days after receiving the medication "probably just that one time that I know." According to Respondent, [redacted] was arrested at some time after Respondent dispensed the May 26, 2005 prescriptions and he has never received payment for the May 2005 prescriptions. (Vol. VI: 142-148, 191, 192, 197; Exhibit 15)

28. The testimony of Respondent was evasive and not credible in certain respects. Regarding many allegations, he either admitted to or failed to dispute the evidence presented; specifically, regarding the conditions of the Pharmacy as shown in the

photographs taken during the Inspection, or other witness testimony (particularly Penta, Roth and Red regarding various practices of the Pharmacy. He claimed a lack of knowledge as to whether he had provided other prescriptions to Re da prior to receiving payment yet acknowledged he provided prescriptions to certain patients prior to receiving payment using "charge account" type arrangements that he described as a longstanding Pharmacy practice. He was not persuasive in his efforts to justify certain substandard conditions in the Pharmacy or explain his Pharmacy practices as confirming to state and federal statutory and regulatory requirements.

VI. Conclusions of Law

1. Respondent's conduct as set forth in the Findings of Fact above warrants disciplinary action by the Board against his license to practice as a Pharmacist pursuant to G.L. c. 112, § 61 for deceit, malpractice, and gross misconduct in the practice of the profession offenses against the laws of the Commonwealth relating thereto.

2. Respondent's conduct as set forth in the Findings of Fact above constitutes failure to conduct professional activities in conformity with federal, state and municipal laws, ordinances and/or regulations of the Board and therefore warrant disciplinary action by the Board pursuant to M.G.L. c. 112, §§ 27, 28, and 42A, M.G.L. c. 94C, §§ 15, 19 and 21A, and 247 CMR 2.00 et seq.; specifically, Respondent failed to:

a. conduct a biennial controlled substance inventory, in violation of 21 CFR 1304.11(c); M.G.L. c. 94C, § 15 and 247 CMR 9.01(1);
b. maintain Pharmacy records and conduct inventories in compliance with federal and state laws, including the Regulations of the Board, in violation of 21 CFR 1304.01; M.G.L. c. 94C, § 15; and 247 CMR 6.03(b), 247 CMR 9.01(1), 9.01(2) and 9.01(14);
c. conduct Pharmacy business in a clean and sanitary manner, in violation of 247 CMR 6.02(1) and 9.01(1);

VI. Discussion

In any adjudicatory matter presented for its consideration, the Board bears the burden of proving by a preponderance of the evidence that a licensee engaged in the misconduct alleged. The standard "by a preponderance of the evidence" means a party bearing that burden must persuade the fact finder that its contention is more probably true than false. *Corsetti v. The Stone Co.*, 396 Mass. 1, 23-24 (1985).

Respondent was not able to dispute the photographic evidence showing the deplorable conditions in the Pharmacy on the date of the Inspection. His efforts to justify the multiple substandard areas observed in the Pharmacy and explain certain of his practices as proper or compliant were unsuccessful. He failed in his attempts to defend or explain the general disorder and dirty conditions in the Pharmacy which contravened basic principles of cleanliness, hygiene and safety.

Respondent was not able to defend or explain his failure to maintain compliant required controlled substance records and inventories, report required drug dispensing information, maintain complete and current patient profile information, or perform adequate and appropriate statutorily mandated DUR and patient counseling. These practice requirements are basic functions applicable and integral to all pharmacies and pharmacists to insure that medications are dispensed pursuant to prescriptions that a pharmacist, after exercise of the "corresponding responsibility" of G.L. c. 94C, § 19, subsection (a), has determined are valid. There was little to no evidence that Respondent documented current, complete or reliable patient information that was obtained though established Pharmacy practices or procedures that would enable him to collect, process or report reliable data regarding patients, medication ordering or prescription dispensing details, relating to the Pharmacy. Drug utilization review plays an important role in assessing drug abuse and misuse as well as monitoring quality of care. Respondent's description of the "DUR" he performed and the "patient profile" information system he maintained reflected a lack of acknowledgment or failure of understanding of the importance of these basic tenets of pharmacy practice to ensure patient safety.

Respondent's Schedule II controlled substance ordering and dispensing patterns should have made him keenly aware of the crucial importance of his performance of both DUR and EDTS functions as part of his Pharmacy practice. His failure to take timely action to comply with EDTS reporting requirements was especially of concern due to the very large quantities of Schedule II controlled substances he routinely ordered and dispensed over a prolonged period. Respondent's dispensing practices did not reflect any heightened concern as to the importance of this mandated duty in light of the fact that the his Pharmacy practice, as evidenced by the wholesale drug distributor order forms in evidence, was primarily Schedule II controlled substances with high abuse potential.

Respondent conduct also demonstrated a lack of appreciation or acceptance of a pharmacist's statutory duty to exercise "corresponding responsibility" in filling certain prescriptions, although he was aware that certain patients traveled long distances to fill prescriptions at the Pharmacy; that certain patients did not consistently fill prescriptions at the Pharmacy; that many Pharmacy patients always paid cash for their prescriptions; and that multiple break-ins had occurred at the Pharmacy, including the February 2004 break-in and assault by a Pharmacy patient. Respondent did not demonstrate any awareness or acknowledgement of any responsibility of a pharmacist to be aware of certain patient behaviors that have been recognized as clear signs of addiction for whom the drugs dispensed would be inappropriate.

As noted, Respondent regularly ordered and dispensed very large amounts of Schedule II controlled substances. Respondent was, or should have known, of the abuse potential and street value of those medications. Dispensing a Schedule II controlled substance, including the highly abused Oxycontin, to any patient prior to receiving payment is a practice for which the Board sees no justification. Contrary to Respondent's description of his credit extension practices as a service he had appropriately and benevolently provided for many years, it was ill advised and dangerous, particularly as described in the case of [redacted] and generally in violation of basic professional practice standards regarding the dispensing of medications with such known high abuse potential.

Respondent, as well as the witnesses appearing on his behalf during the hearing and at the sanction hearing following the hearing, testified that although the Pharmacy may have been disorganized and he may have been unable to manage the various operational aspects of "modern" pharmacy practice, such as computerization of records and accurate database reporting, he was a responsible and caring individual attentive to the needs of his family, including his elderly mother, and pharmacist attentive to the needs of his patients. The Board does not, however, contrary to Respondent's description, view the conditions at Bourne Pharmacy as just a matter of "housekeeping" violations nor does the Board view Respondent, a pharmacist licensed by the Board, as simply a person overwhelmed by technology and the various maintenance responsibilities that go along with operating a pharmacy or any other business. Respondent's conduct of dispensing high risk of abuse Schedule II controlled substances to certain patients prior to receiving payment cannot be explained or excused in any way as patient supportive or professionally appropriate.

Whether aware or not, Respondent should have known that his personal practices as a pharmacist as well as his operation of the Pharmacy, as owner and manager of record, were practices and operations **not** conducted in accordance with professional practice standards and multiple statutes and regulations pertaining to the practice of pharmacy in the Commonwealth. There was no indication that the multiple practices issues of concern to the Board were known to Respondent to be non-complaint or identified by him as the focus of any corrective action had the practices not been identified in the Inspection. The extent to which Respondent had become non-compliant with statutory and regulatory requirements applicable to Pharmacy operations was of major concern to the Board.

The Board has considered the prior Board decisions presented by Respondent's counsel at the Sanction Hearing.

In making its decision as to sanction, the Board has the authority and statutory mandate to discipline Respondent in order to protect the public health, safety, and welfare. The Board's mission is not to punish pharmacists, but to protect the public health, safety, and welfare. In addition, "[t]he board has broad discretion to determine the proper sanctions for misconduct...." *Sugarman v. Board of Registration in Medicine*, 422 Mass. 338, 347-8 (1996); *Kvitka v. Board of Registration in Medicine*, 407 Mass. 140, 143 (1990).

Accordingly, based on the Board's authority to oversee conduct that reflects unfavorably on the practice of pharmacy and in accordance with the Board's responsibility to protect the image and integrity of the profession, and having considered all of the evidence presented to it, the Board **ORDERS** as follows:

ORDER

Based on the Findings of Fact and Conclusions of Law set forth herein, the Board hereby **REVOKES** the previously suspended pharmacist license of Respondent (Pharmacist License No. 15152) and any right to renew such license. The Board envisions no conditions pursuant to which Respondent should be permitted to apply for the reinstatement of his pharmacist license in the Commonwealth in the future. This vote indicates the strong concern of the members that Respondent's pharmacy practices and history of licensure discipline in the Commonwealth require that he not be authorized to practice pharmacy in the future under any terms or conditions.

The Board hereby **REVOKES** the previously suspended registration of the Pharmacy (Pharmacy Registration No. 3078).

The Board voted to issue this *Final Decision and Order* at on January 12, 2010 by the following vote: In favor - Joanne M. Trifone, R.Ph.; James T. DeVita, R.Ph.;

Michael Tocco, R.Ph., M.Ed.; Steven Budish, Public Member;.; William Gouveia, R.Ph., M.S.; and Stanley B. Walczyk , R.Ph. Opposed - None. Abstain - None. Absent - George A. Cayer, R.Ph., Kathy Fabiszewski, Ph.D., N.P.; Sophia Pasedis, R.Ph., Pharm.D.; and Donald D. Accetta, M.D.

EFFECTIVE DATE OF ORDERS

The Orders of the Board shall be effective as of the date this *Final Decision and Order* is issued by the Board (see "Date Issued") below.

RIGHT TO APPEAL

Respondent is hereby notified of his right to appeal this *Final Decision and* Order pursuant to G.L. c. 112, s. 64 and G.L. c. 30A, ss. 14 and 15 within thirty (30) days of this *Final Decision and Order*.

BOARD OF REGISTRATION
IN PHARMACY

Joanne M. Trifone

Joanne M. Trifone, R.Ph.
President
Date Issued: January 12, 2010

Notify:
FIRST CLASS and CERTIFIED MAIL RET REC REQ No. 7009 1680 0001 1520 1412
to Respondent at [redacted]
(prior attorney of record bar status not current per Board of Bar Overseers website notice)

BY HAND

James G. Lavery, Prosecuting Counsel

Board ID Dec. Nos. 2253 and 2254