COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

Board of Registration in Pharmacy, Petitioner v. **GLENN CHIN** PH License No. 21609 License expiration date 12/31/2012, Respondent	Docket No. PHA-2012-0210

FINAL DECISION AND ORDER BY DEFAULT

On November 28, 2012, the Board of Registration in Pharmacy (Board) issued and duly served on Glenn Chin (Respondent) an Order to Show Cause (OTSC)[1] related to a complaint against Respondent's license. In addition to stating the allegations against Respondent, the OTSC notified Respondent that an Answer to the OTSC (Answer) was to be submitted within 21 days of receipt of the OTSC[2]. The OTSC notified Respondent of the right to request a hearing on the allegations[3], and that any hearing request (Request for Hearing) was to be submitted within 21 days of receipt of the OTSC.[4] On August 7, 2013, the Board filed its initial request for a stay of the proceedings and on January 16, 2014, the Board filed its renewed motion to stay the licensure proceedings until the conclusion of the the Federal criminal prosecution. On May 21, 2014, over the Respondent's objection, the Administrative Hearing Counsel issued a Ruling and allowed the Prosecution's request to stay the proceedings.

[1] Pursuant to 801 CMR 1.01(6)(a).
[2] In accordance with 801 CMR 1.01(6)(d)(2).
[3] Pursuant to M.G.L. c. 112, s. 61.
[4] Respondent was also notified that failure to timely submit a Request for Hearing would constitute a waiver of the right to a hearing.

On January 11, 2019, Prosecuting Counsel served on Respondent's attorney of record Paul W. Shaw, Esq., a Motion to Lift Stay and for Leave to Amend OTSC (Motion) and First Amended OTSC (FAOTSC). On April 11, 2019, during a telephone status conference with the Chief Administrative Magistrate Jason Barshak (CAM Barshak), Attorney Paul Shaw indicated that he no longer represents the Respondent. By order dated April 11, 2019, Attorney Paul Shaw's Motion to Withdraw was allowed. After confirmation of the Respondent's incarceration location, on April 17, 2019, Prosecuting Counsel sent Respondent a copy of the Motion and FAOTSC by first class mail to: Mr. Glenn Chin, Register No. 96354-038, LSCI Allenwood, PO Box 1000, White Deer, PA 17887 (Address). The cover letter, Motion, and FAOTSC notified the Respondent of the right to request a hearing on the allegations and that any Request for Hearing was to be submitted within 21 days of receipt of the FAOTSC. Respondent was further notified that failure to submit an Answer within 21 days "shall result in the entry of default in the captioned matter" and, if defaulted, "the Board may enter a Final Decision and Order that assumes the truth of the allegations in the FAOTSC and may revoke, suspend, or take other disciplinary action against Respondent's license…including any right to renew Respondent's license." A copy of the FAOTSC is attached to this Final Decision and Order by Default and is incorporated herein by reference.

On July 5, 2019, the Sheriff of Union County served the Respondent in hand two (2) copies of the Motion and the FAOTSC, at the Address. The FAOTSC advised the Respondent that he must file an Answer and Request for a hearing within twenty-one (21) days. More than twenty-one (21) days have passed since the FAOTSC was served, in-hand, and to date, Respondent has failed to answer it or file a request for a hearing.

On July 30, 2019, Prosecuting Counsel sent notice to Respondent to file an Answer and a Request for Hearing by August 6, 2019. The notice again advised Respondent that if defaulted, the Board may enter a Final Decision and Order that

assumes the truth of the allegations stated in the FAOTSC and impose license discipline, including discipline on any right to renew.

As of the date of this Final Decision and Order by Default, Respondent has failed to file either an Answer or a Request for Hearing.

The Board has afforded Respondent an opportunity for a full and fair hearing on the allegations in the FAOTSC as required by M.G.L. c. 30A, § 10, and sufficient notice of the issues involved to afford Respondent reasonable opportunity to prepare and present evidence and argument as required by M.G.L. c. 30A, § 11(1). The Board has also notified Respondent of the obligation under 801 CMR 1.01(6)(d) to file an Answer to the Show Cause Order within 21 days of its receipt and of the consequences of failing to file an Answer or otherwise respond.

As authorized by M.G.L. c. 30A, § 10(2), the Board may make informal disposition of any adjudicatory proceeding by default. Upon default, the allegations of the complaint against Respondent are accepted as true. *Danca Corp. v. Raytheon Co.*, 28 Mass. App. Ct. 942, 943 (1990).

Based on the foregoing, the Board enters a default in the above-captioned matter and, consequently, the allegations in the FAOTSC are deemed to be true and Respondent has waived the right to be heard. In accordance with the Board's authority and statutory mandate, the Board orders as follows:

ORDER

On September 5, 2019, in accordance with the Board's authority and statutory mandate, the Board voted to issue this Final Decision and Order by Default and **REVOKE** Respondent's pharmacist license, PH21609, effective ten days from the Date Issued, by the following vote:

In favor:	Timothy Fensky; Patrick Gannon; Leah Giambarresi; Michael Godek; Sebastian Hamilton; Julie Lanza; Richard Lopez; Dawn Perry
Opposed:	None
Abstained:	None
Recused:	None
Absent:	Susan Cornacchio; Stephanie Hernandez; Carly Jean-Francois; Andrew Stein; Kim Tanzer

The Board does not foresee any circumstance in which it would reinstate Respondent's pharmacist license.

EFFECTIVE DATE OF ORDER

The Final Decision and Order by Default shall be effective 10 days from the Date Issued.

RIGHT TO APPEAL

Respondent is hereby notified of the right to appeal this Final Decision and Order to the Supreme Judicial Court, pursuant to M.G.L. c. 112, § 64 and M.G.L. c. 30A, §§ 14 and 15, within thirty (30) days of receipt of notice of this Final Decision and Order by Default.

BOARD OF REGISTRATION
IN PHARMACY

David Sencabaugh, R. Ph.
Executive Director

Date Issued: 9/9/19

Glenn Chin
PH21609
PHA-2012-0210
Final Decision and Order by Default

Notice to:

BY FIRST CLASS & CERTIFIED MAIL NO.7019 0700 0000 1934 7158, RETURN RECEIPT REQUESTED

Glenn Chin
Register No. 96354-038
LSCI Allenwood
PO Box 1000
White Deer, PA 17887

BY HAND
Jodi Greenburg
Prosecuting Counsel
Massachusetts Department of Public Health
Office of the General Counsel
250 Washington Street
Boston, MA 0210

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of **Glenn A. Chin, R.Ph.** License No. PH21609 Exp. 12-31-12	Docket No. PHA-2012-0210

FIRST AMENDED ORDER TO SHOW CAUSE

Glenn A. Chin ("You" or "Registrant") are hereby ordered to show cause why the Massachusetts Board of Registration in Pharmacy ("Board") should not permanently revoke or otherwise take action against your registration to practice as a pharmacist in the Commonwealth of Massachusetts, License No. PH21609, or your right to renew such registration, pursuant to Massachusetts General Laws ("G. L.") Chapter 112, sections 27, 28, 42A and 61 and Board regulations at 247 CMR 2.00 *et. seq.*, based upon the following facts and allegations:

1. On or about November 21, 1991, the Board issued to you a license to practice Pharmacy in the Commonwealth of Massachusetts, License No. PH21609. On October 8, 2012, you voluntarily agreed to cease all clinical pharmacy services. That agreement remains in effect.

2. At all times relevant to the allegations in this Order to Show Cause, you were employed by, and a staff pharmacist at New England Compounding Pharmacy d/b/a New England Compounding Center ("NECC" or "Pharmacy"), Registration No. 2848.

3. At all times relevant to the allegations in this Order to Show Cause, NECC was located at 697 Waverly Street, Framingham, Massachusetts.

4. At all times relevant to the allegations in this Order to Show Cause, Barry J. Cadden ("Cadden") was manager of record ("MOR") of NECC.

5. Among your various duties as a staff pharmacist at NECC, you were the pharmacist responsible for verifying the formulation and production of the sterile drug product, methylprednisolone acetate 80 mg/ml preservative free.

6. As verification pharmacist responsible for verifying the formulation and production of the sterile drug product, methylprednisolone acetate 80 mg/ml preservative free, you were

responsible for maintaining sterility, accuracy, and purity of finished compounded sterile preparations ("CSPs").

7. Adherence to strict procedures and sterilization methods for CSPs is critical to prevent harm, including death, to patients that receive CSPs. Contaminated CSPs are potentially most hazardous to patients when administered into the central nervous system.

8. As the pharmacist responsible for formulation and production of sterile drug products, including methylprednisolone acetate 80 mg/ml preservative free, your responsibilities included, but are were not limited to, insuring that CSPs are accurately identified, measured, diluted, mixed and are correctly purified and sterilized.

9. On or about September 24, 2012, the Board received information that a widespread outbreak of fungal meningitis may have originated from an epidural injection of a steroid (methylprednisolone acetate 80 mg/ml preservative free) compounded by NECC.

10. Board investigators, in collaboration with the United States Food and Drug Administration (collectively, "investigators"), began a joint investigation of NECC.

11. On September 26, 2012, investigators on site at NECC were informed that the methylprednisolone acetate products were quarantined, were not currently being produced and a voluntary recall of three lots (Lot#: 05212012@68, Lot#: 06292012@26 and Lot#: 08102012@51) was taking place.

12. On multiple dates beginning on or about September 26, 2012, investigators inspected NECC and observed numerous violations of state and federal statutes and regulations pertaining to the practice of pharmacy and those directly relating to your duties as a pharmacist responsible for verifying the formulation and production of sterile drug products, including but not limited to:

    a. There were inconsistencies in sterilization processes of materials were identified through review of records containing your signature.

    b. There was no evidence that biological indicators were used during the autoclave cycle to verify the effectiveness of the sterilization cycle.

    c. The product was not kept in the autoclave for the required minimum twenty minute sterilization period.

    d. The autoclave utilized to sterilize injectable suspensions was not validated.

    e. The autoclave was not validated for minimum and maximum load volumes.

    f. Numerous observations were made of discoloration and condensation on or within the autoclaves used in the formulation of sterile drug products.

g. There was visual evidence of black contaminant inside multiple sealed vials of methylprednisolone acetate 80 mg/ml preservative free in Lot # 08102012@51. These products were in quarantine and had not yet been distributed to facilities.

h. There was visual evidence of black contaminant within several of the recalled sealed vials of methylprednisolone acetate 80 mg/ml preservative free from Lot# 08102012@51 that had been returned to NECC.

i. Two of the recalled lots of methylprednisolone acetate 80 mg/ml preservative free were distributed prior to receiving results of sterility testing:

i. Lot# 06292012@26 was made on June 29, 2012. The final sterility test was completed on July 17, 2012. On two occasions products were shipped prior to the final sterility test results of July 17, 2012.

ii. Lot# 08102012@51 was made on August 10, 2012. The final sterility test was completed on August 28, 2012. On eleven occasions products were shipped prior to the final sterility test results of August 28, 2012.

j. The sterility sample taken by NECC consisting of one 5ml vial of methylprednisolone acetate 80 mg/ml preservative free from lot 08102012@51, resulted in a sterile result according to the NECC sample testing record. However, analysis of samples taken by investigators from the same lot (08102012@51) confirmed the presence of viable microbial growth in 50 out of 50 vials tested. One vial examined microscopically showed fungal morphological features.

k. NECC failed to send out the required number of sample vials from a batch of methylprednisolone consisting of 12,500 ml to an outside lab for sterility and potency analysis.

l. NECC used non sterile active pharmaceutical ingredients and raw materials, with the exception of sterile water for injection, to formulate injectable suspensions, contrary to documentation provided by NECC indicating that all raw materials were sterile.

m. No evidence was provided that any corrective actions were taken to prevent contamination of the sterile drug products.

13. As a result of allegations against you including those listed in paragraphs 2-12 above, on or about December 18, 2014, you were arraigned in the United States District Court for the District of Massachusetts on one (1) count of Racketeering in violation of 18 U.S.C. §1962(c), one (1) count of Conspiracy to commit Racketeering in violation of 18 U.S.C.

§1962(d), forty-one (41) counts of Mail Fraud in violation of 18 U.S.C. §1341, and thirty-one (31) counts of Introduction of Adulterated Drugs Into Interstate Commerce with Intent to Defraud and Mislead in violation of 21 U.S.C. §331(a) and 333(a)(2). (Docket 1:14-cr-10363-RGS-2).

14. On or about October 25, 2017, following a jury trial, you were convicted of one (1) count of Racketeering in violation of 18 U.S.C. §1962(c), one (1) count of Conspiracy to commit Racketeering in violation of 18 U.S.C. §1962(d), at least forty-one (41) counts of Mail Fraud in violation of 18 U.S.C. §1341, and at least thirty-one (31) counts of Introduction of Adulterated Drugs Into Interstate Commerce with Intent to Defraud and Mislead in violation of 21 U.S.C. §331(a) and 333(a)(2). (Docket 1:14-cr-10363-RGS-2).

15. Following a sentencing hearing associated with Docket 1:14-cr-10363-RGS-2 which was conducted on or about January 31, 2018, you were committed to the custody of the Bureau of Prisons to be imprisoned for a term of ninety-six (96) months.

16. As the pharmacist responsible for formulation and production of sterile drug products, including methylprednisolone acetate 80 mg/ml preservative free, you were responsible for maintaining sterility, accuracy, and purity of finished CSPs. Your conduct, practices and operations as specifically enumerated in Paragraph 12 constitute conduct warranting disciplinary action by the Board, pursuant to M.G.L. c. 112, §§ 27, 28, 40, 42A and 61; 247 CMR 9.01(1) (3) and 10.03(1), specifically:

a. Registrant failed to comply with 247 CMR 9.01(3) and United States Pharmacopeia Standard 797 (USP 797) by not conducting proper finished preparation release checks and tests of CSPs .

b. Registrant failed to comply with 247 CMR 9.01(3) and USP 797 in regard to maintaining sterility, purity and stability of dispensed and distributed CSPs.

c. Registrant failed to comply with 247 CMR 9.01(3) and USP 797 regarding proper verification of the effectiveness of autoclaves to insure proper sterilization.

d. Registrant failed to comply with 247 CMR 9.01(3) and USP 797 by failing to maintain proper environmental quality and control necessary for achieving and maintaining sterility and overall freedom from contamination of CSPs.

e. Registrant failed to comply with 247 CMR 9.01(3) and USP 797 regarding the minimum frequency of cleaning and disinfecting compounding areas.

f. Registrant failed to comply with 247 CMR 9.01(3) and USP 797 regarding surface cleaning and disinfectant sampling and assessment.

g. Registrant failed to comply with 247 CMR 9.01(3) and USP 797 regarding action levels, documentation, and data evaluation pertaining to viable microbial monitoring of the compounding environment.

h. Registrant violated 247 CMR 10.03(1)(a) by violating duties and standards set out in Board regulations (247 CMR 2.00 *et seq.*) or any rule or written policy adopted by the Board.

i. Registrant violated 247 CMR 10.03(1)(b) by violating any provision of M.G.L. c. 112, §§ 24 through 42A or any provision of state or federal statutes or rules or regulations promulgated thereunder related to the practice of the profession.

j. Registrant violated 247 CMR 10.03(1)(e) by engaging in misconduct in the practice of the profession.

k. Registrant violated 247 CMR 10.03(1)(k) by engaging in conduct that has the capacity or potential to place the public health, safety or welfare at risk.

l. Registrant violated 247 CMR 10.03(1)(*l*) by engaging in conduct that has the capacity or potential to deceive or defraud.

m. Registrant violated 247 CMR 10.03(1)(n) by being convicted of any crime.

n. Registrant violated 247 CMR 10.03(1)(r) by engaging in conduct that demonstrates a lack of good moral character.

o. Registrant violated 247 CMR 10.03(1)(u) by engaging in conduct which undermines public confidence in the integrity of the profession.

p. Registrant violated 247 CMR 10.03(1)(v) by committing an act that violates recognized standards of pharmacy practice.

q. Registrant violated 247 CMR 10.03(1)(w) by failing to comply with recognized ethical standards of the profession, including, but not limited to, the standards of practice of pharmacists, pharmacy interns, pharmacies and pharmacy departments set forth in 247 CMR 9.01: *Code of Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments*.

q. Registrant violated 247 CMR 10.03(1)(x) by committing a violation of M.G.L. c. 94C or any rules or regulations promulgated thereunder.

14. Your conduct as alleged above warrants disciplinary action by the Board against your pharmacy license pursuant to G. L. c. 112, § 61, for deceit, malpractice and gross misconduct in your practice as a pharmacist and offenses against the laws of the Commonwealth relating thereto.

15. Your conduct as described above also constitutes unprofessional conduct and conduct, which undermines public confidence in the integrity of the profession. *Sugarman v. Board of Registration in Medicine*, 422 Mass. 338, 342 (1996); see also *Kvitka v. Board of Registration in Medicine*, 407 Mass. 140, cert. denied, 498 U.S. 823 (1990); *Raymond v. Board of Registration in Medicine*, 387 Mass. 708, 713 (1982).

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You have a right to an adjudicatory hearing ("hearing") on the allegations contained in the Order to Show Cause before the Board determines whether to suspend, revoke, or impose other discipline against your registration pursuant to G.L. c. 112, §§ 27, 28, 40, 42A and 61. Your right to a hearing may be claimed by submitting a written request for a hearing *within twenty-one (21) days of receipt of this Order to Show Cause*. The Board will give you prior written notice of the time and place of the hearing following receipt of a written request for a hearing. You must also submit an Answer to this Order to Show Cause in accordance with 801 CMR 1.01(6)(d) *within twenty-one (21) days of receipt of this Order to Show Cause*.

Hearings will be conducted in accordance with the State Administrative Procedure Act, G.L. c. 30A, §§ 10 and 11, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 and 1.03, under which you are granted certain rights including, but not limited to, the rights: to a hearing, to secure legal counsel or another representative to represent your interests, to call and examine witnesses, to cross-examine witnesses who testify against you, to testify on your own behalf, to introduce evidence, and to make arguments in support of your position.

The Board will make an audio recording of any hearing conducted in the captioned matter. In the event that you wish to appeal a final decision of the Board, it is incumbent on you to supply a reviewing court with a "proper record" of the proceeding, which may include a written transcript. *New Bedford Gas and Light Co. v. Board of Assessors of Dartmouth*, 368 Mass. 745, 749-50 (1975). Upon request, the Board will make available a copy of the audio recording of the proceeding at your own expense. Pursuant to 801 CMR 1.01 (10)(i)(1), upon motion, you "may be allowed to provide a public stenographer to transcribe the proceedings at [your] own expense upon terms ordered by the Presiding Officer." Those terms may include a requirement that any copy of the transcript produced must be sent promptly upon completion and on an ongoing basis directly to the Presiding Officer by the stenographer or transcription service. The transcript will be made available to the Prosecutor representing the Board. Please note that the administrative record of the proceedings, including but not limited to, the written transcript of the hearing is a public record and subject to the provisions of G.L. c. 4, § 7 and G. L. c. 66, § 10.

Your failure to submit an Answer to the Order to Show Cause within 21 days of receipt of the Order to Show Cause *will result in the entry of default* in the captioned matter. Your failure to submit a written request for a hearing within 21 days of receipt of this Order to Show Cause *will constitute a waiver of the right to a hearing* on the allegations herein and on any Board disciplinary action.

Notwithstanding the earlier filing of an Answer and/or request for a hearing, your failure to respond to notices or correspondence, failure to appear for any scheduled status conference,

pre-hearing conference or hearing dates, or failure to otherwise defend this action will result in the entry of default.

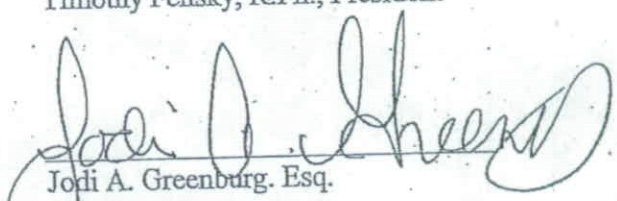
If you are defaulted, the Board may enter a Final Decision and Order that assumes the truth of the allegations in this Order to Show Cause, and may revoke, suspend, or take other disciplinary action against your pharmacy registration in the Commonwealth of Massachusetts, including any right to renew your registration.

Your Answer to the Order to Show Cause and your written request for a hearing must be filed with Jodi A. Greenburg, Chief Board Prosecutor at the following address:

Jodi A. Greenburg. Esq.
Chief Board Prosecutor
Department of Public Health
Office of the General Counsel
250 Washington Street
Boston, MA 02108

You or your representative may examine Board records relative to this case prior to the date of the hearing during regular business hours at the office of the Chief Board Prosecutor. If you elect to undertake such an examination, then please contact Prosecuting Counsel in advance at (617) 624-5229 to schedule a time that is mutually convenient.

Board of Registration in Pharmacy,
Timothy Fensky, R.Ph., President

By: 
Jodi A. Greenburg. Esq.
Chief Prosecutor
Department of Public Health

Date: June 14, 2019