COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

| In the Matter of | .) | | PHA-2013-0 | 061 |
|---------------------------|-----|--|------------|-----|
| Jeffrey D. Lynch |) | | | |
| PH Registration No. 24722 |) | | | |
| Expires December 31, 2014 |) | | | |

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Jeffrey D. Lynch ("Licensee"), PH24722, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Licensee's record maintained by the Board:

- 1. Licensee acknowledges that a complaint has been opened by the Board against his Massachusetts pharmacist license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2013-0061.
- 2. The Board and Licensee acknowledge and agree to the following facts:
 - a. The Licensee was the Manager of Record of Pharmacy Corporation of America, DS3599, 1123 Pearl Street, Brockton, Massachusetts ("Pharmerica Brockton") on December 28, 2012, and has been the Manager of Record since at least November 16, 2010.
 - b. As described in 247 CMR 6.07, Licensee, as Manager of Record, was responsible for the operation of Pharmerica Brockton in compliance with 247 CMR 2.00 et seq. and applicable state and federal laws and regulations.
 - c. Board investigators conducted an unannounced inspection of Pharmerica Brockton on or about December 27 & 28, 2012. During the inspection, Board investigators made observations from which they determined Pharmerica Brockton to be non-complaint with 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding Sterile Preparations, with regard to its compounding of sterile medications.

¹ The term "license" applies to both a current license and the right to renew an expired license.

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- d. As a result of this determination of non-compliance, on or about December 27, 2012, Pharmerica Brockton was notified to "immediately cease all pharmacy operations pertaining to the preparation and dispensing of sterile compounded medications," and to quarantine all sterile compounded medications on Pharmerica's premises.
- e. Pharmacy Corporation of America owns and/or operates a another sterile compounding pharmacy located at 83 Vermont Avenue, Unit 2, Warwick, Rhode Island ("Pharmerica Warwick").
- f. On and/or after December 27, 2012, six pharmacy technicians employed by Pharmerica Brockton, and acting at the instruction of Pharmerica Brockton and Licensee, performed the following activities: (1) transported multiple totes of legend pharmaceuticals and compounding supplies from Pharmerica Brockton to Pharmerica Warwick; (2) prepared sterile compounded products ("CSPs") at Pharmerica Warwick; (3) packaged the CSPs at Pharmerica Warwick without patient labeling and transported said CSPs back to Pharmerica Brockton; and (4) affixed a Pharmerica Brockton label to the CSPs at Pharmerica Brockton. The CSPs prepared at Pharmerica Warwick were then dispensed from Pharmerica Brockton. The six pharmacy technicians that compounded CSPs at Pharmerica Warwick were not licensed in Rhode Island.
- 3. Licensee agrees that his pharmacist license shall be placed on PROBATION for two (2) years ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
- 4. During the Probationary Period, the Licensee further agrees that he shall comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.
- 5. The Licensee agrees to submit documentation evidencing successful completion of 10 live contact hours of continuing education in the area of pharmacy law and 10 live contact hours of continuing education pertaining to sterile compounding on or before December 31, 2014. This continuing education shall be in addition to the continuing education required by 247 CMR 4.03.
- 6. The Board acknowledges the receipt of Licensee's attestation swearing that he has read and reviewed 247 CMR. The Licensee and the Board

- acknowledge that the Board's receipt of this attestation was a precondition to be met before the Board enters into this Agreement.
- 7. The Board agrees that in return for Licensee's execution and successful compliance with the requirements of this Agreement it will not prosecute the Complaint.
- 8. If the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate **two** (2) **years** after the Effective Date upon written notice to the Licensee from the Board².
- 9. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint³ during the Probationary Period, the Licensee agrees to the following:
 - a. The Board may upon written notice to the Licensee, as warranted to protect the public health, safety, or welfare:
 - i. EXTEND the Probationary Period; and/or
 - ii. MODIFY the Probation Agreement requirements; and/or
 - iii. IMMEDIATELY SUSPEND the Licensee's pharmacist license.
 - b. If the Board suspends the Licensee's pharmacist license pursuant to Paragraph 7(a)(iii), the suspension shall remain in effect until:
 - i. the Board provides Licensee written notice that the Probationary Period is to be resumed and under what terms; or
 - ii. the Board and Licensee sign a subsequent agreement; or
 - iii. the Board issues a written final decision and order following adjudication of the allegations (1) of

² In all instances where this Agreement specifies written notice to the Licensee from the Board, such notice shall be sent to the Licensee's address of record.

³ The term "Subsequent Complaint" applies to a complaint opened after the Effective Date concerning acts, omissions, or events occurring after the Effective Date, which (1) alleges that the Licensee engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Licensee shall have an opportunity to respond.

noncompliance with this Agreement, and/ or (2) contained in the Subsequent Complaint.

- 10. Licensee agrees that if the Board suspends his pharmacist license in accordance with Paragraph 9, he will immediately return his current Massachusetts pharmacist license to the Board, by hand or certified mail. Licensee further agrees that upon said suspension, he will no longer be authorized to practice as a pharmacist in the Commonwealth of Massachusetts and shall not in any way represent himself as a pharmacist until such time as the Board reinstates his pharmacist license or right to renew such license.
- 11. Licensee understands that he has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication he would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on his own behalf, to contest the allegations, to present oral argument, to appeal to the courts, and all other rights as set forth in the Massachusetts Administrative Procedures Act, M.G.L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 et seq. The Licensee further understands that by executing this Agreement he is knowingly and voluntarily waiving his right to a formal adjudication of the Complaints.
- 12. The Licensee acknowledges that he has been represented by legal counsel in connection with the Complaint and this Agreement.
- 13. The Licensee acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board. The Board may forward a copy of this Agreement to other licensing boards, law enforcement entities, and other individuals or entities as required or permitted by law.

| 14. | understands and agrees that | sentering into this Agreement is a set subject to reconsideration, appeal or Signature and Date TEFFLEY D Lynch Print Name Jeffrey D. Lynch |
|-------|--|---|
| Lerri | Signed Agreement Sent to fied No. <u>70/0 /870 0002</u> 2380 | |