STATE OF FLORIDA DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner.

Case No. 2012-04248
J

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health ("Petitioner" or "Department"), by and through its undersigned counsel, files this Administrative Complaint before the Board of Medicine ("Board") against Respondent, Mark Robin Geier, M.D. ("Respondent"), and in support thereof alleges:

- 1. Petitioner is the state agency charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes (2012), and Chapters 456 and 458, Florida Statutes (2012).
- 2. At all times material to this Complaint, Respondent was licensed to practice as a physician in the State of Florida, having been issued license number ME 103406.

- 3. Respondent's address of record is 7162 North University Drive, Tamarac, Florida 33321.
- 4. A secondary address for Respondent is 14 Redgate Court, Silvery Spring, Maryland 20905.
- 5. On or about February 20, 2012, Petitioner conducted a routine inspection of Prescription Depot, a licensed community pharmacy located in Tamarac, Florida.
- 6. During the inspection, H.G., a licensed pharmacist serving as the prescription department manager of Prescription Depot, informed Petitioner's inspector that Respondent performed all of the compounding at Prescription Depot.
- 7. H.G. further informed Petitioner's inspector that he did not know how to compound.
- 8. On or about December 30, 2011, Respondent compounded a lot of Leuprolide Acetate Powder ("December Lot").
- 9. Leuprolide is a man-made form of a hormone that over-stimulates the body's production of certain hormones, which causes that production to shut down temporarily. Leuprolide reduces the amount of testosterone in men or estrogen in women. Leuprolide is a legend drug.

- 10. On or about February 1, 2012, a portion of the December Lot was dispensed to patient Q.S., pursuant to a prescription written by Dr. D.C.
- 11. On or about February 8, 2012, a portion of the December Lot was dispensed to patients J.N. and I.T., pursuant to prescriptions written by Dr. G.D.
- 12. On or about February 8, 2012, a portion of the December Lot was dispensed to patient K.C., pursuant to a prescription written by Dr. J.Y.
- 13. On or about February 10, 2012, a portion of the December Lot was dispensed to patient M.B., pursuant to a prescription written by Dr. D.C.
- 14. On or about February 21, 2012, a portion of the December Lot was dispensed to patient M.C., pursuant to a prescription written by Dr. J.Y.
- 15. On or about February 28, 2012, a portion of the December Lot was dispensed to patients J.N. and I.T., pursuant to prescriptions written by Dr. G.D.
- 16. On or about January 19, 2012, Respondent compounded a lot of Leuprolide Acetate Powder ("January 19 Lot").

- 17. On or about February 8, 2012, a portion of the January 19 Lot was dispensed to patients B.R., J.L., V.M., S.K., T.L., W.H., S.G., S.M., D.M., R.M., D.N., and J.W., pursuant to prescriptions written by Dr. J.Y.
- 18. On or about February 8, 2012, a portion of the January 19 Lot was dispensed to patient G.R., pursuant to a prescription written by Dr. D.C.
- 19. On or about January 24, 2012, Respondent compounded a lot of Leuprolide Acetate Powder ("January 24 Lot").
- 20. On or about February 8, 2012, a portion of the January 24 Lot was dispensed to patients A.U., M.H., S.D., A.V., W.V., C.D., and M.K., pursuant to prescriptions written by Dr. J.Y.
- 21. On or about February 8, 2012, a portion of the January 24 Lot was dispensed to patients C.P., A.G., and G.Q., pursuant to prescriptions written by Dr. D.C.
- 22. On or about February 2, 2012, Respondent compounded a lot of Leuprolide Acetate Powder ("February 2 PF Lot").
- 23. On or about February 8, 2012, a portion of the February 2 PF Lot was dispensed to patient A.S., pursuant to a prescription written by Dr. J.Y.

- 24. On or about February 8, 2012, a portion of the February 2 PF Lot was dispensed to patients G.E. and A.E., pursuant to prescriptions written by Dr. D.C.
- 25. On or about February 21, 2012, a portion of the February 2 PF Lot was dispensed to patient M.C., pursuant to a prescription written by Dr. D.C.
- 26. On or about February 28, 2012, a portion of the February 2 PF Lot was dispensed to patient A.S., pursuant to a prescription written by Dr. J.Y.
- 27. On or about February 2, 2012, Respondent compounded a lot of Leuprolide Acetate Powder ("February 2 #1 Lot").
- 28. On or about February 8, 2012, a portion of the February 2 #1 Lot was dispensed to patient B.M., pursuant to a prescription written by Dr. D.C.
- 29. On or about February 8, 2012, a portion of the February 2 #1 Lot was dispensed to patient E.G., pursuant to a prescription written by Dr. J.Y.
- 30. On or about February 21, 2012, a portion of the February 2 #1 Lot was dispensed to patients N.V. and D.J., pursuant to prescriptions written by Dr. J.Y.

- 31. On or about February 21, 2012, a portion of the February 2 #1 Lot was dispensed to patient M.W., pursuant to a prescription written by Dr. D.C.
- 32. On or about February 28, 2012, a portion of the February 2 #1 Lot was dispensed to patients N.M. and M.S., pursuant to prescriptions written by Dr. J.Y.
- 33. Pursuant to Rule 64B16-27.700, Florida Administrative Code, "compounding" is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent....
- 34. Rule 64B16-27.700(1), Florida Administrative Code, further states that compounding includes:
 - (a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
 - (b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.
 - (c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist....

- 35. Respondent compounded Leuprolide Acetate Powder on or about December 30, 2011, January 19, 2012, January 24, 2012, and February 2, 2012.
- 36. Pursuant to Section 458.305(3), Florida Statutes (2011), the "practice of medicine" is defined as the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.
- 37. Pursuant to Section 465.003(10), Florida Statutes (2011), a pharmacist is a person licensed pursuant to Chapter 465, Florida Statutes, to practice the profession of pharmacy.
- 38. Pursuant to Section 465.003(13), Florida Statutes (2011), the "practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services.
- 39. Compounding a medicinal drug is the practice of the profession of pharmacy and not the practice of the profession of medicine.

- 40. Pursuant to Rule 64B16-27.1001, Florida Administrative Code, those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), Florida Statutes, are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist.
- 41. At all times material to this Complaint, Respondent was not licensed as a pharmacist in the State of Florida.
- 42. At all times material to this Complaint, Respondent was not licensed as a pharmacy technician in the State of Florida.
- 43. At all times material to this Complaint, Respondent was not duly registered as a pharmacy intern in the State of Florida.
- 44. Section 458.331(1)(v), Florida Statutes (2011), subjects a physician to discipline for practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities which the licensee knows or has reason to know that he or she is not competent to perform.
- 45. Respondent violated Section 458.331(1)(v), Florida Statutes (2011), in one or more of the following ways:

- a. By compounding Leuprolide Acetate Powder on or about December 30, 2011, to be dispensed to patients pursuant to prescriptions written another physician;
- b. By compounding Leuprolide Acetate Powder on or about
 January 19, 2012, to be dispensed to patients pursuant to
 prescriptions written another physician;
- c. By compounding Leuprolide Acetate Powder on or about January 24, 2012, to be dispensed to patients pursuant to prescriptions written another physician; and
- d. By compounding Leuprolide Acetate Powder on or about February 2, 2012, to be dispensed to patients pursuant to prescriptions written another physician.
- 46. Based on the foregoing, Respondent violated Section 458.331(1)(v), Florida Statutes (2011), by practicing beyond the scope permitted by law.

WHEREFORE, Petitioner respectfully requests that the Board of Medicine enter an order imposing one or more of the following penalties: revocation or suspension of Respondent's license, imposition of an administrative fine,

placement of Respondent on probation, corrective action, remedial education, and/or any other relief that the Board deems appropriate.

SIGNED this 24th day of Mac

John H. Armstrong, MD, FACS Surgeon General & Secretary of Health

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FILED DEPARTMENT OF HEALTH DEPUTY CLERK CLERK Angel Sanders MAY 2 8 2013 DATE

PCP Date:

May 24, 2013

PCP Members:

Mark Avila, M.D.; Donald Mullins

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition any other discipline imposed.