BEFORE THE INDIANA
BOARD OF PHARMACY
CAUSE NUMBER: 2021 IBP 0045

IN THE MATTER OF THE LICENSE OF:)
)
LEONARD GUYER, M.D.)
)
LICENSE NO: 01040481B (ACTIVE))

ADMINISTRATIVE COMPLAINT

The State of Indiana ("Petitioner"), by counsel, Deputy Attorney General Ryan P. Eldridge, on behalf of the Office of the Indiana Attorney General, and pursuant to Ind. Code § 25-1-7-7, the Administrative Orders and Procedures Act, Ind. Code Art. 4-21.5, and Ind. Code ch. 25-1-9, files its Administrative Complaint against the Indiana Controlled Substance Registration ("C.S.R.") of Leonard Guyer, M.D. ("Respondent"), and in support alleges and states the following:

FACTS

1. Respondent is a physician in the State of Indiana having been issued license number 01040481A by endorsement on July 1, 1992.

2. Respondent holds a controlled substance registration ("C.S.R.") in the State of Indiana having been issued 01040481B by application on July 1, 1992.

3. Respondent's address on file with the Indiana Professional Licensing Agency ("IPLA") is 836 East 86th Street, Indianapolis, Indiana 46240.

4. Respondent is a "practitioner" as that term is defined by Ind. Code § 25-1-9-2.

5. On or about February 12, 2002, the Guyer Institute of Molecular Medicine (also referred to as Advanced Medical Center, P.C.) was created in Indianapolis, Indiana. Respondent is the president. Located at the IPLA abovementioned address.

6. On or about August 16, 2004, Advanced Nutriceuticals, LLC was created in Indianapolis, Indiana. Respondent is the president and registered agent. Located at the IPLA abovementioned address.

7. Respondent compounds with controlled substances at his clinic including but not limited to Ketamine, Phentermine, and Dextroamphetamine.

8. In January 2020, IPLA conducted a C.S.R. inspection at the Guyer Institute of Molecular Medicine. IPLA found the following:

a. Respondent dispensed controlled substances from the clinic without being registered with INSPECT.

b. Respondent had never completed an initial nor biennial inventory for controlled substances at the clinic.

c. The compounding hood was left off the majority of the time. The staff claimed the hood was too loud. In addition, the room with the hood had a door left ajar.

d. Respondent used arbitrary beyond use dates ("BUDs") for compounded drugs.

e. Staff reused alcohol pads for cleaning.

f. Items in the lab were not properly labeled.

g. Single-use syringes were used multiple times in compounding.

h. Staff members failed to wear gloves when compounding.

i. Some products did not have drug names, detailed instructions, or expiration dates listed.

j. The hood certification was expired.

k. No policies or procedures were available for IPLA inspection and review.

9. United States Pharmacopeia (USP) 795 and 797—the accepted standards for the market for compounding nonsterile and sterile drug product—anyone compounding should create a formulary for all products and should complete compounding logs/documentation for all compounded products.

10. Between February 2017 and February 2020, Respondent only maintained two (2) pages of compounding logs containing drug ingredient names, measurements, lot numbers, expiration dates, and manufacturers.

11. Respondent creates compounded drugs for which they fail to keep formularies.

12. Under USP 795 and 797, a compounding entity is expected to observe and follow formularies or create new formularies.

13. Respondent failed to follow formularies in regard to BUDs that require endotoxin and sterility tests. Respondent failed to complete any endotoxin, sterility, and potency tests for any compounded drugs, except for one (1) or two (2) limited exceptions over the last three (3) years.

14. Between October 13, 2020 and October 29, 2020, the Food and Drug Administration (FDA) completed an inspection of Advanced Nutriceuticals. The FDA inspection resulted in a 483 Form—a federal inspection report that notes all violations of USP, federal law, and Good Manufacturing Practices (GMPs) enforced by the FDA—due to the following observations:

a. Respondent performed aseptic processing outside of a classified ISO 5 area.

b. The ISO 5 classified aseptic processing areas was located within a non-classified room (segregated production area).

c. Respondent's employees touched equipment and other surface areas outside the ISO 5 area with gloved hands and proceeded to aseptically process drug product without changing or sanitizing gloves.

d. Respondent's sterile technician moved rapidly in the vicinity of open sterile units or instruments.

e. Respondent's sterile technician conducted aseptic manipulation and placed equipment/supplies in an area that blocks the movement of first pass air around an open unit.

f. Respondent's sterile technician stoppered sterile drug vials.

g. Supplies outside of the ISO 5 Cleanroom hood were not disinfected prior to entering the aseptic processing areas.

h. Systems for monitoring processing and environmental conditions in aseptic processing areas were deficient.

i. Respondent's firm exposed stock solutions, used in production of drug products intended to be sterile, to worse than ISO 5 quality air.

j. The use of sporicidal agents in the aseptic processing area were inadequate.

k. The final containers/closures used for drug product intended to be sterile were not sterilized.

l. Respondent's employee produced a sterile drug product using expired material.

m. The ISO-classified aseptic processing areas and surrounding areas had difficult to clean and visibly dirty equipment or surfaces.

n. Respondent's facility design allowed the influx of poor-quality air into a higher classified area.

o. Beta-lactam and hazardous drugs were produced without providing adequate containment, segregation, and cleaning of work surfaces, utensils, and personnel to prevent cross-contamination.

p. Staff were not required to complete documentation or training for compounding actions at the facility.

15. Respondent advertised that citizens do not need to be patients to receive IV therapy that included receipt of certain compounded medications.

16. Respondent allowed unlicensed personnel to perform compounding and allowed personnel to complete compounding actions with little to no physician or pharmacist oversight.

17. Respondent compounds both FDA-approved products and non-FDA-approved products at his facility.

VIOLATIONS

COUNT I: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

18. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-3(1) & 21 U.S.C. 351 (a)(1), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be adulterated under the following conditions: (1) If the drug or device consists in whole or in part of any filthy, putrid, or decomposed substance. Respondent violated Ind. Code § 16-42-3-3(1) & 21 U.S.C. 351 (a)(1) by his failure to ensure cleanliness procedures

in the pharmacy for sterile and nonsterile pharmaceutical compounding and utilized expired materials in pharmaceutical compounding.

COUNT II: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

19. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-3(2) & 21 U.S.C. 351 (a)(2)(A), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be adulterated under the following conditions: (2) If the drug or device has been produced, prepared, packed, or held under unsanitary conditions under which the drug or device may have been contaminated with filth or made injurious to health. Respondent violated Ind. Code § 16-42-3-3(2) & 21 U.S.C. 351 (a)(2)(A) by the unsanitary conditions of the compounding room, lack of sterile measures, failures of the hood(s), and other areas that Respondent was not in compliance with USP 795 and USP 797.

COUNT III: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

20. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-3(3)(A) & 21 U.S.C. 351 (a)(2)(B), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be adulterated under the following conditions: (3)(A) If the methods used in or the facilities or controls used for a drug's manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that: (A) the drug meets the requirements of this article as to safety. Respondent violated Ind. Code § 16-42-3-3(3)(A) & 21 U.S.C. 351 (a)(2)(B) by

Respondent's failure to utilize the hood during compounding and failure to utilize formularies for some compounded drugs under USP 795 and USP 797.

COUNT IV: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

21. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-3(3)(B)(i) & 21 U.S.C. 351 (a)(2)(B), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be adulterated under the following conditions: (3)(B) If the methods used in or the facilities or controls used for a drug's manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that: (B) the drug: (i) has the identity and strength that the drug purports or is represented to possess. Respondent violated Ind. Code § 16-42-3-3(3)(B)(i) & 21 U.S.C. 351 (a)(2)(B) by Respondent's failure to complete any potency testing for any compounded drugs and failure to follow formularies.

COUNT V: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

22. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-3(3)(B)(ii) & 21 U.S.C. 351 (a)(2)(B), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be adulterated under the following conditions: (3)(B) If the methods used in or the facilities or controls used for a drug's manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that: (B) the drug: (ii) meets the quality and purity

characteristics that the drug purports or is represented to possess. Respondent violated Ind. Code § 16-42-3-3(3)(B)(ii) & 21 U.S.C. 351 (a)(2)(B) by Respondent's failure to follow formularies when an endotoxin or sterility test is required for the determination of BUDs (Beyond Use Dates) for a compounded drug.

COUNT VI: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

23. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-3(6) & 21 U.S.C. 351 (b), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be adulterated under the following conditions: (6) If (A) the drug or device purports to be or is represented as a drug, the name of which is recognized in an official compendium; and (B) the strength of the drug differs from or the drug's quality or purity falls below the standard set forth in that compendium. Respondent violated Ind. Code § 16-42-3-3(6) & 21 U.S.C. 351 (b) by Respondent's failure to follow formularies when an endotoxin or sterility tests were required, failure to complete potency tests for almost all compounded drugs, re-use of single-use syringes in the compounding procedures, and failure to ensure cleanliness procedures in the facility according to USP 795 and USP 797 for compounding.

COUNT VII: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

24. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-3(7) & 21 U.S.C. 351 (c), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be adulterated under the following conditions: (7) If: (A) the drug or

device is not subject to the provisions of subdivision (6); and the drug's or device's strength differs from or the drug's or device's purity or quality falls below that which the drug or device purports or is represented to possess. Respondent violated Ind. Code § 16-42-3-3(7) & 21 U.S.C. 351 (c) by Respondent's compounding of non-FDA approved products, failure to create and follow formularies for all compounded drugs, intermixing of compounded lots through the re-use of single-use syringes, and failure to follow USP 795 and USP 797 as to cleanliness of procedures.

COUNT VIII: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

25. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-3(8)(A) & 21 U.S.C. 351 (d), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be adulterated under the following conditions: (8) If the drug or device is a drug and any substance has been: (A) mixed or packed with the drug or device so as to reduce the drug's or device's quality or strength. Respondent violated Ind. Code § 16-42-3-3(8)(A) & 21 U.S.C. 351 (d) by Respondent's re-use of single-use syringes in compounding and packaging of sterile drug preparations into nonsterile packages without adequate sterilization procedures.

COUNT IX: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

26. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-4(2) & 21 U.S.C. 352 (b), rules regulating drugs in Indiana and federally, which states that a drug or

device is considered to be misbranded under any of the following conditions: (2) If the drug or device is in package form unless the drug or device bears a label containing: (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Respondent violated Ind. Code § 16-42-3-4(2) & 21 U.S.C. 352 (b) by Respondent's failure to ensure that drug labeling contains an accurate statement of the items included within, as "IV bag" is not a specific and accurate statement," in regards to weight, measure, or numerical count within the package.

COUNT X: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

27. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-4(3) & 21 U.S.C. 352 (c), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be misbranded under any of the following conditions: (3) If any word, statement, or other information required to appear on the label or labeling is not prominently placed on the drug with conspicuousness. Respondent violated Ind. Code § 16-42-3-4(3) & 21 U.S.C. 352 (c) by Respondent's failure to ensure that drug name, expiration date, and other required items under state and federal law appear on drug labeling.

COUNT XI: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

28. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-4(6)(A) & 21 U.S.C. 352 (f)(1), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be misbranded under any of the following conditions: (6)

Unless the drug's labeling bears: (A) adequate directions for use. Respondent violated Ind. Code § 16-42-3-4(6)(A) & 21 U.S.C. 352 (f)(1) by Respondent's failure to put adequate directions on IV bags and other compounded drugs.

COUNT XII: KNOWING VIOLATION OF THE FOOD, DRUG, AND COSMETIC ACT

29. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 16-42-3-4(6)(B) & 21 U.S.C. 352 (f)(2), rules regulating drugs in Indiana and federally, which states that a drug or device is considered to be misbranded under any of the following conditions: (6) Unless the drug's labeling bears: (B) adequate warnings against use in those pathological conditions or by children where the drug's use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in manner and form that is necessary for the protection of users. Respondent violated Ind. Code § 16-42-3-4(6)(B) & 21 U.S.C. 352 (f)(2) by Respondent's failure to prevent cross contamination with adequate compounding procedures, and Respondent's compounding with Beta-lactam and hazardous drugs coupled with the lack of warnings on compounded medication.

COUNT XIII: ALLOWING ONE'S LICENSE TO BE USED BY ANOTHER TO PERFORM ACTIONS BEYOND THEIR TRAINING, EXPERTISE, OR COMPETNECE.

30. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(6) in the Respondent has allowed his license to be used in connection with an individual who renders services beyond the scope of that individual's training, experience, or competence. Specifically, Respondent violated Ind. Code § 25-1-9-4(a)(6) by Respondent allowing unlicensed and

untrained staff to perform compounding activities when state and federal law requires physician and/or pharmacist oversight and training of personnel to be completed.

COUNT XIV: FAILURE TO KEEP ABREAST OF CURRENT PROFESSIONAL THEORY AND PRACTICE.

31. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(4)(B) in that Respondent has continued to practice although the practitioner has become unfit to practice due to failure to keep abreast of current professional theory or practice. Specifically, Respondent failed to follow numerous provisions of the Food, Drug, and Cosmetic Act, failed to follow state law on drug manufacturing, failed to follow USP 795 and USP 797 on the compounding of nonsterile and sterile drugs, and numerous other provisions that impact his practice as a physician and a compounder in Indiana and the United States.

COUNT XV: KNOWING VIOLATION OF INDIANA INSPECT STATUTE

32. Respondent actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated Ind. Code § 25-26-24-20, a regulating practitioners that dispense and prescribe controlled substances in Indiana, which states, a practitioner who is permitted to dispense and prescribe a controlled substance in the course of practitioner's professional practice must be certified to receive information from the INSPECT program. Respondent violated Ind. Code § 25-26-24-20 by Respondent's failure to register with INSPECT prior to the IPLA inspection in January 2020.

COUNT XVI: KNOWING VIOLATION OF CODE OF FEDERAL REGULATIONS

33. Respondent's actions constitute a violation of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated 21 C.F.R. § 1304.11(b),

a rule regulating DEA registrants, which states every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribute, or dispensing of controlled substances. Respondent violated 21 C.F.R. § 1304.11(b) by failing to complete an initial inventory when Respondent opened in 2002.

COUNTS XVII-XXIV: KNOWING VIOLATION OF CODE OF FEDERAL REGULATIONS

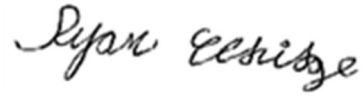
34. Respondent's actions constitute eight (8) violations of Ind. Code § 25-1-9-4(a)(3) in that Respondent has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question. Specifically, Respondent violated 21 C.F.R. § 1304.11(b), a rule regulating DEA registrants, on eight (8) separate occasions. The rule states that after an initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two (2) years. Respondent failed to complete biennial inventories in 2004, 2006, 2008, 2010, 2012, 2014, 2016, and 2018.

ACCORDINGLY, Petitioner respectfully requests this Board enter an order finding that:

1. Respondent is subject to discipline according to Ind. Code § 25-1-9;
2. Imposes an appropriate disciplinary sanction;
3. Directs the Respondent to immediately pay all cost incurred in the prosecution of this case; and
4. Provides any further relief that the Board deems just and proper.

Respectfully submitted,

Office of the Indiana Attorney General

By: 

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CERTIFICATE OF SERVICE

I certify that a copy of the foregoing "Administrative Complaint" has been served upon the Respondent and Respondent's counsel at the addresses listed below, by United States First Class Mail on this 18th day of August, 2021.

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