IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. MAIN STREET FAMILY PHARMACY, LLC, d/b/a/ MAIN STREET COMPOUNDING PHARMACY, a corporation, and CHRISTY R. NEWBAKER, and DAVID A. NEWBAKER individuals, Defendants.	)	Civil Action No.: 14-1326 **COMPLAINT FOR PERMANENT INJUNCTION**

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows.

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin the defendants, Main Street Family Pharmacy, LLC, d/b/a Main Street Compounding Pharmacy ("MSFP"), a corporation, and Christy R. Newbaker and David A. Newbaker, individuals (collectively, "Defendants"), from: (a) violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval; (b) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), 351(a)(2)(B), and/or 351(b), and/or misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1), and/or 352(j); and, (c) violating 21 U.S.C. § 331(k) by causing the adulteration of articles of drug within the

meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), 351(a)(2)(B) and/or 351(b), and/or the misbranding of articles of drugs within the meaning of 21 U.S.C. §§ 352(a) 352(f)(1), and/or 352(j) while the drugs are held for sale after shipment of one or more of their components in interstate commerce.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) & (c).

Defendants and Their Operations

4. MSFP is a Tennessee limited liability corporation, located at 126 East Main Street in Newbern, Tennessee, within the jurisdiction of this Court. MSFP is licensed by the Tennessee Board of Pharmacy as both a retail and compounding pharmacy. It has also been licensed to distribute pharmaceutical products in other states.

5. MSFP manufactures, processes, packs, labels, holds, and/or distributes articles of drug within the meaning of 21 U.S.C. § 321(g)(1).

6. Christy R. Newbaker is a co-owner and pharmacist at MSFP. She performs her duties at 126 East Main Street, Newbern, Tennessee, within the jurisdiction of this Court.

7. David A. Newbaker is a co-owner and pharmacist at MSFP. He is ultimately responsible for all drug manufacturing activities at MSFP, including all drug compounding and finished product testing; he also has the authority to prevent, detect, and correction violations. Mr. Newbaker performs his duties at 126 East Main Street, Newbern, Tennessee, within the jurisdiction of this Court.

8. Defendants have manufactured drugs that by virtue of their labeling or route of administration purport to be or are intended to be sterile ("sterile drugs"), as well as non-sterile drugs, for health care facilities and physicians' offices throughout the United States. Defendants' sterile drug products include, but are not limited to, methylprednisolone acetate.

9. Defendants have manufactured and distributed drugs without receiving a valid prescription for an individually-identified patient.

10. Defendants have been engaged in manufacturing, processing, packing, labeling, holding, and distributing drugs in interstate commerce to states outside of Tennessee, including, among others, Arkansas, Florida, Illinois, North Carolina, and Texas.

11. Defendants manufacture drugs using components that they receive in interstate commerce. For example, Defendants receive a component of their methylprednisolone acetate from New York. Defendants also manufacture drugs using components that they receive in interstate commerce.

Requirements of the Act

12. Under the Act, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), or that is "intended to affect the structure or any function of the body . . . ," 21 U.S.C. § 321(g)(1)(C).

13. The Act requires, subject to certain exceptions not applicable here, that drug manufacturers obtain FDA approval of a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to any new drug they introduce into interstate commerce. 21 U.S.C. §§ 331(d), 355(a). A "new drug" includes any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific

training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

14. A drug is deemed to be adulterated if it "consists in whole or in a part of any filthy, putrid, or decomposed substance." 21 U.S.C. § 351(a)(1).

15. A drug is also deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).

16. The Act also requires that drugs be manufactured in accordance with Current Good Manufacturing Practice ("CGMP"). 21 U.S.C. § 351(a)(2)(B); see also 21 C.F.R. § 210.1(b). A drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP to assure that it meets the requirements of the Act as to its safety and that it has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, regardless of whether the drug is actually defective in some way. FDA has promulgated CGMP regulations for drugs. 21 C.F.R. Parts 210-211.

17. A drug is deemed to be adulterated if "it purports to be or is represented as a drug the name of which is recognized in an official compendium and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium." 21 U.S.C. § 351(b).

18. A drug is deemed to be misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 352(a).

19. A drug is also deemed to be misbranded "unless its labeling bears adequate directions for use." 21 U.S.C. § 352(f)(1).

20. A drug is further deemed to be misbranded if "it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j).

21. Under the Act, compounded drugs may be exempt from the CGMP, adequate directions for use, and premarket approval requirements if the compounded drugs comply with the criteria in 21 U.S.C. § 353a. Among other things, 21 U.S.C. § 353a requires that the drug product be "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient . . . ." 21 U.S.C. § 353a(a). Moreover, the compounding must be by a licensed pharmacy or physician either "on the prescription order for such individual patient," or "in limited quantities before the receipt of a valid prescription order for such individual patient" and "based on a history of" the pharmacist or physician "receiving valid prescription orders for the compounding of the drug product . . . ." 21 U.S.C. § 353a(a)(1) & (2).

Adverse Events

22. On or about May 2, 2013, FDA received a report from an outpatient medical clinic in Illinois that a patient who had received an injection of Defendants' methylprednisolone acetate developed an abscess at the injection-site.

23. On or about May 20, 2013, FDA was notified of four additional patients at the same Illinois clinic who developed injection-site abscesses after being injected with Defendants' methylprednisolone acetate.

24. On or about May 22, 2013, FDA received a report from a physician in North Carolina of two additional cases of patients developing injection site abscess after being injected with Defendants' methylprednisolone acetate.

25. To date, there have been twenty-six confirmed cases of adverse events associated with the use of Defendants' methylprednisolone acetate.

FDA's Inspection Revealed Numerous Violations of the Act

26. In response to the adverse event reports, FDA inspected MSFP's facility between May 22 and June 11, 2013. During that inspection, FDA investigators observed and documented insanitary conditions and numerous CGMP violations. During the inspection, FDA investigators also collected environmental samples from Defendants' facility.

27. FDA's Southeast Regional Laboratory analyzed the environmental samples collected from Defendants' facility and confirmed the presence of bacteria, yeast, and mold in Defendants' aseptic processing area.

28. FDA investigators collected samples of Defendants' methylprednisolone acetate from an Illinois clinic that reported adverse events. FDA's Denver District Laboratory analyzed the samples and confirmed the presence of microbiological contamination in Defendants' methylprednisolone acetate.

Unapproved New Drugs

29. During FDA's inspection, FDA investigators observed that Defendants market numerous drug products, including, but not limited to, methylprednisolone acetate, 80mg/mL, preservative free, and methylprednisolone acetate, 100mg/mL. These drug products lack an approved NDA or an ANDA, as required by 21 U.S.C. § 355, and are not exempt from approval.

30. Defendants' drug products, including, but not limited to methylprednisolone acetate, 80mg/mL, preservative free, and methylprednisolone acetate, 100mg/mL are not generally recognized as safe and effective because there are no published adequate and well-controlled clinical studies of those drugs manufactured by MSFP for any indication. Therefore, they are new drugs within the meaning of 21 U.S.C. § 321(p).

31. The new drugs Defendants manufacture are not the subject of an approved NDA or ANDA or an effective investigational new drug application. *See* 21 U.S.C. § 355.

32. The new drugs for which Defendants fail to obtain patient-specific prescriptions do not qualify for the exemption from 21 U.S.C. § 355 in 21 U.S.C. § 353a, and therefore Defendants' distribution of those drugs in interstate commerce violates the Act, 21 U.S.C. §§ 331(d), 355(a).

Adulteration Due To Filth

33. Defendants distributed purportedly sterile drug products that were later found to contain microbiological contamination, as alleged in paragraph 28. Any microbiological contamination in a purportedly sterile drug product is filth within the meaning of the Act. 21 U.S.C. § 351(a)(1).

34. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(1), in that they consist in whole or in part of any filthy, putrid, or decomposed substance.

35. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(1), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Adulteration Due To Insanitary Conditions

36. Conditions observed in the MSFP facility by FDA investigators during FDA's inspection establish that all drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). These conditions include, but are not limited to, the following:

a. Environmental test results indicating the presence of microbiological contamination in samples collected from MSFP's clean room and environmentally-controlled areas that meet particle size and airflow parameters established by the International Organization for Standardization (ISO Class-5 areas);

b. The presence of two spiders in MSFP's clean room;

c. The ceiling above MSFP's clean room is open to an adjacent, uncontrolled area with exposed insulation, potentially exposing the clean room to contamination;

d. The use of non-sterile disinfecting agents in MSFP's aseptic processing area;

e. Drug components are brought into MSFP's clean room from uncontrolled rooms without being disinfected;

f. Insanitary employee practices in the clean room, including, but not limited to, use of non-sterile and non-protective clothing and employees processing sterile drug products while their skin is exposed;

g. Failure to adequately measure pressure differentials from the clean room and uncontrolled rooms during operations; and

h. Failure to qualify the airflow in the clean room with airflow/smoke studies under dynamic conditions.

37. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that they are prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health.

38. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(A), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Adulteration Due To Deviations from Drug CGMP Requirements

39. During the inspection, FDA investigators documented numerous deviations from CGMP requirements for drugs. These observations establish that Defendants' drugs are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B). The observed CGMP violations included, but were not limited to:

a. Failure to establish procedures to prevent microbiological contamination of drug products purporting to be sterile. See 21 C.F.R. § 211.113(b);

b. Failure to maintain the building used in the manufacture, processing, packing, or holding of a drug product in a clean and sanitary condition, as required by 21 C.F.R. § 211.56(a);

c. Failure to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions, as required by 21 C.F.R. § 211.42(c)(10);

d. Failure of personnel engaged in the manufacture, processing, packing or holding of a drug product to wear clean clothing appropriate for the duties they perform, and to wear, as necessary, protective apparel, such as head, face, hand, and arm coverings, to protect drug products from contamination, as required by 21 C.F.R. § 211.28(a);

e. Failure to conduct appropriate laboratory testing on each batch of drug product purporting to be sterile and/or pyrogen-free to determine conformance to such requirements, as required by 21 C.F.R. § 211.167(a);

f. Failure to establish an adequate system for maintaining equipment used to control the aseptic conditions, as required by 21 C.F.R. § 211.42(c)(10); and

g. Failure of Defendants' drug products to bear an expiration date supported by appropriate stability testing, as required by 21 C.F.R. § 211.137(a).

40. The adulterated drug products for which Defendants do not obtain patient-specific prescriptions do not qualify for the exemption from 21 U.S.C. § 351(a)(2)(B) as set forth in 21 U.S.C. § 353a. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform with CGMP, to assure that they meet the requirements of the Act as to their safety and that they have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess. Defendants also violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Adulteration Due To Substandard Quality and/or Purity

41. Defendants distributed purportedly sterile drug products that were later found to contain microbiological contamination, as alleged in paragraph 28. Thus Defendants' drug products were below the quality and/or purity standards set forth in the United States Pharmacopeia, within the meaning of the Act, 21 U.S.C. § 351(b).

42. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(b), in that they purport to be or are represented as drugs the names of which are recognized in an official compendium and their quality and/or purity fall below the standards set forth in such compendium.

43. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(b), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Misbranding Due To False and Misleading Labeling

44. Defendants' drugs are labeled as sterile, otherwise purport to be sterile, and/or, by the nature of their intended use or method of administration, are expected to be sterile. Because Defendants' purportedly sterile drugs were later found to contain microbiological contamination, as alleged in paragraph 28, Defendants' labeling for such products was false or misleading and the drugs were, therefore, misbranded within the meaning of 21 U.S.C. § 352(a).

45. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(a), in that their labeling is false or misleading in any particular.

46. Defendants violate 21 U.S.C. § 331(k) by causing the misbranding, within the meaning of 21 U.S.C. § 352(a), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Misbranding Due to Inadequate Directions for Use

47. Due to their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, Defendants' drugs are not safe for use

except under the supervision of a practitioner licensed by law to administer such drugs. As such, Defendants' drugs are "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1)(A).

48. "Adequate directions for use" means directions under which a layperson could use a drug safely and effectively for the purposes for which the drug was intended. 21 C.F.R. § 201.5. A prescription drug, by definition, cannot bear adequate directions for use by a layperson because such drug must be administered under the supervision of a licensed practitioner. *See* 21 U.S.C. § 353(b)(1). FDA has established exemptions from the requirement that labeling bear adequate directions for use, but because Defendants' drug products are unapproved new drugs, they do not satisfy the conditions for any of these exemptions. *See, e.g.*, 21 U.S.C. § 355; 21 C.F.R. § 201.115. As a result, Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

49. The Act, 21 U.S.C. § 353a, exempts certain drugs from the requirements of 21 U.S.C. § 352(f)(1) if certain conditions are met. The misbranded drug products for which Defendants do not obtain patient-specific prescriptions do not qualify for the exemption from 21 U.S.C. § 352(f)(1) in 21 U.S.C. § 353a. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that the labeling of the drugs fails to bear adequate directions for use, and the drugs are not exempt from that requirement. Defendants also violate 21 U.S.C. § 331(k) by causing the misbranding, within the meaning of 21 U.S.C. § 352(f)(1), of drugs while such drugs are held for sale after shipment of one or more of their components in interstate commerce, in that the labeling of the drugs fails to bear adequate directions for use and they are not exempt from that requirement.

Misbranding Because Defendants' Drugs Are Dangerous to Health

50. Defendants distributed purportedly sterile drug products that were later determined to contain microbiological contamination, as alleged in paragraph 28. To date, there have been twenty-six confirmed cases of adverse events associated with the use of these drugs. Such drug products are dangerous to health because they introduce virulent organisms directly into the bloodstream when used in the dosage or manner prescribed, recommended, or suggested in the labeling thereof. The presence of such organisms can result in bacterial subcutaneous abscesses, joint and bursa infection, and bloodstream infection. Because microbiological contamination renders these drug products dangerous to health, they are misbranded within the meaning of 21 U.S.C. § 352(j).

51. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(j), in that they are dangerous to health when used in the dosage or manner prescribed, recommended, or suggested in the labeling thereof.

52. Defendants violate 21 U.S.C. § 331(k) by causing the misbranding, within the meaning of 21 U.S.C. § 352(j), of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them from manufacturing, processing, packing, labeling, holding, or distributing any article of drug, unless and until Defendants bring their manufacturing, processing, packing, labeling, holding, and distribution operations into compliance with the Act and its implementing regulations to the satisfaction of FDA;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(d) by introducing or delivering without receiving a valid patient-specific prescription, or causing to be introduced or delivered without receiving a valid patient-specific prescription, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355, nor exempt from approval;

B. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), 351(a)(2)(B) and/or 351(b), and/or misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1) and/or 352(j); and

C. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(1), 351(a)(2)(A), 351(a)(2)(B) and/or 351(b), and/or misbranded within the meaning of 21 U.S.C. §§ 352(a), 352(f)(1) and/or 352(j);

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and other such relief as the Court deems just and proper.

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