

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
LEXINGTON

Eastern District of Kentucky
FILED
OCT - 1 2015
AT LEXINGTON
ROBERT R. CARR
CLERK U.S. DISTRICT COURT

UNITED STATES OF AMERICA

V.

INDICTMENT NO. 5:15-CR-87-DCR

SAMUEL A. GIROD

* * * * *

THE GRAND JURY CHARGES:

BACKGROUND

At all times relevant to this Indictment:

1. Defendant **SAMUEL A. GIROD** operated an establishment at 409 Satterfield Lane, Owingsville, KY 40360, which is in Bath County, in the Eastern District of Kentucky. This establishment, which did business under various names, including “Satterfield Naturals”, “S.A.E.G.”, and “A.M.S. Associates”, manufactured and marketed products for the treatment of various ailments, including skin disorders, cancer, and sinus infections.

2. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (“FDCA”), existed to protect the health and safety of the American public by regulating the manufacture and distribution of all drugs shipped or received in interstate commerce. The Food and Drug Administration (“FDA”) was the federal agency charged with enforcing the FDCA.

3. The FDCA required persons who owned or operated an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug to register annually with the FDA. *See* 21 U.S.C. §§ 360(b)(1), (c)(1). Every establishment in which a drug was manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction was subject to inspection by the FDA. *See* 21 U.S.C. §§ 360(h)(1) and 374. **GIROD** did not register his establishment with the FDA.

4. **GIROD** manufactured and distributed a product called “Chickweed Healing Salve.” This product typically bore labeling claiming that the product was “[g]ood for skin disorders. Dry skin, cuts, burns, draws, and poison ivy.” In many cases, **GIROD** also distributed sales pamphlets touting the product’s effectiveness in treating skin cancer, diaper rash, fungus infections, and various other skin ailments.

5. **GIROD** manufactured and distributed a product called “TO-MOR-GONE.” This product typically bore labeling identifying the product as a “black salve” and a “natural herbal remedy.” In many cases, **GIROD** also distributed sales pamphlets touting the product’s effectiveness in removing warts, moles, and other skin growths, and stating: “TO-MOR-GONE is very good at removing tumors.” **GIROD** used an extract of the bloodroot plant (*Sanguinaria Canadensis*) in TO-MOR-GONE. This ingredient was an escharotic agent, meaning that it had a caustic, corrosive effect on human skin.

6. **GIROD** manufactured and distributed a product called “R.E.P.” This product typically bore labeling that instructed the consumer as follows: “For sinus infection, put on forehead and cheeks. For breath freshener put drop on tongue.” In

many cases, **GIROD** also distributed sales pamphlets touting the product's effectiveness in treating sinus infections, cold symptoms, and sore throats.

7. The FDCA defined a "drug" as an article that was: (a) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; and/or (b) intended to affect the structure or any function of the body of man. *See* 21 U.S.C. § 321(g)(1)(B) and (C). Chickweed Healing Salve, TO-MOR-GONE, and R.E.P., were "drugs," as defined within the FDCA.

8. The FDCA prohibited the introduction or delivery for introduction into interstate commerce (or the causing thereof) of any drug that was misbranded. *See* 21 U.S.C. § 331(a).

9. A drug was misbranded if it was manufactured, prepared, propagated, compounded, or processed in an establishment that was not registered with the FDA. *See* 21 U.S.C. § 352(o). Chickweed Healing Salve, TO-MOR-GONE, and R.E.P. were each manufactured, prepared, propagated, and processed in **GIROD**'s unregistered establishment and, thus, were each misbranded.

10. A drug was also misbranded unless its labeling contained "adequate directions for use." 21 U.S.C. § 352(f)(1). Adequate directions for use were directions under which a layman "can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. Chickweed Healing Salve and TO-MOR-GONE did not bear labeling containing adequate directions for use and, thus, were each misbranded.

11. A drug was also misbranded unless its labeling contained a listing of each active ingredient. *See* 21 U.S.C. § 352(e)(1)(A)(ii). R.E.P. did not bear labeling that contained a listing of each active ingredient and, thus, was misbranded.

12. A drug was also misbranded unless its labeling contained “such adequate warnings against use in those pathological conditions . . . where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.” 21 U.S.C. § 352(f)(2). TO-MOR-GONE did not bear labeling warning of its caustic, corrosive effect on human skin and the scarring that could result. TO-MOR-GONE also did not bear labeling warning against its exclusive use to treat skin cancer. As such, TO-MOR-GONE was misbranded.

13. A drug was also misbranded if it was “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). TO-MOR-GONE was dangerous to health when used in the dosage, manner, frequency, and duration that was recommended and suggested in the labeling and, thus, was misbranded.

14. On or about September 17, 2013, the United States District Court for the Western District of Missouri entered an order (hereinafter, “the injunction”) permanently restraining and enjoining **GIROD** from manufacturing, processing, packaging, labeling, holding, selling, or distributing certain products, until various conditions were met. The products covered by the injunction included Chickweed Healing Salve, TO-MOR-GONE, R.E.P., and any other products similar in composition or effect to Chickweed

Healing Salve, TO-MOR-GONE, or R.E.P. The conditions under which the injunction could be lifted included: (a) **GIROD**'s removal from his products, labels, labeling, and promotional materials, of all claims that caused Chickweed Healing Salve, TO-MOR-GONE, and R.E.P. to be "drugs" within the meaning of the FDCA; (b) **GIROD**'s removal of all extracts or components of bloodroot plant (*Sanguinaria Canadensis*) from his products intended for human use; (c) the FDA's inspection of **GIROD**'s establishment; and (d) the FDA's notification to **GIROD** of his compliance with the terms of the injunction.

15. The injunction permitted the FDA to inspect **GIROD**'s establishment, without prior notice and when reasonably deemed necessary, for five years from the date of entry of the order. Among other things, the injunction provided that these inspections would include reasonable and immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other material therein.

16. Following the injunction, **GIROD** continued to manufacture, market, and distribute, in interstate commerce, Chickweed Healing Salve, TO-MOR-GONE, R.E.P., and other products similar in composition and effect. **GIROD** did not inform the purchasers of these products that he was under a court ordered injunction and was prohibited from distributing these products.

COUNT 1
18 U.S.C. § 372

17. Paragraphs 1 through 16 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

18. On or about November 21, 2013, in Bath County, in the Eastern District of Kentucky,

SAMUEL A. GIROD

knowingly and willfully conspired with others to prevent, by force, intimidation, and threat, FDA Compliance Safety Officers (“CSOs”) N.L.P. and M.D.S. from discharging the duties of their offices, trust, and places of confidence under the United States; and to induce, by force, intimidation, and threat, FDA CSOs N.L.P. and M.D.S. to leave the place where their duties as officers of the United States were required to be performed.

MANNER AND MEANS OF THE CONSPIRACY

The manner and means used to accomplish the objectives of the conspiracy included, among others, the following:

19. Members of the conspiracy, including **GIROD**, physically surrounded N.L.P. and M.D.S. when they arrived to inspect **GIROD**’s establishment pursuant to the injunction.

20. Members of the conspiracy, including **GIROD**, obstructed N.L.P.’s and M.D.S.’s attempts to gather information about **GIROD**’s establishment.

21. Members of the conspiracy, including **GIROD**, prevented N.L.P. and M.D.S. from inspecting **GIROD**’s establishment.

22. Members of the conspiracy, including **GIROD**, demanded that N.L.P. and M.D.S. leave **GIROD**'s establishment.

All in violation of 18 U.S.C. § 372.

COUNT 2
18 U.S.C. § 1505

23. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

24. On or about November 21, 2013, in Bath County, in the Eastern District of Kentucky,

SAMUEL A. GIROD

corruptly, by threats and force, and by threatening communication, influenced, obstructed and impeded, and endeavored to influence, obstruct, and impede the due and proper administration of the law under which a pending proceeding was being had before the FDA, all in violation of 18 U.S.C. § 1505.

COUNT 3
21 U.S.C. § 331(p)

25. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

26. In or about September 2013, and continuing through in or about July 2015, in Bath County, in the Eastern District of Kentucky,

SAMUEL A. GIROD,

with the intent to defraud or mislead, operated an establishment at 409 Satterfield Lane, Owingsville, KY 40360, at which location **GIROD** manufactured, prepared, propagated,

and processed Chickweed Healing Salve, TO-MOR-GONE, R.E.P., and products similar in composition and effect, and which **GIROD** had failed to register with the United States Food and Drug Administration in accordance with 21 U.S.C. § 360, all in violation of 21 U.S.C. §§ 331(p) and 333(a)(2).

COUNT 4
21 U.S.C. § 331(a)

27. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

28. On or about September 27, 2013, in Bath County, in the Eastern District of Kentucky, and elsewhere,

SAMUEL A. GIROD,

with the intent to defraud or mislead, introduced and delivered for introduction into interstate commerce a quantity of Chickweed Healing Salve, which was misbranded in that it: (a) was manufactured, prepared, propogated, and processed in an establishment that was not registered with the FDA; and (b) failed to bear labeling containing adequate directions for use; all in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

COUNT 5
21 U.S.C. § 331(a)

29. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

30. On or about October 14, 2013, in Bath County, in the Eastern District of Kentucky, and elsewhere,

SAMUEL A. GIROD,

with the intent to defraud or mislead, introduced and delivered for introduction into interstate commerce a quantity of Chickweed Healing Salve, which was misbranded in that it: (a) was manufactured, prepared, propogated, and processed in an establishment that was not registered with the FDA; and (b) failed to bear labeling containing adequate directions for use; all in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

COUNT 6
21 U.S.C. § 331(a)

31. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

32. On or about October 14, 2013, in Bath County, in the Eastern District of Kentucky, and elsewhere,

SAMUEL A. GIROD,

with the intent to defraud or mislead, introduced and delivered for introduction into interstate commerce a quantity of TO-MOR-GONE, which was misbranded in that it: (a) was manufactured, prepared, propogated, and processed in an establishment that was not registered with the FDA; (b) failed to bear labeling containing adequate directions for use; (c) failed to bear labeling containing such adequate warnings against use in those pathological conditions where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and (d) was dangerous to health when used in

the dosage or manner or with the frequency or duration recommended or suggested in the labeling thereof; all in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

COUNT 7
21 U.S.C. § 331(a)

33. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

34. On or about November 13, 2013, in Bath County, in the Eastern District of Kentucky, and elsewhere,

SAMUEL A. GIROD,

with the intent to defraud or mislead, introduced and delivered for introduction into interstate commerce a quantity of Chickweed Healing Salve, which was misbranded in that it: (a) was manufactured, prepared, propagated, and processed in an establishment that was not registered with the FDA; and (b) failed to bear labeling containing adequate directions for use; all in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

COUNT 8
21 U.S.C. § 331(a)

35. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

36. On or about November 13, 2013, in Bath County, in the Eastern District of Kentucky, and elsewhere,

SAMUEL A. GIROD,

with the intent to defraud or mislead, introduced and delivered for introduction into interstate commerce a quantity of TO-MOR-GONE, which was misbranded in that it: (a)

was manufactured, prepared, propogated, and processed in an establishment that was not registered with the FDA; (b) failed to bear labeling containing adequate directions for use; (c) failed to bear labeling containing such adequate warnings against use in those pathological conditions where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and (d) was dangerous to health when used in the dosage or manner or with the frequency or duration recommended or suggested in the labeling thereof; all in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

COUNT 9
21 U.S.C. § 331(a)

37. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

38. On or about November 13, 2013, in Bath County, in the Eastern District of Kentucky, and elsewhere,

SAMUEL A. GIROD,

with the intent to defraud or mislead, introduced and delivered for introduction into interstate commerce a quantity of R.E.P., which was misbranded in that it: (a) was manufactured, prepared, propogated, and processed in an establishment that was not registered with the FDA; and (b) failed to bear labeling that contained a listing of each active ingredient; all in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

COUNT 10
21 U.S.C. § 331(a)

39. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

40. On or about November 13, 2013, in Bath County, in the Eastern District of Kentucky, and elsewhere,

SAMUEL A. GIROD,

with the intent to defraud or mislead, introduced and delivered for introduction into interstate commerce a quantity of TO-MOR-GONE, which was misbranded in that it: (a) was manufactured, prepared, propogated, and processed in an establishment that was not registered with the FDA; (b) failed to bear labeling containing adequate directions for use; (c) failed to bear labeling containing such adequate warnings against use in those pathological conditions where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and (d) was dangerous to health when used in the dosage or manner or with the frequency or duration recommended or suggested in the labeling thereof; all in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

COUNT 11
21 U.S.C. § 331(a)

41. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

42. On or about January 10, 2014, in Bath County, in the Eastern District of Kentucky, and elsewhere,

SAMUEL A. GIROD,

with the intent to defraud or mislead, introduced and delivered for introduction into interstate commerce a quantity of Chickweed Healing Salve, which was misbranded in that it: (a) was manufactured, prepared, propagated, and processed in an establishment that was not registered with the FDA; and (b) failed to bear labeling containing adequate directions for use; all in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

COUNT 12
18 U.S.C. § 1512(b)(2)(A)

43. Paragraphs 1 through 22 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

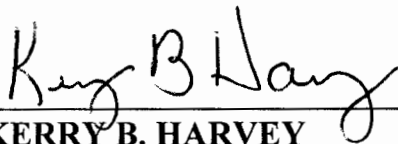
44. On or about December 15, 2014, in Bath County, in the Eastern District of Kentucky, and elsewhere,

SAMUEL A. GIROD

knowingly threatened, attempted to threaten, and attempted to corruptly persuade M.M., and engaged in misleading conduct toward M.M., with the intent to cause and induce M.M. to withhold records and documents from an official proceeding, to wit, the

investigation of a federal grand jury in the Eastern District of Kentucky, all in violation of
18 U.S.C. § 1512(b)(2)(A).

A TRUE BILL



KERRY B. HARVEY
UNITED STATES ATTORNEY

PENALTIES

COUNT 1: Not more than 6 years imprisonment, \$250,000 fine, and 3 years supervised release

COUNT 2: Not more than 5 years imprisonment, \$250,000 fine, and 3 years supervised release.

COUNTS 3-11: Not more than 3 years imprisonment, \$250,000 fine, and 1 year supervised release.

COUNT 12: Not more than 20 years imprisonment, \$250,000 fine, and 3 years supervised release.

PLUS: Mandatory special assessment of \$100 per count.

PLUS: Restitution, if applicable.