SUPPLEMENTAL APPENDIX

SUPPLEMENTAL APPENDIX CONTENTS

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D/B/A HOPE PHARMACEUTICALS

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HOPE MEDICAL ENTERPRISES, INC. D/B/A HOPE PHARMACEUTICALS,

Plaintiff,

v.

FAGRON COMPOUNDING SERVICES, LLC; JCB LABORATORIES, LLC; ANAZAOHEALTH CORPORATION; COAST QUALITY PHARMACY, LLC,

Defendants.

Case No. 2:19-cv-07748-CAS-PLA

PLAINTIFF HOPE MEDICAL ENTERPRISES, INC.'S FIRST AMENDED COMPLAINT

[JURY TRIAL DEMANDED]

Plaintiff Hope Medical Enterprises, Inc., d/b/a Hope Pharmaceuticals ("Hope"), brings this action against the jointly-owned and affiliated Defendants Fagron Compounding Services, LLC ("Fagron"), JCB Laboratories, LLC ("JCB"), AnazaoHealth Corporation ("AnazaoHealth") and Coast Quality Pharmacy, LLC ("Coast") (collectively "Defendants") and alleges the following:

I. NATURE OF THE ACTION

1. Hope brings this action to stop Defendants from unlawfully manufacturing and selling unapproved new drugs under the false guise that they are engaged in lawful "compounding." Federal and state law require drug manufacturers to demonstrate that their drugs are safe and effective in order to obtain regulatory approval to market them. Defendants purport to avoid drug-approval requirements by falsely presenting their products as lawfully "compounded" when in fact Defendants' products cannot lawfully be sold.

A. State Laws Against Unlawful and Unfair Business and Trade Practices

2. California's Unfair Competition Law ("UCL") exists to stop these types of unscrupulous practices by "prohibiting unfair, dishonest, deceptive, destructive, fraudulent and discriminatory practices by which fair and honest competition is destroyed or prevented." Cal. Bus. & Prof. Code §§ 17001, 17200.

3. Similarly, Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA") also "protect[s] the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.202(2). FDUTPA further

forbids Defendants from violating "[a]ny law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. Ann. § 501.203(3)(c).

4. Tennessee's Consumer Protection Act ("TCPA") likewise prohibits "advertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state." Tenn. Code Ann. § 47-18-104(b)(44)(C).

5. South Carolina's Unfair Trade Practices Act ("SCUTPA") and Connecticut's Unfair Trade Practices Act ("CUTPA") both prohibit "unfair methods of competition" and "unfair [ ] acts or practices in the conduct of any trade or commerce." S.C. Code Ann. § 39-5-20; Conn. Gen. Stat. § 42-110b.

B. State Laws Prohibiting the Sale of Unapproved Drugs

6. California regulates the manufacture and sale of prescription drugs under the Sherman Food, Drug, and Cosmetic Law (the "Sherman Law"). As relevant here, the Sherman Law specifies that "[n]o person shall sell, deliver, or give away any new drug" that has not been approved by the California Department of Health Services or the United States Food and Drug Administration ("FDA"). Cal. Health & Safety Code § 111550(a)—(b). The Sherman Law's drug-approval provision is designed to ensure that when Californians are treated with prescription drugs, they can rest assured that the products are safe and effective for their intended uses.

7. Florida also regulates the manufacture and sale of prescription drugs under the state's Drug and Cosmetic Act. As relevant here, the Florida Drug and Cosmetic Act specifies that no person may "sell, offer

for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug" that has not been approved by FDA. Fla. Stat. Ann. § 499.023. Florida's drug-approval provision is, similarly, designed to ensure that when Floridians are treated with prescription drugs, they can rest assured that the products are safe and effective for their intended uses.

8. Like California and Florida, Tennessee, South Carolina and Connecticut regulate the manufacture and sale of prescription drugs. The Tennessee Food, Drug and Cosmetic Act specifies that "no person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the federal act." Tenn. Code Ann. § 53-1-110.

9. Under South Carolina law: "No person shall introduce or deliver for introduction into intrastate commerce any new drug unless an application filed pursuant to subsection (b) is effective with respect to such drug, or an application with respect thereto has been approved and such approval has not been withdrawn under § 505 of the Federal act." S.C. Code Ann. § 39-23-70(a).

10. The Connecticut Uniform Food, Drug and Cosmetic Act, Conn. Gen. Stat. § 21a-110, states: "No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved under section 355 the federal act [the premarket approval requirement]. . . ."

11. Defendants disregard these and other state laws respecting the distribution of unapproved drugs. Rather than invest the time and resources necessary to research, develop, and test their products in order

to ensure that they are safe and effective and to obtain regulatory approval to market them, Defendants are simply creating, marketing, and selling unapproved new drugs for unapproved uses throughout the United States, including California, Florida, Tennessee, South Carolina, and Connecticut, under the false guise of "compounding."

C. Compounding and Defendants' Unlawful and Unfair Business and Trade Practices

12. "Compounding" is "a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." *Compounding and the FDA: Questions and Answers* (Oct. 6, 2015); *see also* United States Pharmacopeia—National Formulary (USP-NF), *General Chapter 1075, Good Compounding Practices.* Defendants' manufacturing and marketing of standardized drugs is the antithesis of compounding.

13. Defendants are under common ownership and control and work closely together. All Defendants are owned either directly or indirectly by Fagron BV, a company registered in Belgium, and/or its affiliate, Fagron NV, a company registered and headquartered in the Netherlands.

14. Defendants Fagron, JCB and AnazaoHealth own "outsourcing facilities" located in Wichita, Kansas (Fagron and JCB), and Las Vegas, Nevada (AnazaoHealth), purporting to operate under Section 503B of the federal Food Drug & Cosmetic Act ("FDCA"). Defendant Coast, which, like its co-defendant and affiliate AnazaoHealth, also operates under the tradename "AnazaoHealth," owns and

operates a compounding pharmacy located in Tampa, Florida, and purports to operate under Section 503A of the FDCA.

15. Defendants' business models are unlawful. Defendants are engaged in unlawful and unfair business and trade practices because Defendants are manufacturing and dispensing drugs in violation of the Sherman Law, the Florida Drug & Cosmetic Act, the Tennessee Food, Drug & Cosmetic Act, the Code of Laws of South Carolina, and the Connecticut Uniform Food, Drug and Cosmetic Act. These laws prohibit the sale of drugs not approved by FDA.

16. Testing new drugs and obtaining the legally required regulatory approval to sell them is time-consuming and very costly. Ignoring drug-approval requirements provides Defendants an unfair competitive advantage over law-abiding pharmaceutical manufacturers like Hope. Worse, it puts patients at risk by exposing them to drugs that have not been shown to be safe or effective.

17. Defendants purport to sell their unproven and unapproved drugs as "compounded" drugs. In reality, however, Defendants are engaged in nothing more than unlawful drug manufacturing.

18. Compounding is typically appropriate when the medical needs of an individual patient cannot be met by a commercially available, approved medication. If a patient has an allergy and needs a medication to be made without a certain dye, for example, compounding may be appropriate. Or if an elderly patient or a child cannot swallow a pill and needs a medicine in liquid form that is commercially available only in tablet form, a compounded drug may warrant clinical consideration. Compounding is thus traditionally a one-to-one service: a pharmacy

dispenses a single compounded drug to a single patient according to a unique prescription tailored to the individual patient's medical needs.

19. Because compounding occurs on the small scale of individual, patient-specific prescriptions tailored to meet medical needs that cannot be met by commercially available, approved drugs, it is generally not practical for compounded drugs to undergo the clinical trials generally required to obtain regulatory approval to market a new drug. And the small scale of compounding means that the risks to public health posed by unapproved compounded drugs are correspondingly limited to the select individuals who receive them. To preserve traditional compounding as a way to treat patients whose needs cannot be met by commercially available, approved drugs, state and federal law permit compounded drugs, in limited circumstances, to forgo approval by state health departments or FDA.

20. Hope fully recognizes the value and legal legitimacy of traditional compounding and does not, through this suit, seek to restrict such legal traditional compounding. But when companies like Defendants misuse these narrow exemptions to mass manufacture and market standardized drugs of unknown quality under the guise of compounding, thousands of patients may be at risk. Such mass manufacturing and marketing of unapproved drugs undermines the drug-approval requirements that are central to the protection of the public from drugs that may be unsafe, ineffective, or both.

21. Unlike Hope and other law-abiding pharmaceutical manufacturers, Defendants falsely claim to be engaged in compounding and thus to be exempt from state and federal approval requirements.

By ignoring drug-approval requirements, Defendants are profiting at the expense of public health.

D. The Importance of Drug Approval and the Purpose of this Action

22. Federal and state law require approval for new drugs for good reason. Drug approval is evidence-based, and it is essential to ensure the quality, safety, and effectiveness of new drugs. When companies circumvent the drug-approval process, safety and efficacy are, at best, unknown. The danger is not merely theoretical, as manufacturing and distribution of unapproved new drugs of unknown quality in the guise of compounding has endangered or adversely impacted public health. For example, in 2012, 753 patients in 20 states were diagnosed with a fungal infection after receiving injections of preservative-free methylprednisolone acetate manufactured by New England Compounding Center in Massachusetts. Of those 753 patients, the U.S. Centers for Disease Control and Prevention reported that 64 patients in nine states died, though other sources report the death toll as exceeding 100 victims.

23. Hope brings this action under the UCL, FDUTPA, TCPA, SCUTPA and CUTPA to stop Defendants from unlawfully manufacturing, marketing, selling, and distributing unapproved new drugs. Hope seeks a declaration that Defendants' business practices violate the UCL, FDUTPA, TCPA, SCUTPA and CUTPA by manufacturing, distributing, and selling unapproved new drugs and an injunction prohibiting Defendants from committing such violations. *See* Cal. Bus. & Prof. Code § 17200; Cal. Health & Safety Code § 111550(a)-(b); Fla. Stat. Ann. §§ 499.005, 499.023, 501.203(3)(c); Tenn. Code Ann. § 47-18-104(b)(44)(C); Tenn. Code Ann. § 53-1-110;

S.C. Code Ann. § 39-23-70(a), Conn. Gen. Stat. § 21a-110, 42-110b; *cf.* 21 U.S.C. § 331(a).

24. Hope further seeks actual damages that it has incurred as a result of Defendants' unlawful business tactics, plus attorney's fees and court costs. *See* Fla. Stat. Ann. § 501.211(2); Tenn. Code Ann. § 47-18-109; S.C. Code Ann. § 39-5¬140; Conn. Gen. St. § 42-110g.

II. THE PARTIES

25. Hope is a corporation organized and existing under the laws of the State of Arizona, with its principal place of business in Scottsdale, Arizona.

26. Doing business using the name Hope Pharmaceuticals, Hope markets and sells Sodium Thiosulfate Injection and Sodium Nitrite Injection in a co-packaged kit, and it also sells Sodium Thiosulfate Injection as an individually-packaged medication separate from Sodium Nitrite Injection. Hope is the exclusive supplier of FDA-approved Sodium Thiosulfate Injection sold in the United States.

27. Hope sells its Sodium Thiosulfate Injection to medical facilities and other customers that are located in states including California, Florida, South Carolina, Tennessee and Connecticut. Of any state, California is the largest individual market for Hope's FDA-approved Sodium Thiosulfate Injection.

28. Hope has invested significant time and resources to research, develop, manufacture, and test both the finished drug product Sodium Thiosulfate Injection and the corresponding active ingredient, bulk sodium thiosulfate pentahydrate drug substance ("bulk sodium thiosulfate"), in order to obtain regulatory approval from FDA to market Sodium Thiosulfate Injection as an antidote for the treatment

of acute cyanide poisoning that is judged to be serious or life-threatening.

29. Fagron is a limited liability company organized and existing under the laws of Missouri, with its principal place of business at 8710 E. 34th St. North, Wichita, Kansas.

30. JCB is a limited-liability company organized and existing under the laws of Kansas, with its principal place of business at 7335 W. 33rd St. North Wichita, Kansas. Upon information and belief, Fagron owns the entire membership interest in JCB.

31. AnazaoHealth is a Florida Profit Corporation with its principal place of business at 7465 W. Sunset Road, Suite 1200, Las Vegas, Nevada.

32. Coast is a Florida limited liability company with a principal place of business at 2400 Pilot Knob Rd. MN #200, St. Paul, Minnesota. Upon information and belief, AnazaoHealth owns the entire membership interest in Coast.

33. Upon information and belief, all Defendants are closely affiliated with each other and share resources, staff, leadership, and business efforts.

34. Defendants sell their unapproved drug products throughout California, including in this judicial District (which is the most populous in the State of California), and in Florida, Tennessee, South Carolina, Connecticut and nationwide, including unapproved sodium thiosulfate drug products that are compounded using bulk sodium thiosulfate.

III. JURISDICTION AND VENUE

35. This Court has subject matter jurisdiction under 28 U.S.C. § 1332. The parties are citizens of different States (¶¶ 25-32, *supra),* and the matter in

controversy exceeds the sum or value of $75,000, exclusive of interest and costs (¶¶ 101-131, *infra).*

36. This Court has personal jurisdiction over Defendants. Defendants have been engaging in business in this District and shipping unapproved drugs into California and this District, and Defendants are violating California statutes within this District. In substantial part, Hope's claims arise out of or relate to Defendants' activities in this District.

37. Venue in this District is proper under 28 U.S.C. § 1391.

IV. FACTUAL ALLEGATIONS

A. Hope Sells the only Sodium Thiosulfate Drug Approved by FDA for Sale in the United States

1. Hope Obtained FDA Approval for Sodium Thiosulfate in 2012

38. Cyanide is a chemical compound with a number of industrial uses. It is also highly toxic and can cause death within minutes of exposure. Hope's Sodium Thiosulfate Injection has been approved by FDA for the treatment of acute cyanide poisoning that is judged to be serious or life-threatening.

39. Hope is a privately-owned pharmaceutical company located in Scottsdale, Arizona.

40. In 2010, Hope submitted New Drug Application #201,444 to FDA for Sodium Nitrite Injection and Sodium Thiosulfate Injection as a co-packaged cyanide antidote kit containing one vial of each medication. New Drug Application #203,923 was submitted in 2011 for Sodium Thiosulfate Injection as an individually packaged medication. Hope invested significant resources over several years

to prepare New Drug Applications #201,444 and #203,923.

41. Hope's New Drug Application #201,444 for the co-packaged cyanide antidote kit that contains Sodium Nitrite Injection and Sodium Thiosulfate Injection was approved by FDA on January 14, 2011.

42. Hope's New Drug Application #203,923 for Sodium Thiosulfate Injection was approved by FDA on February 14, 2012.

43. As described above, Hope is the only supplier of FDA-approved Sodium Thiosulfate Injection in the United States. Additionally, Hope is the only supplier of bulk sodium thiosulfate that has been approved by FDA for use as an active ingredient in medications that are intended for administration to humans.

B. Defendants' Activities Violate State and Federal Drug-Approval Provisions

1. California, Florida, Tennessee, South Carolina and Connecticut law require FDA approval

44. Defendants' manufacturing, marketing, sale, and distribution of unapproved new drugs, under the guise of compounding, is unlawful.

45. Under California, Florida, Tennessee, South Carolina and Connecticut law, a new drug may not be introduced or delivered for introduction into interstate (California, Florida, Tennessee, Connecticut) commerce or for introduction into intrastate (South Carolina) commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. *See* Cal. Health & Safety Code § 111550(a); Fla. Stat. § 499.023; Tenn. Code Ann. § 53-1-110; SC-ST § 39¬23-70; Conn. Gen. Stat. 21a-110; 21 U.S.C. §§ 331(d) and 355(a).

46. California's Sherman Law provides that "[n]o person shall sell, deliver, or give away any new drug" that has not been approved by FDA or by the State of California. Cal. Health & Safety Code § 111550(a)—(b).

47. The Sherman Law incorporates "[a]ll regulations relating to . . . new drug applications . . . adopted pursuant to Section 505" of the FDCA. *Id. §* 110110(a).

48. California's Sherman Law and the FDCA's definitions of "drug" and "new drug" are the same. *See id. §* 109925(c) (drug), § 109980 (new drug); 21 U.S.C. § 321(g)(1), (p).

49. California's Sherman Law incorporates the FDCA's requirement that pharmaceutical manufacturers must obtain approval before selling a new drug. *See* Cal. Health & Safety Code § 110105; 21 U.S.C § 355.

50. Florida's Drug and Cosmetic Act provides that no person may "sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug" that has not been approved by FDA. Fla. Stat. Ann. § 499.023.

51. Florida's Drug and Cosmetic Act's and the FDCA's definitions of "drug" and "new drug" are the same. Fla. Stat. Ann. § 499.003(17) (drug), § 499.003(32) (new drug); 21 U.S.C. § 321(g)(1), (p).

52. The Tennessee Food, Drug and Cosmetic Act provides that "no person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the federal act." Tenn. Code Ann. § 53-1-110.

53. Under South Carolina law, a new drug may not be introduced or delivered for introduction into intrastate commerce unless an application under South Carolina Statute § 39-23-70(b) or section 505 of the FDCA is in effect for the drug. S.C. Code Ann. § 39-23-70.

54. The Connecticut Uniform Food, Drug and Cosmetic Act states that "no person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect thereto has been approved under Section 355 of the federal act [the premarket approval requirement]." Conn. Gen. Stat. § 21a-110.

55. Defendants are violating California's Sherman Law, Florida's Drug and Cosmetic Act, the Tennessee Food, Drug and Cosmetic Act, South Carolina Statutes § 39-23-70 and the Connecticut Uniform Food, Drug and Cosmetic Act because they have not obtained the approval of FDA (or any other relevant regulatory authority) to introduce the compounded sodium thiosulfate drugs that they manufacture, market, sell, and distribute.

2. Section 503B precludes use, in any Section 503B outsourcing facility, of a bulk drug substance not on FDA's clinical need ("bulks") list, except to manufacture drugs in shortage

56. Defendants formulate, manufacture, market, sell, and distribute unapproved new drugs that they claim are lawful "compounded" drugs. Defendants market dozens of drugs as alternatives to FDA-approved drugs throughout the United States, including California, Florida, Tennessee, South Carolina and Connecticut. Defendants' drugs include

a compounded sodium thiosulfate drug product, which they manufacture using bulk sodium thiosulfate.

57. Defendants do not have an approved New Drug Application or Abbreviated New Drug Application for any sodium thiosulfate drug product.

58. Defendants purport to avoid the need for compliance with the 21 U.S.C. § 355(a) pre-market approval requirement by relying on Section 503B of the FDCA, 21 U.S.C. § 353b.

59. Enacted in 2013 as part of the Drug Quality and Security Act, Section 503B limits the circumstances in which bulk drug substances may be used in compounding. Pursuant to 21 U.S.C. § 353b(a)(2)(A)(i) and (ii), an outsourcing facility may use a bulk drug substance in compounding only if it appears on a list, to be developed by FDA, of bulk substances "for which there is a clinical need" (known as, alternatively, the "503B Bulks List" or "503B Clinical Need List," and referenced herein as "503B Clinical Need List") or, alternatively, "the drug compounded from such bulk drug substance" appears on FDA's drug shortage list at the time of compounding, distribution, and dispensing.

60. Sodium thiosulfate has never appeared on FDA's shortage list at any time since Section 503B was signed into law on November 27, 2013, as part of the Drug Quality and Security Act.

61. FDA has solicited nominations from the public for the 503B Clinical Need List, but has not yet initiated the notice-and-comment process mandated by the statute for establishing the formal list. *See* 78 Fed. Reg. 72838 (Dec. 4, 2013); 79 Fed. Reg. 37747 (July 2, 2014). The most recent iteration of the 503B Clinical Need List provides: "At this time, FDA has not placed any bulk drug substances on the 503B

bulks [clinical need] list."[1] And FDA has not determined that there is a clinical need to use any bulk substance in compounding.

3. Defendants' drugs are not exempted from FDA approval under Section 503B because of Defendants' unlawful use of bulk sodium thiosulfate

62. Defendants Fagron, JCB, and AnazaoHealth each operate an FDA 503B outsourcing facility. Fagron operates Fagron Sterile Services in Wichita, Kansas. JCB operates JCB Laboratories, also in Wichita, Kansas. AnazaoHealth operates AnazaoHealth in Las Vegas, Nevada. Defendants are engaged in the unlawful manufacture and sale of drugs because they are manufacturing drugs using bulk sodium thiosulfate in their 503B outsourcing facilities and (1) sodium thiosulfate does not appear on FDA's 503B Clinical Need List; and (2) Hope's FDA-approved Sodium Thiosulfate Injection is not on FDA's shortage list and, once again, FDA has not approved any other medication containing sodium thiosulfate as an active pharmaceutical ingredient.

63. A section 503B outsourcing facility or a compounding pharmacy may obtain the active pharmaceutical ingredients from which it makes compounded drugs in two ways: (1) by purchasing and altering a finished, FDA-approved drug product; or (2) by purchasing bulk drug substances and using those bulk substances to create the drugs. Defendants do not purchase Hope's FDA-approved Sodium Thiosulfate Injection and alter it to manufacture the

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[1] FDA has determined that there is *not* a clinical need to compound using two bulk drug substances: nicardipine hydrocholoride and vasopressin.

compounded sodium thiosulfate drug products they sell to physicians and medical facilities.

64. Defendants ship their compounded sodium thiosulfate drug products from one or more 503B facilities to physicians and medical facilities around the country, including to California, Florida, Tennessee, South Carolina and Connecticut, with the knowledge that physicians and medical facilities in those states prescribe, sell, dispense, and/or administer their compounded sodium thiosulfate drug products to patients in those states.

4. Section 503B precludes the sale of drugs that are essentially a copy of an approved drug

65. Section 503B prohibits the compounding and sale of any drug that is essentially a copy of an approved drug. 21 U.S.C. § 353b(a)(5).

66. Section 503B defines a compounded drug to be essentially a copy of an approved drug if a component of the compounded drug is a bulk drug substance that is also a component of an FDA-approved drug, "unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug." 21 U.S.C. § 353b(d(2).

67. In January 2018, FDA explained the statutory "essentially a copy" definition for Section 503B outsourcing facilities: "If an outsourcing facility compounds a drug, the component of which is a bulk drug substance that is a component of an approved drug, there must be a change that produces a clinical difference for an individual patient as determined by the prescribing practitioner. If an outsourcing facility intends to rely on such a determination to establish

that a compounded drug is not essentially a copy of an approved drug, the outsourcing facility should ensure that the determination is noted on the prescription or order . . . for the compounded drug." *Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503E of the Federal Food, Drug, and Cosmetic Act Guidance for Industry* (January 2018).

68. The FDA continued: "FDA is aware that a health care practitioner who orders a compounded drug from an outsourcing facility for office stock will not know the identity of the individual patients who will receive the compounded drug at the time of the order. In that case, the outsourcing facility should obtain a statement from the practitioner that specifies the change between the compounded drug and the comparable approved drug and indicates that the compounded drug will be administered or dispensed only to a patient for whom the changes produces a clinical difference, as determined by the prescribing practitioner for that patient." *Id.*

69. FDA's Guidance also provides: "An order that only identifies the product formulation, without more information, would not be sufficient to establish that the determination described by section 503B(d)(2)(B) has been made." *Id.* And, "[i]f a prescription identifies only a patient name and product formulation, this would not be sufficient to establish that the determination described by section 503B(d)(2)(B) has been made.

70. Finally, FDA's Guidance states: "Other factors such as a lower price are not sufficient to establish that the compounded product is not essentially a copy of the approved drug." *Id.*

71. Defendants' compounded sodium thiosulfate drug product sold from their Section 503B outsourcing facilities is essentially a copy of Hope's FDA-approved Sodium Thiosulfate Injection drug product in that the two drugs have the same active pharmaceutical ingredient, sodium thiosulfate; the prescribing practitioners to whom Defendants sell their Section 503B sodium thiosulfate have not made the determination that Defendants' drug produces, for each individual patient to whom Defendants' 503B sodium thiosulfate drugs are administered, a clinical difference as compared to Hope's Sodium Thiosulfate Injection; and the prescriptions and orders received by Defendants do not make clear that the determination required by section 503B and FDA has been made.

5. Defendants' unlawful use of bulk sodium thiosulfate and noncompliance with the Essentially a Copy requirement means that all drugs compounded in the same 503B outsourcing facility do not meet the conditions required for the 503B exemption to apply

72. Title 21 U.S.C. § 353b(a) provides for an exemption from the drug-approval requirements for "outsourcing facilities" registered with FDA only "if each of [eleven] conditions are met." The last of those conditions, 21 U.S.C. § 353b(a)(11), requires that the drug be "compounded in an outsourcing facility in which the compounding of drugs occurs *only* in accordance with [section 353b]." (Emphasis added). That is, if *any* drug compounded in an outsourcing facility does not comply with all of Section 503B's conditions, then *none* of the drugs produced in that outsourcing facility are exempt from the FDA's drug-approval requirements.

73. Because FDA has not found a clinical need for the use of bulk sodium thiosulfate by outsourcing facilities, Defendants' manufacture and sale of drugs containing bulk sodium thiosulfate violates 21 U.S.C. § 353b(a)(2)(A)(i) and (ii). And because Defendants violate the "Essentially a Copy" prohibition, Defendants' manufacture and sale of drugs containing sodium thiosulfate violates 21 U.S.C. § 353b(a)(5). This means that Defendants' outsourcing facilities are not compounding drugs only in accordance with Section 503B. Therefore, no drug produced in those outsourcing facilities is eligible for the exemption from FDA's drug approval requirements. 21 U.S.C. § 353b(a)(11).

6. Section 503A includes an individual customization requirement, which Defendant Coast violates

74. Defendant Coast owns and operates a compounding pharmacy in Tampa, Florida operating under the tradename AnazaoHealth, purportedly under Section 503A. Coast's compounding pharmacy manufactures and sells large quantities of a compounded, non-customized sodium thiosulfate drug product.

75. Section 503A exempts a drug from the premarket approval requirement only if the drug:

> is compounded [1] for an identified individual patient [2] 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, [3] if the drug product meets the requirements of this

> section, and listing conditions of the "prescription" requirement].

21 U.S.C. § 353a(a). This "individual customization requirement" prohibits Section 503A compounding pharmacies from using the exemption from the pre-market approval requirement as a path to mass-market standardized drugs intended for any and all patients, in unlawful competition with FDA-approved drugs like Hope's.

76. FDA agrees that the practice of Section 503A compounding pharmacies selling drugs to patients who can tolerate FDA approved drugs is inappropriate. In its Human Drug Compounding Progress Report (Jan. 2017), FDA wrote: "[S]ome compounders engage in *inappropriate* compounding activities. For example, FDA is aware that some compounders produce drugs for patients even though an FDA-approved drug may have been medically appropriate for them." (emphasis added.)

77. Defendants' 503A compounding pharmacy, Coast, does not comply with the individual customization requirement. The compounded sodium thiosulfate drug product Defendants sell from their 503A compounding pharmacy is not compounded for individual patients based on the need for an alternative to an FDA-approved drug. Coast does not compound or dispense its compounded sodium thiosulfate drug product based on the need for an alternative to an FDA-approved drug or dispense its compounded sodium thiosulfate drug product based on the receipt of a prescription order (or a prescriber's notation on the order) specifying that (a) a compounded sodium thiosulfate drug product is necessary for the identified patient and (b) the patient's needs cannot be met by an FDA-approved drug. Coast sells, and has sold, vials of its

standardized compounded sodium thiosulfate drug product in response to prescription orders in which doctors do not specify, and have not specified, both (1) that a compounded drug product was necessary for an identified, individual patient, and (2) that such patient's needs could not be met by an FDA-approved drug. Coast therefore does not comply with Section 503A's individual customization requirement.

78. Defendants ship their sodium thiosulfate drug product from Coast's 503A facility to physicians and medical facilities, including to California, South Carolina, Tennessee, and Connecticut, and to and within Florida, thereby impacting patients around the country.

7. **Section 503A precludes the sale of drugs that are essentially a copy of a commercially available drug product; Defendant Coast (AnazaoHealth) violates this requirement**

79. Another of Section 503A's requirements is that drug products that are essentially copies of a commercially available drug product must not be compounded regularly or in inordinate amounts. 21 U.S.C. § 353a(b)(1)(D).

80. In January 2018, FDA defined "essentially a copy" in the context of Section 503A compounding pharmacies as a compounded drug product that has the same active pharmaceutical ingredient (API) as the commercially available drug product; has the same, similar, or an easily substitutable dosage strength; and can be used by the same route of administration. *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food,*

Drug, and Cosmetic Act Guidance for Industry (January 2018).

81. Defendants' compounded sodium thiosulfate drug product is essentially a copy of Hope's FDA-approved Sodium Thiosulfate Injection drug product in that the two drugs have the same active pharmaceutical ingredient, in the identical dosage strength, with the same route of administration. Both Hope and Defendants' products are 50 mL glass vials with 12.5 grains of the active ingredient sodium thiosulfate (250 mg/mL), and both drugs are only administered intravenously. Defendants are compounding their sodium thiosulfate drug products regularly and in inordinate amounts. Defendants' sale of their sodium thiosulfate drug products therefore violates the Section 503A prohibition against selling drugs that are essentially a copy of an FDA-approved drug regularly or in inordinate amounts.

C. Defendants' business and trade practices jeopardize public health

82. Defendants' unfair competition jeopardizes public health. FDA has acknowledged that compounded drugs pose a higher risk to patients than FDA-approved drugs because they have not undergone FDA premarket review for safety, effectiveness, and quality. FDA's *Guidance for Industry, Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act* at 4 (December 2016). Within the past year, FDA cited Defendants for the lack of testing to confirm the identity, strength, quality, and purity of their products at the time of use. Underdosing or overdosing may result from the administration of drug products that do not conform with label claims. To avoid potentially devastating clinical harm from underdosing or overdosing, critically ill patients

should be treated with high-quality, FDA-approved medications whenever available.

83. In addition to the risks posed by compounded drugs generally, Defendants' history of manufacturing problems poses risk to public safety, as evidenced by FDA inspection reports, state board of pharmacy disciplinary actions, and product recalls or supply disruptions over the past six years.

i. JCB

84. In a press release dated August 26, 2013, JCB announced that it had recalled six lots of sterile drug products due to concerns of sterility assurance. Three of the recalled lots were compounded sodium thiosulfate. The press release is published on FDA's website. (Exhibit A.)

85. FDA inspected Defendant JCB in 2013, 2015 and 2018. FDA noted in the 2013 inspection report that "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." (Exhibit B.) The 2013 report also noted that "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established." *(Id.)* FDA noted in the 2015 inspection report that "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." (Exhibit C.) The 2015 report also noted that "Aseptic processing areas are

deficient regarding the system for monitoring environmental conditions." *(Id.)* FDA noted in the 2018 inspection report that "There is no testing to assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use." (Exhibit D.) The 2018 report also noted that "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established or followed." (*Id.)*

86. FDA issued Defendant JCB a Warning Letter dated July 7, 2014 in which FDA wrote: "FDA investigators noted that your sterile drug products were prepared, packed or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health." (Exhibit E.)

87. In 2018, upon information and belief, Defendant JCB advised customers that recently manufactured lots of compounded sodium thiosulfate drug product had failed quality inspections and that JCB would not release those lots, causing Defendant JCB to be unable to fulfill orders for compounded sodium thiosulfate drug product for several months.

ii. Coast

88. FDA inspected the Florida facility of Defendant Coast in 2013, 2018 and 2019. FDA noted in the 2013 inspection report that "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed." (Exhibit F.) The 2013 report also noted "Aseptic processing areas are deficient regarding the system for monitoring environmental conditions...", "Aseptic processing areas are deficient regarding the system for cleaning

and disinfecting the room and equipment to produce aseptic conditions...", "Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use..." and "Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform." *(Id.)* FDA noted in the 2018 inspection report that "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed." (Exhibit G.) The 2018 report also noted that "You used a non-pharmaceutical grade component in the formulation of a drug product...", "Equipment was and Materials or supplies were not disinfected prior to entering the aseptic processing areas..." , and "Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions." *(Id.)* A 2019 report noted that "You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production. (Exhibit H.) The 2019 report also included several repeat observations from the 2018 report, indicating that Coast failed to remedy the observations FDA found in 2018. *(Id.)*

89. In a letter dated February 21, 2014, FDA notified the Florida Board of Pharmacy about the 2013 inspection at Coast and wrote that "FDA inspectors observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk." (Exhibit I.)

90. Defendant Coast recalled two lots of a sterile product in 2018 due to "lack of assurance of sterility". (Exhibit J (excerpt of PerformRx Drug Information Update report, listing drug recalls).)

iii. AnazaoHealth

91. FDA inspected Defendant AnazaoHealth in 2015 and 2017. FDA noted in a 2015 Warning Letter that "FDA investigators noted that drug products that were intended or expected to be sterile were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health, causing them to be adulterated within the meaning of section 501 (a)(2)(A) of the FDCA. Furthermore, FDA investigators observed significant CGMP violations at your facility, causing your drug products to be adulterated within the meaning of section 501 (a)(2)(B) of the FDCA." (Exhibit K.) The 2015 Warning Letter also noted that "Because your compounded drug products have not met all of the conditions in section 503B, they are not eligible for the exemptions under section 503B from the FDA approval requirements in section 505..." *(Id.)* FDA noted in the 2017 inspection report that "Drug products failing to meet established specifications and quality control criteria are not rejected." (Exhibit L.) The 2017 report also noted that "Procedures designed to prevent microbiological contamination of drug product purporting to be sterile do not include adequate validation of the sterilization process..." and "Employees engaged in the processing of a drug product lack the training required to perform their assigned functions." *(Id.)*

iv. Fagron

92. FDA inspected Defendant Fagron in 2016. FDA noted in the 2016 inspection report that "Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release." (Exhibit M.) The 2016 report also noted that "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established." *(Id.)*

93. Defendant Fagron recalled in 2016 selected suspending agents due to microbial contamination with yeast. (Exhibit N.) In 2017, Fagron recalled a product due to lack of sterility assurance. (Exhibit O.) In 2018, Fagron recalled a different product due to mislabeling. (Exhibit P.)

D. Hope has been Injured by Defendants' Unlawful and Unfair Competition

94. Defendants' actions are also harming the public by unfairly competing with Hope.

95. Hope is the only supplier in the United States of FDA-approved Sodium Thiosulfate Injection.

96. As a result of Defendants' unlawful and unfair competition, Hope has been deprived of money or property and has suffered damages in the form of the sales and market share that have been diverted from Hope to Defendants. Because the demand for sodium thiosulfate is inelastic and there are no substitutes, each purchase of a vial of unlawfully compounded sodium thiosulfate from Defendants would have been a purchase of a vial of Hope's FDA-approved Sodium Thiosulfate Injection but for Defendants' unlawful and unfair competition.

V. CLAIMS FOR RELIEF

COUNT ONE

Violation of California's Unfair Competition Law ("UCL")
(Cal. Bus. & Prof. Code § 17200, et. seq.)

97. Hope realleges and incorporates by reference each and every allegation set forth in paragraphs 1-90, above, as if fully stated herein.

98. Defendants' practices, as described in this Complaint, constitute unlawful and/or unfair business practices in violation of California's UCL, Cal. Bus. & Prof. Code, § 17200, *et seq*.

99. Defendants' products are "drugs" under California and federal law, namely Cal. Health & Safety Code sections 109925(b)-(c), 110110, and 21 U.S.C. § 321(g)(1) and 21 C.F.R. § 310.527(a), because they are intended to cure, mitigate, treat, or prevent disease and/or affect the structure and/or function of the human body and are promoted by Defendants for those purposes and used by healthcare professionals and consumers in California for those purposes.

100. Defendants' products are "new drugs" under California law, namely Cal. Health & Safety Code section 109980, and 21 U.S.C. § 321(p)(1) and 21 C.F.R. § 310.527(a), as incorporated by Cal. Health & Safety Code section 110110, because they are not generally recognized by qualified experts as safe and effective for their intended uses.

101. Defendants' products have not been approved by FDA or by the California Department of Health Services as required by Cal. Health & Safety Code sections 111550(a)—(b).

102. Defendants have violated the UCL by engaging in the unlawful business practice of

marketing, selling, and distributing their products in violation of the California Sherman Law.

103. Defendants' practices as alleged in this Complaint constitute unfair business practices in violation of the UCL because they are substantially injurious to consumers and any utility of such practices is outweighed by the harm to consumers. Defendants' practices violate California's legislative policy of protecting patients and consumers by prohibiting the marketing, sale, and distribution of new drugs that have not been approved by FDA or the California Department of Health Services. Defendants' practices have caused and are causing substantial injuries to Hope and to the public. Those injuries are not outweighed by any benefits.

104. Hope has lost money or property because of Defendants' unlawful and unfair business practices.

105. Hope seeks declaratory and injunctive relief requiring Defendants to cease the unlawful actions alleged herein.

106. In addition, Hope is entitled to an award of its attorney's fees under California Code of Civil Procedure section 1021.5.

COUNT TWO

Violation of Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA")
(Fla. Stat. Ann. § 501.201, et seq.)

107. Hope realleges and incorporates by reference each and every allegation set forth in paragraphs 1-100 above, as if fully stated herein.

108. FDUTPA makes "unlawful" "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in

the conduct of any trade or commerce." Fla. Stat. Ann. § 501.204.

109. FDUTPA also creates a cause of action for "anyone aggrieved" by a violation of FDUTPA to bring an action against "a person who has violated, is violating, or is otherwise likely to violate" the Act. Fla. Stat. Ann. § 501.211.

110. Hope is "aggrieved" under FDUTPA.

111. Defendants are "persons" who have violated and are violating FDUTPA.

112. Defendants engage in unfair, unconscionable, and deceptive conduct in "trade" and "commerce" in violation of FDUTPA when they unlawfully manufacture and sell unapproved drugs.

113. Given that Defendants' drugs are unapproved (and therefore potentially dangerous to consumers), Defendants' manufacture and sale of their drugs is a practice that is immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to physicians, medical facilities and patients alike.

114. The practices described herein also offend established public policy regarding the protection of consumers against companies, like Defendants, that engage in unfair methods of competition. Defendants' conduct has caused substantial injury to Hope that is not outweighed by countervailing benefits to any consumers or competition.

115. Defendants' business acts and practices are also unfair because they have caused harm and injury-in-fact to Hope for which Defendants have no justification other than to increase, beyond what Defendants would have otherwise realized, their

market share and revenue from the sale of unapproved drugs.

116. Defendants further violated FDUTPA by violating a "statute ... which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." Fla. Stat. 501.203(3)(c). Here, Defendant violated the FDCA and Florida's Drug and Cosmetic Act, both of which proscribe unfair methods of competition and unfair, deceptive, and unconscionable acts and practices.

117. In addition to actual damages which are in excess of $75,000, Hope is entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to Fla. Stat. § 501.201, *et seq.*

COUNT THREE

(Violation of Tennessee Consumer Protection Act, Tenn. Code Ann. 47-18-104(b)(44)(C))

118. Hope realleges and incorporates by reference each and every allegation set forth in paragraphs 1-111, above, as if fully stated herein.

119. Tennessee's Consumer Protection Act ("TCPA") prohibits "unfair or deceptive acts or practices affecting the conduct of any trade or commerce." Tenn. Code Ann. § 47-18-104(a). The TCPA explicitly defines "advertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state" to be an unfair or deceptive act or practice that is declared to be unlawful. Tenn. Code Ann. § 47-18-104(b)(44)(C).

120. Defendants have engaged in unfair or deceptive acts or practices declared unlawful by the TCPA by advertising, promoting, selling and offering for sale their unapproved sodium thiosulfate drugs in

violation of the Tennessee Food, Drug & Cosmetic Act and the FDCA.

121. Defendants' conduct has caused Hope to suffer an ascertainable loss of money or property.

122. Over and above the fact that Defendants' sale of their unapproved sodium thiosulfate drugs explicitly falls within the scope of Tenn. Code Ann. § 47-18-104(b)(44)(C), Defendants also violate the prohibition against "unfair" acts and practices in that their sale of unapproved sodium thiosulfate drugs is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and is not outweighed by countervailing benefits to consumers or to competition.

123. In addition to actual damages which are in excess of $75,000 and treble damages, Hope is entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to Tenn. Code Ann. § 47-18-109. //

COUNT FOUR

(Violation of South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-20)

124. Hope realleges and incorporates by reference each and every allegation set forth in paragraphs 1-117, above, as if fully stated herein.

125. South Carolina's Unfair Trade Practices Act ("SCUTPA") prohibits "unfair methods of competition or unfair [ ] acts or practices in the conduct of any trade or commerce." S.C. Code Ann. § 39-5-20(a). Under South Carolina law, an act is "unfair" when it is offensive to public policy or when it is immoral, unethical or oppressive.

126. Defendants have engaged in unfair methods of competition and unfair trade acts and practices in

violation of SCUTPA by unlawfully delivering for introduction into intrastate commerce drugs that have not been approved under South Carolina or federal law, in violation of S.C. Code Ann. § 39-23-70. Defendants' delivering such drugs for introduction into intrastate commerce is offensive to public policy, immoral, unethical and oppressive, as it is unlawful under South Carolina law.

127. Hope has suffered actual, ascertainable damages as a result of Defendants' unlawful trade practices and unfair methods of competition and unfair acts.

128. Defendants' unlawful trade practices have had an adverse impact on the public interest in the manner set forth above.

129. In addition to actual damages which are in excess of $75,000 and treble damages, Hope is entitled to declaratory and injunctive relief as well as reasonable attorney's fees and costs pursuant to S.C. Code Ann. § 39-5-140.

COUNT FIVE

(Violation of Connecticut Unfair Trade Practices Act, Conn. Gen. St. § 42-110b)

130. Hope realleges and incorporates by reference each and every allegation set forth in paragraphs 1-123, above, as if fully stated herein.

131. Connecticut's Unfair Trade Practices Act ("CUTPA") prohibits "unfair methods of competition or unfair [ ] acts or practices in the conduct of any trade or commerce." Conn. Gen. St. § 42-110b. Under Connecticut law, an act is "unfair" when it offends public policy as it has been established by statutes,

the common law, or otherwise, or when it is immoral, unethical, oppressive or unscrupulous.

132. Defendants' practices described above are both offensive to public policy, and are immoral, unethical, oppressive and unscrupulous.

133. Hope is a competitor of Defendants in that both Hope and Defendants sell prescription sodium thiosulfate injection drugs.

134. Defendants' conduct was in the course of their primary trade or commerce—the selling of compounded drugs.

135. Defendants' unlawful practices described herein have caused substantial injuries to Hope and to consumers: the injuries caused by Defendants have been substantial; they are not outweighed by any countervailing benefits to consumers or competitors that the practice produces; and the injuries are ones that Hope and consumers could not reasonably have avoided.

136. Within three years of the commencement of this action, Hope has suffered an actual, ascertainable loss of money or property as a result of Defendants' unlawful trade practices and unfair methods of competition and unfair acts. Defendants' sales of its sodium thiosulfate drugs are the proximate cause of Hope's losses. Hope is therefore entitled to damages which are in excess of $75,000 and attorney's fees. Conn. Gen. St. § 42-110g.

137. Hope is entitled to declaratory and injunctive relief under CUTPA.

VI. PRAYER FOR RELIEF

WHEREFORE, Hope respectfully requests that this Court enter judgment in its favor:

1. A preliminary and permanent injunction enjoining Defendants from continuing the unlawful and unfair business practices alleged in this complaint, which injunction has a value to Plaintiff in excess of $75,000;

2. A judgment that Defendants violated the UCL;

3. A judgment that Defendants violated FDUTPA;

4. A judgment that Defendants violated TCPA;

5. A judgment that Defendants violated SCUTPA;

6. A judgment that Defendants violated CUTPA;

7. Declaratory relief;

8. Damages which are in excess of $75,000 and other monetary relief according to proof;

9. Attorneys' fees and costs incurred in this action;

10. Prejudgment interest; and

11. Any further relief the Court may deem just and proper.

VII. REQUEST FOR JURY TRIAL

Hope demands a trial by jury on all claims and issues so triable.

Dated: November 12, 2019

KING & SPALDING LLP

By: /s/ *Joseph N. Akrotirianakis*
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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

HOPE MEDICAL ENTERPRISES, INC. D/B/A HOPE PHARMACEUTICALS,

Plaintiff,

v.

FAGRON COMPOUNDING SERVICES, LLC; JCB LABORATORIES, LLC; ANAZAOHEALTH CORPORATION; COAST QUALITY PHARMACY, LLC,

Defendants.

Case No. 2:19-cv-07748-CAS-PLA

PLAINTIFF HOPE MEDICAL ENTERPRISES, INC.'S NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION

Date: June 29, 2020
Time: 10:00 a.m.
Place: Courtroom 8D

Filed Concurrently:

1. Declaration of Craig Sherman, MD, and Exhibits
2. Declaration of Joseph N. Akrotirianakis and Exhibits
3. Request for Judicial Notice and Exhibits; [Proposed] Order
4. Ex Parte Application to Seal; Declaration of Aaron S. Craig and Exhibits; [Proposed] Order
5. [Proposed] Order Granting Motion for Preliminary Injunction

TO THE COURT AND DEFENDANTS AND THEIR ATTORNEYS:

PLEASE TAKE NOTICE that, on June 29, 2020 at 10:00 a.m. or on such other date and time convenient to (and ordered by) the Court, in Courtroom 8D of the First Street Courthouse, 350 W. First Street, 8th Floor, Los Angeles, California, Plaintiff Hope Medical Enterprises, Inc. d/b/a Hope Pharmaceuticals ("Plaintiff" or "Hope"), will, and hereby does, move this Court under Federal Rule of Civil Procedure 65(a) and Local Rule 65-1 to enter a preliminary injunction, enjoining Defendants Fagron Compounding Services, LLC; JCB Laboratories, LLC; AnazaoHealth Corporation; and Coast Quality Pharmacy, LLC (collectively, "Defendants"), from (1) filling prescription orders from a 503A compounding pharmacy that do not specify that a compounded drug product is necessary for the identified patient and that an FDA-approved product would not be medically appropriate for that identified patient; (2) selling any drug from a 503A compounding pharmacy that is essentially a copy of Plaintiff's Sodium Thiosulfate Injection; and (3) selling any drug from a 503B outsourcing facility that is essentially a copy of Plaintiff's Sodium Thiosulfate Injection.

Specifically, Plaintiff requests that Defendants and their officers, agents, servants, employees, and attorneys, and any other persons who are in active concert or participation with any of them (including any corporate parents, subsidiaries, and affiliates so acting in concert or participation), be enjoined from directly or indirectly:

1. Dispensing any drug product from any facility claiming to operate pursuant to section 503A of the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 353a (a "503A Facility"), without a Valid Prescription Order, to the extent such drug products are compounded in, distributed from or dispensed to California, Florida, Tennessee, South Carolina, or Connecticut. For purposes of compliance with this Order, a Valid Prescription Order is defined as a prescription order received:

   a. for an identified individual patient; and

   b. (i) stating that a compounded drug is necessary for the identified individual patient because that patient's clinical needs cannot be met by an FDA-approved drug product; or

      (ii) bearing a notation, approved by the prescribing practitioner, stating that a compounded drug is necessary for such patient because that patient's clinical needs cannot be met by an FDA-approved drug product.

2. Compounding, distributing, or dispensing any drug product from any 503A Facility that is essentially a copy of Plaintiff's Sodium Thiosulfate Injection, to the extent such drug products are compounded in, distributed from, or dispensed to California, Connecticut, Florida, South Carolina, or Tennessee. For purposes of compliance with this Order, a drug compounded by a 503A pharmacy is

"essentially a copy" of a "commercially available" drug if: (a) the compounded drug and the commercially available drug(s) have the same Active Pharmaceutical Ingredient ("API"); (b) the API(s) have the same, similar, or an easily substitutable dosage strength; and (c) the commercially available drug product can be used by the same route of administration as the compounded drug.

3. Compounding, distributing, or dispensing any drug product from any outsourcing facility registered pursuant to section 503B of the FDCA, as defined in 21 U.S.C. § 353b(d)(4)(A) that is essentially a copy of Plaintiff's Sodium Thiosulfate Injection, to the extent such drug products are compounded in, distributed from, or dispensed to California, Connecticut, Florida, South Carolina, or Tennessee. For purposes of compliance with this Order, a drug compounded in a 503B outsourcing facility is "essentially a copy" of a "commercially available" drug if that drug: (a) is identical or nearly identical to an approved drug; or (b) includes, as a component, a bulk drug substance that is also a component of an approved drug, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

4. Selling or transferring Defendants' sodium thiosulfate drug compounded in 503B outsourcing facilities through a wholesaler or distributor, in violation of 21 U.S.C. § 353b(a)(8).

Plaintiff's Motion for Preliminary Injunction is made on the grounds:

1. Defendants are engaged in the business practices described above—which are illegal—and

Plaintiff is likely to succeed on the merits in this lawsuit;

2. Unless the business practices described above are enjoined pending a trial of this action, Plaintiff will continue to suffer irreparable harm to its goodwill and will lose customers and market share;

3. Plaintiff would suffer greater harm if the Court were to deny injunctive relief than would Defendants if the injunctive relief were imposed, and the balance of the hardships tips in favor of imposing the injunctive relief sought; and

4. The public interest weighs in favor of granting injunctive relief.

This Motion is based on this Notice of Motion and the attached Memorandum of Points and Authorities; the concurrently-filed declarations of Craig Sherman, M.D., and Joseph N. Akrotirianakis, and the exhibits appended to those declarations; the concurrently filed Request for Judicial Notice and exhibits; all evidence received in connection with the hearing on this motion; all matters of record in the Court's files; and such other evidence and written or oral argument as the Court may consider and direct the parties to submit.

Dated: June 1, 2020

KING & SPALDING LLP
By: */s/Joseph N. Akrotirianakis*
JOSEPH N. AKROTIRIANAKIS
Attorneys for Plaintiff
HOPE MEDICAL
ENTERPRISES, INC. D/B/A
HOPE PHARMACEUTICALS

TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Defendants' illegal sale of drugs is causing imminent and irreparable harm to Hope and the public. Hope asks this Court to enjoin those illegal sales.

Hope produces and sells Sodium Thiosulfate Injection, the only FDA-approved drug containing sodium thiosulfate as an active pharmaceutical ingredient ("API"). Hope's Sodium Thiosulfate Injection is approved by FDA for the treatment of life-threatening cyanide poisoning.

Defendants, all of whom are owned by the Dutch multinational corporation Fagron, compete with Hope by selling their own sodium thiosulfate injection drug. Defendants' sodium thiosulfate drug is not FDA - approved and does not qualify for any exemption to the general requirement, under the federal Food, Drug, and Cosmetic Act ("FDCA"), that a drug be FDA-approved before it can be marketed or sold. 21 U.S.C. § 355. Defendants purport to manufacture and sell sodium thiosulfate drugs pursuant to the "compounding" exemptions to the pre-market approval requirement, 21 U.S.C. §§ 353a, 353b, but do not meet the requirements of either exemption.

Defendants' sodium thiosulfate drug product compounded in pharmacies operating pursuant to 21 U.S.C. § 353a ("section 503A") is not exempt for two independent reasons: (1) Defendants' drug is "essentially a copy" of Hope's FDA- approved Sodium Thiosulfate Injection; and (2) Defendants do not comply with section 503A's individual prescription requirement with respect to drugs compounded in Defendants' section 503A pharmacy. The 21 U.S.C.

§ 353b ("section 503B") exemption is inapplicable to Defendants' section 503B "outsourcing facilities" because Defendants' drug is "essentially a copy" of Hope's FDA-approved Sodium Thiosulfate Injection, and because Defendants are illegally selling their sodium thiosulfate drug through a wholesaler/distributor, AmerisourceBergen Corporation. The documentary evidence demonstrates that Defendants sell their sodium thiosulfate drug to customers who purchase it for financial reasons, and any medical justification claimed by Defendants is pure pretext.

Defendants' distribution of their unapproved (and nonexempt) drug violates state laws in California, Connecticut, Florida, South Carolina, and Tennessee (the "Five States"). The Five States' laws generally require FDA premarket approval (or an exemption from premarket approval) of any drug distributed. Defendants' violation of these state laws constitutes unfair competition in each of the Five States.

The Court should enjoin Defendants' illegal conduct. Hope satisfies each of the requirements for injunctive relief. Hope is highly likely to succeed on the merits of its claims against Defendants. Hope has suffered irreparable harm—lost customers, market share, reputation, and goodwill—due to Defendants' actions. The balance of hardships favors Hope because remedying its harms through an injunction will not significantly injure Defendants, which sell a wide variety of other drugs and have no right to conduct an illegal business. Similarly, the public interest supports an injunction protecting the public from unfair competition and unapproved, unsafe drugs.

II. BACKGROUND

A. The FDCA's Compounding Provisions Are Narrow

"Compounding" refers to the practice of combining, mixing or altering ingredients of a drug to create a medication tailored to the needs of an individual patient. (Request for Judicial Notice ("RJN") Exh. A at 12.) To preserve compounding as a way to treat patients whose needs (as determined by a patient's prescribing practitioner) cannot be met by FDA-approved drugs, federal law permits compounded drugs to be sold without FDA approval in limited circumstances defined in sections 503A and 503B of the FDCA. 21 U.S.C. §§ 353a, 353b.

1. Section 503A. Section 503A exempts compounded drugs from the premarket approval requirement only if each of a number of conditions is met. 21 U.S.C. § 353a.

First, section 503A provides that a 503A pharmacy must "not compound regularly or in inordinate amounts ... any drug products that are essentially copies of a commercially available drug product." 21 U.S.C. § 353a(b)(1)(D).[1] A drug is "essentially a copy" of a "commercially available" drug if (a) the compounded drug and the commercially available drug(s) have the same API(s), (b) the API(s) have the same, similar, or an easily substitutable dosage strength, and (c) the commercially available drug

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[1] A drug is compounded "regularly" or "in inordinate amounts" if it is compounded "at regular times or intervals, usually, or very often." According to FDA, "only very rarely should a compounded drug that is essentially a copy of a commercially available drug be offered to a patient." (RJN Exh. C at 51.)

product can be used by the same route of administration as the compounded drug. (RJN Exh. C at 46-47.) Drugs that are "essentially copies" of "commercially available" FDA-approved drugs should not be "compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances." (*Id.* at 51.) The only exception to the "essentially a copy" prohibition applies if the compounded drug includes a change, made for an identified individual patient, that produces for that patient a significant difference from the comparable commercially available FDA-approved product, as determined and documented by the prescribing practitioner. 21 U.S.C. 353a(b)(2); RJN Exh. C at 49. To come within this exception, a compounder must show that all of the prescriptions for its products contain "Significant Difference Statements" that identify both the change to the commercially available drug and the difference it will make for the patient. (RJN Exh. C at 49.)

Second, section 503A requires that drugs be compounded for an identified individual patient with a valid prescription. The section 503A exemption applies only to drugs "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation . . . on the prescription order that a compounded product is necessary for the identified patient." 21 U.S.C. § 353a(a). "A drug that can be used for all [patients] is clearly not compounded for an identified individual patient and therefore violates section 503A." *Allergan USA, Inc. v. Imprimis Pharm., Inc.*, 2017 WL 10526121, at *7 (C.D. Cal. Nov. 14, 2017). Therefore, "anticipatory mass compounding of standardized drugs in a 503A facility without identified individual patients based

on valid prescription orders" violates the FDCA. *Allergan USA, Inc. v. Imprimis Pharm., Inc,* No. 8:17-cv-01551-DOC-JDE, Order Granting Motion for Summary Judgment, Dkt. No. 138 at 21 (C.D. Cal. Mar. 27, 2019) ("*Imprimis MSJ Order*"), RJN Exh. W at 263.

This requirement limits compounding to its proper role of meeting individual patient needs that cannot be met by FDA-approved drugs, while preventing compounding pharmacies from circumventing FDA's drug-approval requirements and mass-producing thousands of identical drugs in exactly the way Defendants do here. As FDA has stressed, patients are to take FDA-approved drugs whenever possible. "Because [compounded drugs] are subject to a lower regulatory standard, compounded drugs should only be distributed to meet the needs of patients whose medical needs cannot be met by an FDA-approved drug." (RJN Exh. D at 57.) "Section 503A is not a window through which compounders may produce drugs for patients even though an FDA-approved drug may have been medically appropriate for them." *Allergan USA, Inc. v. Imprimis Pharm., Inc.*, 2019 WL 3029114, at *10 (C.D. Cal. July 11, 2019).

2. Section 503B. Section 503B created a new kind of entity, an "outsourcing facility" that is neither a compounding pharmacy nor a drug manufacturer.[2] While traditional compounding is inherently small-scale given the requirement of patient- specific

[2] Congress created the section 503B exemption in 2013, after hundreds were injured and dozens were killed in a fungal meningitis outbreak caused by a compounded injectable steroid distributed by a nationwide 503A compounder, New England Compounding Center.

tailoring, Congress permits 503B facilities to produce drugs on a larger scale and to sell them in large quantities without individual patient prescriptions. But it does so only in strictly limited circumstances where necessary to meet the clinical needs of an individual patient whose prescribing practitioner has determined cannot be met by commercially available, FDA-approved drugs. 21 U.S.C. § 353b(a).[3]

Among other limitations, a 503B outsourcing facility may not compound drugs using bulk drug substances if the compounded drug is essentially a copy of FDA- approved drugs. *Id.* § 353b(a)(5). A compounded drug made in a 503B facility is essentially a copy of an approved drug if the compounded drug uses a bulk drug substance that is also a component of an FDA-approved drug, "unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug." *Id.* § 353b(d)(2).

FDA has given further guidance as to the "essentially a copy" definition for 503B facilities. If an outsourcing facility relies on a clinical difference determination to establish that a compounded drug is not essentially a copy of an approved drug, "the

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[3] Where an FDA-approved drug is in shortage and appears on the FDA's drug shortage list, 503B outsourcing facilities may use bulk drug substances to compound that drug. 21 U.S.C. 353b(a)(2)(A)(ii). This exception is not implicated here, however, as Hope's Sodium Thiosulfate Injection has never appeared on the drug shortage list at any time since the enactment of section 503B. (Declaration of Craig Sherman ("Sherman Decl.") ¶ 6.)

outsourcing facility should ensure that the determination is noted on the prescription or order ... for the compounded drug." (RJN Exh. E at 75.) When an outsourcing facility is providing office stock for a health care practitioner, "the outsourcing facility should obtain a statement *from the practitioner* that specifies the change between the compounded drug and the comparable approved drug and indicates that the compounded drug will be administered or dispensed only to a patient for whom the changes produces a clinical difference, *as determined by the prescribing practitioner for that patient*." (*Id.* (emphasis added.) FDA has made clear that "[o]ther factors such as a lower price are not sufficient to establish that the compounded product is not essentially a copy of the approved drug." (*Id.* at 77.)

Section 503B also contains a "prohibition on wholesaling," barring the sale or transfer of drugs "by an[y] entity other than the outsourcing facility that compounded such drug." 21 U.S.C. § 353b(a)(8).

B. Hope Sells an FDA-Approved Drug, While Defendants Sell Illegal, Unsafe Copies of Hope's Drug

1. Hope sells the only FDA-approved drug with sodium thiosulfate as an API

In 2012, Hope obtained FDA approval to sell its Sodium Thiosulfate Injection as a treatment for acute cyanide poisoning. (RJN Exh. F at 87-88; Sherman Decl. Exh. A.) Hope's Sodium Thiosulfate Injection is an intravenous solution with the API sodium thiosulfate, with a concentration of 12.5g/50mL. (RJN Exh. F at 87-88; Sherman Decl. ¶ 2.) Hope sells its Sodium Thiosulfate Injection across the country, including in California, Connecticut, Florida, South

Carolina, and Tennessee (the "Five States"). (Sherman Decl. ¶ 7.)

2. Defendants sell compounded sodium thiosulfate drugs

Defendants are affiliated companies sharing a single corporate parent, Fagron N.V. Fagron touts itself as a "global market leader and consolidator in the market of pharmaceutical compounding," operating "in over 60 countries around the world." (Declaration of Joseph N. Akrotirianakis ("Akro. Decl.") Exh. A at 11.)

Defendants own and operate three section 503B outsourcing facilities: Fagron Compounding Services (Wichita, KS), JCB Laboratories (North Wichita, KS), and AnazaoHealth (Las Vegas, NV). (RJN Exh. G.) Fagron acquired AnazaoHealth and JCB Laboratories in 2013 and 2015. (Akro. Decl. Exhs. B-C.) Also in 2015, Fagron's affiliate Fagron Compounding Services, LLC, opened its eponymous 503B facility. At least two of Defendants' 503B facilities manufacture drugs using bulk sodium thiosulfate. (RJN Exh. H at 113.)

When Fagron acquired AnazaoHealth, it also acquired a 503A compounding pharmacy operated by AnazaoHealth's subsidiary, Coast Quality Pharmacy, LLC. (Akro. Decl. Exhs. D-E.) Coast's 503A compounding pharmacy is located in Tampa, Florida, and operates under the trade name AnazaoHealth. (RJN Exh. I at 150.)

Other than Hope, Defendants are the only companies selling, in the United States, a human drug product that contains sodium thiosulfate as the API. (RJN Exh. H at 113; Sherman Decl. ¶¶ 2-9.) Defendants mass produce and sell thousands of identical vials of compounded sodium thiosulfate

drugs. The API in Defendants' compounded sodium thiosulfate drugs is sodium thiosulfate, in the same concentration as in Hope's Sodium Thiosulfate Injection (12.5g/50mL). (Sherman Decl. Exhs. A-B and ¶ 9.) Defendants' compounded sodium thiosulfate drug has the same route of administration as Hope's Sodium Thiosulfate Injection, in that both are administered by intravenous injection. (Sherman Decl. ¶ 9; RJN Exh. J at 167.)

Defendants sell their compounded sodium thiosulfate drug products across the United States, including the Five States. In 2018 and 2019 alone, Defendants sold to the Five States more than **[REDACTED]** of compounded sodium thiosulfate from its 503B facilities (Akro. Decl. ¶ 8) and more than **[REDACTED]** of compounded sodium thiosulfate from its 503A pharmacy (Akro. Decl. Exh. F and ¶ 7).

3. Defendants' customers purchase Defendants' compounded drugs for economic, not clinical, reasons

Several pieces of evidence establish that Defendants' customers purchase defendants' sodium thiosulfate drugs for purely financial reasons.

[REDACTED][4] (Akro. Decl. ¶ 10.) During a seven-month period in selling sodium thiosulfate drugs

[4] Dialysis companies purchase sodium thiosulfate to treat calciphylaxis, a painful condition suffered by some end stage renal disease patients. Treatment of calciphylaxis is an off-label use for Hope's FDA-approved Sodium Thiosulfate Injection; Hope does not market its product for this use, but it has sold Sodium Thiosulfate Injection to dialysis providers, including

because their 503B facilities failed multiple quality inspections, and their 503A facility was unable to meet demand; Fresenius and DaVita purchased substantial amounts of Hope's Sodium Thiosulfate Injection during this period. (Sherman Decl. ¶¶ 16-21 and Exh. B.) This establishes that **[REDACTED]** believe that Hope's Sodium Thiosulfate Injection can satisfy their patients' medical needs, and that Defendants' compounded product does not produce a necessary or significant clinical difference.

[REDACTED]

4. Defendants sell their compounded sodium thiosulfate drugs without clinical difference statements

As explained above, FDCA Sections 503A and 503B prohibit the sale of compounded drugs that are essentially copies of FDA-approved drugs, absent a statement by the prescribing practitioner on the prescription order that a compounded drug would produce a significant or clinical difference, as compared to the FDA- approved drug, in the patient for whom the drug is being prescribed. Defendants' 503A or 503B facilities both sell compounded sodium thiosulfate drugs without the required statements. Because the vast majority of Defendants' sales of sodium thiosulfate are made from their 503B facilities, this motion addresses those facilities first.

a. 503B Facilities. Defendants' 503B facilities fulfill orders for their sodium thiosulfate injection drug that is "essentially a copy" of Hope's drug (because Defendants use the bulk drug substance sodium thiosulfate that is also a component of Hope's

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DaVita and Fresenius. (Sherman Decl. ¶¶ 16-17 and 23.)

FDA-approved drug), without requiring a doctor to attest that the drugs will be administered only to patients for whom a compounded drug will make a clinical difference; **[REDACTED]**

b. 503A Pharmacy. The compounded sodium thiosulfate drug product Defendants sell from their section 503A compounding pharmacy is essentially a copy of Hope's FDA-approved Sodium Thiosulfate Injection in that the two drugs have the same API, in the identical dosage strength, with the same route of administration. (Sherman Decl. ¶ 9 and Exhs. A-B.) Both are 50 mL glass vials with 12.5 grams of the API sodium thiosulfate, and both are exclusively administered intravenously. (*Id.*) This makes Defendants' drug "essentially a copy" of Hope's unless the prescribing doctor includes a Significant Difference Statement on the prescription. 21 U.S.C. § 353a(b)(1)(D) and (b)(2).

Defendants' 503A pharmacy fills prescriptions for compounded sodium thiosulfate drugs without requiring a Significant Difference Statement. Defendants simply ask doctors ordering through Defendants' website to certify that "this compounded preparation is necessary for the patient(s) identified below." (Sherman Decl. Exh. E at 26.) **[REDACTED]** This statement is inadequate because (i) it is pre-printed on the form and is not an affirmative statement made by the prescribing practitioner, and (ii) the **[REDACTED]** language does not satisfy section 503A. Any drug prescribed to a patient must be clinically necessary for that patient—otherwise doctors are not allowed to prescribe that drug. Section 503A requires that a doctor make—and document—an additional determination that the compounded drug produces a significant difference for the particular patient as compared to the comparable

FDA- approved drug. Courts have also found that section 503A further requires the doctor to affirmatively document on the prescription that the FDA-approved drug is not suitable. *Allergan USA, Inc. v. Imprimis Pharm., Inc.*, 2019 WL 3029114, at *13 (C.D. Cal. July 11, 2019) ("*Imprimis Injunction Order*"). Defendants' website ordering screen and pre-printed forms do not come close on either requirement.

In the entirety of Defendants' 150,000-page document production, Plaintiff has not found even one section 503A prescription that includes either a Significant Difference Statement or a statement that the comparable FDA-approved drug is not suitable. (Akro. Decl. ¶ 20.) The closest is a single prescription order dated September 30, 2019, which noted simply that "Dr. Woorner does not want the product from Hope." (Akro. Decl. Exh. Q at 281.) While this could be interpreted as a statement that the prescribing practitioner thinks Hope's drug is not suitable for this patient, the prescription still lacks a Significant Difference Statement that the compounded drug will produce a significant difference for this patient as compared to Hope's drug.

5 Defendants sell their 503B sodium thiosulfate through distributor AmerisourceBergen Corporation

AmerisourceBergen Corporation ("ABC") is a leading distributor of drugs in the United States. (Sherman Decl. ¶15.) The Integrated Nephrology Network, www.inn- online.com, is a group purchasing organization operated by ABC, and lists "JCB Laboratories (now Fagron Sterile Services)" as a "Compounding Pharmacy" whose drugs are "available to all INN members" as a "contracted service." (Akro. Decl. Exh. T.) The Fax Order Form for Fagron Sterile

Services and JCB Laboratories' 503B sodium thiosulfate contains the logo for "INN AmerisourceBergen Specialty Group," showing that ABC distributes or resells Defendants' 503B sodium thiosulfate drug. (Sherman Decl. Exh. B.) Moreover, a representative of ASD Healthcare, a subsidiary of ABC, informed Hope that ASD Healthcare was distributing Defendants' sodium thiosulfate. (Sherman Decl. ¶ 15.) ASD Healthcare, https://www.asdhealthcare.com/products/nephrology-dialysis, claims to be "the number one distributor of nephrology and dialysis products in the U.S."

6. Defendants' compounded drugs endanger public health

Defendants have a poor track record with respect to the quality of their sodium thiosulfate products and their compliance with FDA regulations. In 2013, FDA announced a recall of drug products from JCB, including three lots of sodium thiosulfate. (RJN Exh. K at 170.) In 2018, JCB advised a customer that it was out of stock of sodium thiosulfate because its recently manufactured lots of compounded sodium thiosulfate drug product had failed quality inspections. (Sherman Decl. Exh. F.) As a result, JCB stopped selling sodium thiosulfate from September 2018 through March 2019. (Sherman Decl. ¶¶ 14-21, Akro. Decl. ¶ 9.)

This information would come as no surprise to those familiar with Defendants' history of FDA warning letters and violations. FDA has stated that, in general, compounded drugs pose a higher risk to patients than FDA-approved drugs, because compounded drugs have not undergone FDA pre-market review for safety, effectiveness and quality. (RJN Exh. L at 179.) But even in the context of compounding, Defendants' track record is dismal. For example, JCB and AnazaoHealth received FDA

warning letters in 2014 and 2015, stating that their sterile drug products "were prepared, packed or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health." (RJN Exh. M at 189; Exh. N at 193.) Fagron has had at least three recent product recalls, including one due to lack of sterility. (RJN Exhs. O-Q.) Coast also had a 2018 recall from its 503A facility due to a lack of assurance of sterility. (Akro. Decl. Exh. R at 285.) And Defendants have received several inspection reports setting forth FDA's concerns about product sterility, contamination, testing, and compliance with good manufacturing practices. (RJN Exhs. R-U.) **[REDACTED]** The presence of particulate matter in intravenous drugs such as sodium thiosulfate can block blood vessels, causing stroke, heart attack, and organ damage. (RJN Exh. V at 240.)

7. Defendants' illegal compounding has injured Hope

Hope has suffered at least two distinct types of injuries from Defendants' illegal compounding. First, Defendants have created confusion in the marketplace that has led to a loss of goodwill. Second, Hope has lost customers and sales.

Defendants' illegal compounding has led directly to Hope losing goodwill. In May 2019, an employee of a Tennessee medical facility sent angry faxes and emails to Hope, asking about the status of a late shipment of Defendants' compounded sodium drugs. (Sherman Decl. Exh. D and ¶ 11.) The purchase order number indicated that this order was actually placed with Defendant JCB, not with Hope. (*Id.*) Hope has also received orders for Defendants' compounded sodium thiosulfate drugs and inquiries about orders actually placed with Defendants. (Sherman Decl.

¶¶ 10-12 and Exhs. C- D.) Customers are associating Defendant's unreliable order- fulfillment practices with Plaintiff, thus eroding Plaintiff's goodwill.

Hope has also lost high-volume customers and substantial market share. Hope and Defendants are the only sellers of sodium thiosulfate injection for humans in the United States. (RJN Exh. H at 113; Sherman Decl. ¶¶ 2-9.) Hope's sales data proves that it has lost a substantial volume of market share and customers in the Five States. (Sherman Decl. ¶ 21.) As described above, Defendants largely stopped selling compounded sodium thiosulfate drug products from September 2018 to March 2019. (Akro. Decl. ¶ 9; Sherman Decl. ¶¶ 14-21.) During that period, sales of Hope's Sodium Thiosulfate Injection were significantly higher than during the immediately preceding period when Defendants were selling compounded sodium thiosulfate. (Sherman Decl. ¶ 16.) The sales difference was substantial in California (44%), Connecticut (146%), Florida (67%), South Carolina (134%) and Tennessee (20%). (*Id.*) These statistics make clear that Defendants' conduct is causing Hope to lose substantial market share.

Those same statistics show that Hope has lost relationships with major customers due to Defendants' compounding. From September 2018 through March 2019, Hope sold thousands of units of Sodium Thiosulfate Injection to Fresenius, including a substantial volume in the Five States. (*Id.* ¶¶ 17-20.) When Defendants resumed selling their compounded sodium thiosulfate drugs, Fresenius stopped ordering from Hope. (*Id.*)

III. ARGUMENT

Each of the state laws under which Hope is suing allows for injunctive relief to enjoin unlawful business

practices. Cal. Bus. Prof. Code § 17203; *Wyndham Vacation Resorts, Inc. v. Timeshares Direct, Inc.*, 123 So. 3d 1149, 1152 (Fla. App. 2012); *Taylor v. Thomas*, 2012 WL 12840225 (W.D. Tenn. 2012); S.C. Code Ann. § 39-5-38(D)(1); Conn. Gen. St. § 42-110(d). Hope is entitled to a preliminary injunction against Defendants' unlawful and unfair trade practices if (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of hardships favors an injunction, and (4) the injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).[5] A preliminary injunction is warranted because Hope meets each of these requirements.

A. Hope is Likely to Prevail on its Claims

1. Defendants' compounding practices violate FDCA Sections 503A and 503B

Defendants' compounded sodium thiosulfate drugs are not approved by the FDA. Accordingly, Defendants may only sell their drugs if they comply with Sections 503A and 503B. Defendants' practices do not comply with either Section.

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[5] A preliminary injunction may also issue when there are "serious questions going to the merits, and a balance of hardships that tips sharply toward the plaintiff ... so long as the plaintiff also shows that there is likelihood of the irreparable injury and that the injunction is in the public interest." *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134-35 (9th Cir. 2011).

a. Defendants do not comply with Section 503A

Defendants' compounding practices violate two separate provisions of section 503A: (1) the "essentially a copy" provision, 21 U.S.C. § 353a(b)(1)(D), and (2) the "individual prescription" requirement, *id.* § 353a(a).

First, Defendants' compounded sodium thiosulfate drug is essentially a copy of Hope's FDA-approved Sodium Thiosulfate Injection, because it has the same API as Hope's Sodium Thiosulfate Injunction, the identical dosage strength, and the same route of administration (intravenous injection). (Sherman Decl. Exhs. A-B and ¶ 9; RJN Exh. C at 46-47.) The prescription orders filled by Defendants' 503A pharmacy lack any language that would exempt them from the essentially a copy prohibition. Defendants' prescriptions do not contain the Significant Difference Statements required by section 503A.[6]

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[6] Defendants' section 503A prescriptions do not contain Significant Difference Statements, but rather, pre-printed statements that **[REDACTED]** (Akro. Decl. Exh. P at 278.) Orders from Defendants' website merely require doctors to agree that "this compounded preparation is necessary for the patient(s) identified below." (Sherman Decl. Exh. E.) Defendants are selling sodium thiosulfate from their 503A compounding pharmacy that is essentially a copy of Hope's, without qualifying for any exemption. Moreover, Defendants cannot persuasively argue that their sodium thiosulfate product is not essentially a copy because they make changes to Hope's drug for identified individual patients. Defendants' website only accepts sodium thiosulfate orders in a single strength and volume, which is the identical strength

Second, Defendants' 503A pharmacy does not compound sodium thiosulfate drugs for "identified individual patient[s]" with "valid prescription order[s]." 21 U.S.C. 353a(a). A court in this district recently ruled, in granting a permanent injunction against another compounder violating the same provision of section 503A, that a valid 503A prescription order must state that "a compounded product is medically necessary for the identified individual patient" and "that an FDA-approved drug is not medically appropriate." *Imprimis Injunction Order*, 2019 WL 3029114, at *13. None of Defendants' section 503A prescriptions contain such a statement. Just like the defendant in *Imprimis*, Defendants sell mass quantities of identical compounded drugs to patients without any indication that the patient's medical needs cannot be met with an FDA- approved drug. **[REDACTED]** These attestations are insufficient. *Imprimis Injunction Order*, 2019 WL 3029114, at *13. Accordingly, section 503A does not exempt Defendants from the FDA-approval requirement for two separate and independent reasons.

b. Defendants do not comply with Section 503B

Defendants' 503B facilities violate section 503B's "essentially a copy" provision. 21 U.S.C. § 353b(a)(5). Defendants' compounded sodium thiosulfate drug contain sodium thiosulfate, the same "bulk drug substance," *id.* § 353b(d)(2), that is in Hope's Sodium Thiosulfate Injection. That makes Defendants' drug essentially a copy of Hope's, unless the prescribing

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and volume as Hope's FDA- Approved Sodium Thiosulfate Injection, 12.5 grams per 50 mL. (Sherman Decl. ¶ 9.)

practitioner determines that the drug "produces for an individual patient a clinical difference" and that determination is documented on each order. *Id;* RJN Exh. E at 68.

[REDACTED][7]

[REDACTED] "[F]actors such as a lower price are not sufficient to establish that the compounded product is not essentially a copy of the approved drug." (RJN Exh. E at 77.) For this additional reason, Defendants violate section 503B's "essentially a copy" prohibition.

To distribute their unlawfully compounded drugs on a large scale, Defendants also violate the "Prohibition on wholesaling" of 21 U.S.C. § 353b(a)(8). That section reads: "The drug will not be sold or transferred by any entity other than the outsourcing facility that compounded such drug." Defendants' 503B outsourcing facilities sell and transfer their sodium thiosulfate through the distributor ABC, a fact evidenced by ABC's "Integrated Nephrology Network" website, the Fax Order Form for sodium thiosulfate, and statements of a representative of ABC's "ASD Healthcare." (Sherman Decl. Exh. B and ¶ 15; Akro. Decl. Exh. T.)

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[7] Even if these group attestations were signed by a doctor, they would still be inadequate because the law is clear that every prescription order for a drug that is essentially a copy of an approved drug must contain the clinical difference statement. (RJN Exh. E at 75.) There is no legal authority that supports Defendants' practice of accepting attestations covering an unspecified amount of time and number of orders the customer will place in the future.

2. Defendants violate California's Unfair Competition Law by selling unapproved drugs that do not satisfy Sections 503A or 503B

By violating Sections 503A and 503B, Defendants also violate California's Unfair Competition Law. The UCL prohibits any "unlawful ... business act or practice." Cal. Bus. Prof. Code § 17200. This provision incorporates other California laws, violations of which are actionable under the UCL. *Chabner v. United Omaha Life Ins. Co.*, 225 F.3d 1042, 1048 (9th Cir. 2000). That includes California's Sherman Law, which specifies that "[n]o person shall sell, deliver, or give away any new drug" that has not been approved by the California Department of Health Services or FDA. Cal. Health & Safety Code § 111550(a)-(b). A claim a defendant has violated California's Sherman Law by "flouting that law's drug-approval requirements" is actionable under the UCL. *Imprimis*, 2017 WL 10526121, at *12. Thus, a compounder who violates Sections 503A or 503B of the FDCA when shipping drugs into California violates the Sherman Law and the UCL. *Allergan USA, Inc. v. Prescribers Choice, Inc.*, 364 F. Supp. 3d 1089, 1107 (C.D. Cal. 2019)[.]

Hope is likely to prevail on its UCL claim. Defendants sell their compounded sodium thiosulfate drugs in California, which is a business practice under the UCL. (Akro. Decl. ¶¶ 7-8.) That business practice, because it does not comply with Sections 503A or 503B, violates the Sherman Law and, by extension, the UCL. Hope has lost money or property as a result of Defendants' unlawful California sales. (Sherman Decl. ¶¶ 14-21.) Accordingly, Hope's UCL claim will succeed.

3. Defendants violate the Florida Deceptive and Unfair Trade Practices Act

Hope is likely to prevail on its claim under the Florida Deceptive and Unfair Trade Practices Act because Defendants are engaged in an unfair practice. A FDUTPA claim has three elements: (1) a deceptive act or unfair practice, (2) causation, and (3) actual damages. *Kertresz v. Net Transactions, Ltd.*, 635 F. Supp. 2d 1339, 1348 (S.D. Fla. 2009). Where only injunctive relief is at issue, the plaintiff is not required to prove the unfair practice caused a loss. *Kelly v. Palmer, Reifler, & Associates, P.A.*, 681 F. Supp. 2d 1356, 1365-66 (S.D. Fla. 2010). Defendants' section 503A pharmacy is located in Tampa, Florida, and Defendants sell compounded sodium thiosulfate in Florida from both its section 503A pharmacy and its section 503B outsourcing facility. (Akro. Decl. ¶¶ 7-8.) Thus, the sole question is whether those sales are an unfair practice. They are.

An unfair trade practice under the FDUTPA is "one that offends established public policy and one that is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers." *PNR, Inc. v. Beacon Prop. Mgmt., Inc.*, 842 So. 2d. 773, 777 (Fla. 2003). While Florida courts have not defined precisely the parameters of what does or does not constitute an "established public policy" or conduct that is "immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers," the Florida legislature has mandated that FDUTPA is to be "construed liberally" to "protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition." *Fla. St. Ann.* § 501.202*; Samuels v. King Motor Co. of Fort Lauderdale*, 782 So. 2d 489 (Fla. App. 2001).

Defendants' trade practice of selling unapproved drugs to patients for whom Hope's FDA-approved drug is medically appropriate violates established public policy, whether that term is construed liberally or otherwise. Like California law, the Florida Drug and Cosmetic Act prohibits the sale of any unapproved new drug. Fla. Stat. Ann. § 499.023. That statute expresses a clear public policy against selling unapproved drugs. By selling compounded drugs that are not FDA-approved or exempt under Sections 503A or 503B, Defendants violate Florida law and policy. In addition, Defendants circumvent the national drug-approval process established by Congress and violate FDA's and Congress's policy that compounded drugs be used only when patients cannot tolerate FDA-approved drugs. Hope is, therefore, likely to succeed on its FDUTPA claim.[8]

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[8] Some Florida courts have held that plaintiffs bringing an "unfair trade practice" FDUTPA claim must show that the injury is substantial, not outweighed by any countervailing benefits to consumers or competition, and could not reasonably have been avoided. *Porsche Cars N.A., Inc. v. Diamond*, 140 So. 3d 1090 (Fla. App. 2014.) Hope will be able to prevail on those requirements as well. Hope's injuries in the form of its lost sales are substantial. (Sherman Decl. ¶ 21). Defendants' unapproved drugs pose a substantial risk to individual patient health and public health. There are no countervailing benefits to consumers or competition, and these injuries could not reasonably have been avoided by Hope or consumers.

4. Defendants violate the South Carolina Unfair Trade Practices Act and the Connecticut Unfair Trade Practices Act

For the same reasons, Hope is likely to prevail on its claim under the South Carolina Unfair Trade Practices Act ("SCUTPA") and the Connecticut Unfair Trade Practices Act ("CUTPA").

The elements of a cause of action under SCUTPA and CUTPA are similar. SCUTPA requires that (1) the Defendant engaged in an unfair or deceptive act in the conduct of trade or commerce, (2) the unfair or deceptive act affected the public interest, and (3) the plaintiff suffered monetary or property loss as a result of the defendant's unfair or deceptive acts. *Health Promotion Specialists, LLC v. S.C. Bd. of Dentistry*, 403 S.C. 623, 638 (2013). In South Carolina, an "act is 'unfair' when it is offensive to public policy or when it is immoral, unethical or oppressive." *Id.* An act violates CUTPA when it "offends public policy as it has been established by statutes, the common law or otherwise," is "immoral, unethical, oppressive or unscrupulous," or "causes substantial injury to consumers, competitors or other businesspersons." *Ramirez v. Health Net of Northeast, Inc.*, 938 A.2d 576 (Conn. 2008).

Defendants' conduct is "unfair" under SCUTPA and CUTPA because, like Florida, South Carolina, and Connecticut both prohibit the sale of unapproved new drugs within the state. S.C. Code Ann. § 39-23-70(a); Conn. Gen. St. § 21a-110. Defendants sell their unapproved compounded sodium thiosulfate drugs in South Carolina and Connecticut (Akro. Decl. ¶¶ 7-8), violating those states' laws and policy. As already explained, those sales also violate U.S. policy as expressed by Congress and FDA. Hope has also suffered a monetary loss in South Carolina and

Connecticut in the form of lost sales and customers. (Sherman Decl. ¶ 21.) Therefore, Hope will succeed on its SCUTPA claim.

5. **Defendants violate the Tennessee Consumer Protection Act**

Hope is likely to prevail on its claim under the Tennessee Consumer Protection Act because Defendants are selling an illegal product in Tennessee. The TCPA prohibits, among other things, "advertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state," Tenn. Code Ann. § 47- 18-104(b)(44)(C), and the Tennessee Food Drug and Cosmetic Act prohibits the sale of "any new drug" that has not been approved by FDA, Tenn. Code Ann. § 53-1-110.

Defendants violate the TFDCA by selling their unapproved sodium thiosulfate drugs in Tennessee. (Sherman Decl. Exh. D and ¶ 11; Akro. Decl. ¶¶ 7-8.) These illegal sales violate the TCPA. Tenn. Code Ann. § 47-18-104(b)(44)(C).

Hope also satisfies the TCPA's requirement "that the defendant's conduct caused an ascertainable loss of money or property." Tucker v. Sierra Builders, 180 S.W. 3d 109 (Tenn. App. 2005). Due to Defendants' illegal conduct, Hope has lost customers and sales in Tennessee. (Sherman Decl. Exh. D and ¶¶ 11, 21.) Accordingly, Hope will succeed on its TCPA claim.

B. Hope Will Suffer Irreparable Harm Without an Injunction

If this Court does not enjoin Defendants' illegal conduct, Hope will continue to suffer irreparable harm. In the recent *Imprimis* case, a court in this district entered an injunction against the defendant's violations of California's UCL, finding the plaintiff's loss of customers, sales, and market share from the

defendant's illegal compounding activities constituted irreparable harm. *Imprimis Injunction Order*, 2019 WL 3029114, at *12. This Court should make a similar finding here.

As explained above, Hope has lost customers, market share, reputation, and goodwill due to Defendants' conduct. *Supra* at II.B.7. Once Defendants resumed selling their illegally compounded sodium thiosulfate drug products, Hope lost a national customer that had ordered many thousands of units during a seven-month period during which Defendants were not engaging in unfair competition. (Sherman Decl. ¶¶ 17-20.) Hope is losing substantial sales, and thus market share, to Defendants in California, Florida, Tennessee, South Carolina, and Connecticut. (Sherman Decl. ¶ 21.) Hope is also losing reputation and goodwill because customers, confused between Hope and Defendants, are blaming Hope for Defendants' tardy shipments of their drugs. (Sherman Decl. ¶¶ 10-12 and Exhs. C-D.) Even worse, confused consumers may associate the many FDA warning letters Defendants have received with Hope (RJN Exhs. I-J, R-U), misleading customers into thinking that Hope's drugs, like Defendants', are unsafe.

These injuries support a preliminary injunction. "Evidence of threatened loss of prospective customers or goodwill certainly supports a finding of the possibility of irreparable harm." *Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 841 (9th Cir. 2001). So does decreased market share, *Cybergun S.A. v. Jag Precision, Inc.*, 533 F. App'x 791, 792 (9th Cir. 2013); *DMF, Inc. v. AMP Plus, Inc.*, 2019 WL 1099982, at *12 (C.D. Cal. Mar. 7, 2019) (Snyder, J.), and "losing control of one's reputation and goodwill in the marketplace," *Athleta, Inc. v. Pitbull Clothing Co.,*

Inc., 2013 WL 142877, at *10 (C.D. Cal. Jan. 7, 2013) (Snyder, J.); *see also Robinson v. Delicious Vinyl Records Inc.*, 2013 WL 3983014 (C.D. Cal. Aug. 1, 2013) (Snyder, J.). The Ninth Circuit has approved injunctions where, as here, plaintiffs submitted evidence of complaints caused by customer confusion. *Life Alert Emergency Response, Inc. v. LifeWatch, Inc.*, 601 F. App'x 469, 473-74 (9th Cir. 2015). Indeed, this Court has found that the precise confusion Defendants have caused—customers blaming a plaintiff for the defendant's untimely shipment of products—supports a preliminary injunction. *Athleta*, 2013 WL 142877, at *10.

In addition, Hope has lost sales that are not compensable by money damages. California law does not provide a damages remedy for lost sales under the UCL. *Korea Supply Co. v. Lockheed Martin Corp.*, 131 Cal. Rptr. 2d 29, 37-41 (2003); RJN Exh. W at 265-67. Therefore, Hope's lost California sales also constitute irreparable harm. *See Ross-Simons of Warwick, Inc. v. Baccarat, Inc.* 102 F.3d 12, 18 (1st Cir. 1996) (holding that "substantial injury that is not ... adequately compensable by money damages" is irreparable harm).

C. The Balance of Hardships Favors Hope

The balance of hardships weighs strongly in Hope's favor. This Court has consistently found that the balance of hardships favors an injunction when the plaintiff has suffered harm to its brand, business, goodwill, reputation, and market share. *E.g.*, *DMF*, 2019 WL 1099982, at *14; *Delicious Vinyl Records*, 2013 WL 3983014, at *7; *Athleta*, 2013 WL 142877, at *11. Hope sells only three products including its FDA-approved Sodium Thiosulfate Injection, so Defendants' practices are substantially harming Hope's business. (Sherman Decl. ¶¶ 2, 21.) In

contrast, Defendants sell a wide variety of compounded drugs.[9] An injunction prohibiting a small part of Defendants' business will not significantly harm Defendants.

In any event, Defendants are not entitled to any equitable consideration because their business is illegal. In the related context of intellectual property infringement, the Ninth Circuit has held that "[w]here the only hardship that the defendant will suffer is lost profits from an activity which has been shown likely to be infringing, such an argument in defense merits little equitable consideration." *Cadence Design Sys., Inc. v. Avant! Corp.*, 125 F.3d 824, 830 (9th Cir. 1997). And this Court has held that "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *DMF*, 2019 WL 1099982, at *14. Here, the only hardship Defendants could possibly face is a loss of profits from an illegal activity. The balance of hardships thus supports an injunction.

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[9] The extent to which Defendants' business depends on the sale of illegal sodium thiosulfate drugs is not precisely known, but likely quite small when compared to their total revenues. Under the requested preliminary injunction, provided Defendants come into compliance with sections 503A and 503B, they can continue to operate their facilities under the injunction and sell their non-sodium thiosulfate drugs to customers in all 50 states. Defendants can also continue to sell sodium thiosulfate, so long as they stop violating the "essentially a copy" prohibitions of section 503A and 503B, and begin complying with the individual prescription requirement of section 503A.

D. Injunctive Relief is in the Public Interest

Finally, the public interest—"the impact upon nonparties of granting or withholding injunctive relief," Hon. V. Phillips and Hon. K. Stevenson, *Federal Civil Procedure Before Trial*, 13:76 at 13-49 (2019)—favors an injunction.

The public interest always favors "upholding the law and having parties abide by their legal duties." *Id.* at 13-50. Here, Hope has gone through the proper channels to obtain FDA approval for its Sodium Thiosulfate Injection. In contrast, Defendants' have circumvented FDA approval through illegal compounding. Granting an injunction would not only protect Hope from unlawful competition but would also put an end to illegal activity, both of which are in the public interest. *Forever Found. & Frame, LLC v. Optional Prod. LLC*, 2014 WL 12585800, at *5 (C.D. Cal. Dec. 19, 2014).

Further, an injunction would protect the public's right to not be deceived or confused. *See Athleta* 2013 WL 142877, at *11 (finding that public interest in avoiding consumer confusion favored injunction). The primary nonparties who will be affected by an injunction are patients in California, Florida, Tennessee, South Carolina, and Connecticut. If an injunction were granted, those patients would now be prescribed Hope's FDA-approved Sodium Thiosulfate Injection, rather than Defendants' illegal copy. Not only would the injunction lessen customer confusion stemming from Defendants' illegal products, but it would also ensure the safety and effectiveness of the sodium thiosulfate drug on the market. *See Nutrition Distrib. LLC v. IronMag Labs, LLC*, 2018 WL 6264986, at *4 (C.D. Cal. Nov. 16, 2018) (holding that public interest favored injunction that would protect against the "possibility of Defendants selling products

in the future which may pose a risk to public health and safety"). Thus, the public interest factor—like all of the other factors—heavily favors an injunction.

IV. CONCLUSION

Hope asks the Court to grant its motion and enter the preliminary injunction described in Hope's notice of motion.

Dated: June 1, 2020

KING & SPALDING LLP
By:*/s/Joseph N. Akrotirianakis*
JOSEPH N. AKROTIRIANAKIS
AARON S. CRAIG
Attorneys for Plaintiff
HOPE MEDICAL
ENTERPRISES, INC. D/B/A
HOPE PHARMACEUTICALS

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

HOPE MEDICAL ENTERPRISES, INC. D/B/A HOPE PHARMACEUTICALS,

Plaintiff,

v.

FAGRON COMPOUNDING SERVICES, LLC; JCB LABORATORIES, LLC; ANAZAOHEALTH CORPORATION; COAST QUALITY PHARMACY, LLC,

Defendants.

Case No. 2:19-cv-07748-CAS(PLAx)

FINAL JUDGMENT

Trial Date: August 24, 2021
9:00 a.m.

Complaint Filed: September 6, 2019

The Court hereby ORDERS, ADJUDGES, and DECREES that judgment be, and hereby is, entered as follows:

1. **Judgment.** Judgment is entered in favor of plaintiff Hope Medical Enterprises Inc. d/b/a Hope Pharmaceuticals ("Hope").

2. **Declaratory Relief.** Defendants Fagron Compounding Services, LLC, JCB Laboratories, LLC, AnazaoHealth Corporation, and Coast Quality Pharmacy LC (collectively "defendants") have violated (1) California's Unfair Competition aw, (2) Florida's Deceptive and Unfair Trade Practices Act, (3) Tennessee's Consumer Protection Act, (4) South Carolina's Unfair Trade Practices Act, and (5) Connecticut's Unfair Trade Practices Act.

3. **Permanent Injunction.** Defendants and their officers, agents, servants, employees, attorneys, and all those acting in concert with any of them, shall be permanently enjoined from directly or indirectly dispensing or distributing any compounded sodium thiosulfate product from a Section 503B outsourcing facility into California, Connecticut, Florida, South Carolina, or Tennessee, unless:

a. defendants are provided with an individual clinic order form for the product; and

b. the order form includes an attestation specifically indicating that defendants' compounded product, which does not contain potassium, will produce a clinical difference; and

c. the attestation specifies why the defendants' compounded product, rather than the comparable commercially available drug product, is "medically necessary" for the specified patients to whom defendants' drug will be distributed or dispensed; and

d. the attestation indicates that it is made or approved by the prescribing practitioners of such specified patients.

An order that only identifies the product formulation, without more information, is insufficient to comply with this injunction.

4. **Attorney's Fees and Costs.** Attorney's fees are awarded to Hope in accordance with the Court's Order dated January 14, 2022. Any application or notion by plaintiff shall be submitted in accordance with Federal Rule of Civil Procedure 54(d) and Local Rule 54.

5. **Service of this Judgment.** This Judgment shall be deemed to have been served upon defendants when distributed through the ECF system of the United States District Court.

6. **Notice Provision.** Defendants shall be required to notify purchasers of their compounded drug that the drug is compounded under Section 503B and as such each order must be made or approved by the prescribing practitioner of specified patients and must contain a statement of clinical difference as defined in Section 503B. Some examples of clinical difference statements from the FDA Guidance on Section 503B include:

a. "Liquid form, compounded drug will be prescribed to patients who can't swallow tablet (if the comparable drug is a tablet)";

b. "Dilution for infusion solution to be administered to patients who need this formulation during surgery (if the comparable drug is not available at that concentration, pre-mixed with the particular diluent in an infusion bag)",

c. "1 mg, pediatric patients need lower dose (if the comparable drug is only available in 25 mg dose)".

IT IS SO ORDERED, ADJUDGED, AND DECREED.

Dated: January 18, 2022

Christina A. Snyder

THE HONORABLE
CHRISTINA A. SNYDER
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

HOPE MEDICAL ENTERPRISES, INC. D/B/A HOPE PHARMACEUTICALS,

Plaintiff,

v.

FAGRON COMPOUNDING SERVICES, LLC; JCB LABORATORIES, LLC; ANAZAOHEALTH CORPORATION; COAST QUALITY PHARMACY, LLC,

Defendants.

Case No. 2:19-cv-07748-CAS-PLAx

The Honorable Christina A. Snyder

AMENDED PERMANENT INJUNCTION

The Court AMENDS the PERMANENT INJUNCTION issued on January 18, 2022, to provide as follows:

1. Defendants and their officers, agents, servants, employees, attorneys, and all those acting in concert with any of them (collectively, "Defendants"), shall be permanently enjoined from directly or indirectly distributing in or to California, Connecticut, Florida, South Carolina, or Tennessee any unapproved drug compounded from bulk sodium thiosulfate, unless:

   a. bulk sodium thiosulfate appears on the Food and Drug Administration's "Clinical Need List" of bulk drug substances for which FDA has found a clinical need for use by Section 503B outsourcing facilities;

   b. the drug compounded by defendants from bulk sodium thiosulfate appears on FDA's "drug shortage" list at the time of

compounding, distribution, and dispensing; or

c. if FDA's January 2017 "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B" remains in effect, bulk sodium thiosulfate appears on FDA's "Category 1" list.

2. In all circumstances, including if any of the conditions in paragraph 1 are satisfied, Defendants must comply with all the terms and conditions set forth in the Court's original permanent injunction (Dkt. 430).

IT IS SO ORDERED.

DATED: March 31, 2022

Christina A. Snyder

THE HONORABLE
CHRISTINA A. SNYDER
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

HOPE MEDICAL ENTERPRISES, INC. D/B/A HOPE PHARMACEUTICALS,

Plaintiff,

v.

FAGRON COMPOUNDING SERVICES, LLC; JCB LABORATORIES, LLC; ANAZAOHEALTH CORPORATION; COAST QUALITY PHARMACY, LLC,

Defendants.

Case No. 2:19-cv-07748-CAS-PLAx

The Honorable Christina A. Snyder

AMENDED FINAL JUDGMENT

The Court hereby ORDERS, ADJUDGES, and DECREES that judgment be, and hereby is, entered as follows:

1. **Judgment.** Judgment is entered in favor of plaintiff Hope Medical Enterprises Inc. d/b/a Hope Pharmaceuticals ("Hope").

2. **Declaratory Relief.** Defendants Fagron Compounding Services, LLC, JCB Laboratories, LLC, AnazaoHealth Corporation, and Coast Quality Pharmacy LLC (collectively "defendants") have violated (1) California's Unfair Competition Law, (2) Florida's Deceptive and Unfair Trade Practices Act, (3) Tennessee's Consumer Protection Act, (4) South Carolina's Unfair Trade Practices Act, and (5) Connecticut's Unfair Trade Practices Act.

3. **Permanent Injunction.**

a. Defendants and their officers, agents, servants, employees, attorneys, and all those acting in concert with any of them, shall be permanently enjoined from directly or indirectly distributing in or to California, Connecticut, Florida, South Carolina, or Tennessee any unapproved drug compounded from bulk sodium thiosulfate, unless:

i. bulk sodium thiosulfate appears on the Food and Drug Administration's "Clinical Need List" of bulk drug substances for which FDA has found a clinical need for use by Section 503B outsourcing facilities;

ii. the drug compounded by defendants from bulk sodium thiosulfate appears on FDA's "drug shortage" list at the time of compounding, distribution, and dispensing; or

iii. if FDA's January 2017 "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B" remains in effect, bulk sodium thiosulfate appears on FDA's "Category 1" list.

b. In addition to the injunction set forth in paragraph 3.a, Defendants and their officers, agents, servants, employees, attorneys, and all those acting in concert with any of them, shall also be permanently enjoined from directly or indirectly dispensing or distributing any unapproved sodium thiosulfate product from a Section 503B outsourcing facility into California, Connecticut, Florida, South Carolina, or Tennessee, unless:

i. defendants are provided with an individual clinic order form for the product; and

ii. the order form includes an attestation specifically indicating that defendants' compounded product, which does not contain potassium, will produce a clinical difference; and

iii. the attestation specifies why defendants' compounded product, rather than the comparable commercially available drug product, is "medically necessary" for the specified patients to whom defendants' drug will be distributed or dispensed; and

iv. the attestation indicates that it is made or approved by the prescribing practitioners of such specified patients.

An order that only identifies the product formulation, without more information, is insufficient to comply with this injunction.

4. **Attorney's Fees and Costs.** Hope is awarded attorneys' fees in the amount of $2,206,785.82 and litigation costs in the amount of $137,036.40.

5. **Service of this Judgment.** This Judgment shall be deemed to have been served upon defendants when distributed through the ECF system of the United State District Court.

6. **Notice Provision.** Defendants shall be required to notify purchasers of their unapproved drug that the drug is compounded under Section 503B and as such each order must be made or approved by the prescribing practitioner of specified patients and must contain a statement of clinical difference as

defined in Section 503B Some examples of clinical difference statements from the FDA Guidance on Sectio 503B include:

a. "Liquid form, compounded drug will be prescribed to patients who can't swallow tablet (if the comparable drug is a tablet)";

b. "Dilution for infusion solution to be administered to patients who need this formulation during surgery (if the comparable drug is not available at that concentration, pre-mixed with the particular diluent in an infusion bag)";

c. "1 mg, pediatric patients need lower dose (if the comparable drug is only available in 25 mg dose)".

IT IS SO ORDERED, ADJUDGED, AND DECREED.

DATED: March 31, 2022

Christina A. Snyder

THE HONORABLE
CHRISTINA A. SNYDER
UNITED STATES DISTRICT JUDGE