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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 22-55173

HOPE MEDICAL ENTERPRISES, INC.,
DBA Hope Pharmaceuticals,
Plaintiff-Appellee,
v.
FAGRON COMPOUNDING SERVICES, LLC; *et al.*,
Defendants-Appellants.

NOT FOR PUBLICATION

Appeal from the United States District Court
for the Central District of California,
D.C. No. 2:19-cv-07748-CAS-PLA
Christina A. Snyder, District Judge, Presiding

Argued and Submitted July 21, 2023,
Pasadena, California
Filed July 26, 2023
Document No. 70-1

MEMORANDUM[*]

Before: S.R. THOMAS, NGUYEN, and FORREST, Circuit Judges.

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[*] This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

Fagron Compounding Services, LLC and others ("Fagron") appeal the district court's judgment in favor of Hope Medical Enterprises, Inc. ("Hope") in Hope's diversity action alleging Fagron violated state unfair-competition laws by selling prescription drugs prohibited by state drug-approval laws. We have jurisdiction pursuant to 28 U.S.C. § 1291. Following a bench trial, we review the district court's conclusions of law de novo. *Oakland Bulk & Oversized Terminal, LLC v. City of Oakland*, 960 F.3d 603, 612 (9th Cir. 2020). We also review a district court's decision regarding preemption de novo. *Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1287 (9th Cir. 2021). We reverse.[1] Because the parties are familiar with the factual and procedural history of the case, we need not recount it here.

Federal law preempts state law when the state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1231 (9th Cir. 2013) (en banc) (citation omitted). The federal Food, Drug, and Cosmetic Act ("FDCA") prohibits private enforcement: "all proceedings to enforce or restrain violations of the FDCA must be 'by and in the name of the United States,' except for certain proceedings by state governments." *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1044 (9th Cir. 2022) (quoting 21 U.S.C. § 337(a)). The FDCA regulates the manufacturing of compounded drugs and exempts manufacturers of compounded drugs

[1] We also deny Fagron's motion for judicial notice (Dkt. 32).

from the requirement to obtain drug approval from the Food and Drug Administration ("FDA") in certain instances. *Id.* at 1042–43; 21 U.S.C. §§ 353a–b.

In *Nexus*, we held that the FDCA preempted a pharmaceutical company's suit alleging that another pharmaceutical company violated several states' unfair competition laws by selling an unapproved, compounded drug that was "essentially a copy" of an FDA-approved drug under section 503B of the FDCA. *Id.* at 1044. We reasoned that the FDCA's prohibition on private enforcement bars a drug manufacturer from suing another drug manufacturer for economic harm "because the defendant violated the FDCA." *Id.* at 1050.

Nexus controls here. Because Hope seeks to "enforce its interpretation" of the FDCA's rules for manufacturing compounded drugs against a competitor, the FDCA's prohibition on private enforcement and the doctrine of implied preemption bar the suit. *Id.* at 1050–51.

We also reverse the district court's award of fees and costs to Hope.

REVERSED.

Appendix B

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

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

HOPE MEDICAL ENTERPRISES, INC.,
Plaintiff,
v.
FAGRON COMPOUNDING SERVICES, LLC; *et al.*,
Defendants.

Filed October 26, 2021
Document No. 418

FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. INTRODUCTION

This case was tried to the Court on August 24, 2021, August 25, 2021, August 26, 2021, August 27, 2021, and September 2, 2021. Attorneys Joseph Akrotirianakis and Aaron Craig of King & Spalding LLP appeared on behalf of plaintiff Hope Medical Enterprises, Inc. ("Hope"). Attorneys Ellen Robbins and Lawrence Silverman of Akerman LLP and Sherylle Francis of Sherylle Francis PA appeared on behalf of defendants Fagron Compounding Services, LLC ("Fagron"), JCB Laboratories, LLC ("JCB"), AnazaoHealth Corporation ("Anazao"), and Coast Quality Pharmacy, LLC ("Coast") (collectively,

"defendants"). Based on the evidence and testimony presented at trial, the Court makes the following findings of fact and conclusions of law. To the extent any finding of fact is better characterized as a conclusion of law, or vice versa, it shall be so characterized.

II. FINDINGS OF FACT

A. Background

1. Hope filed this action against defendants Fagron, JCB, Anazao, and Coast on September 6, 2019. Dkt. 1. Fagron and JCB are hereinafter sometimes referred to as "the 503B defendants." Defendants are all owned either directly or indirectly by Fagron BV, a company registered in Belgium, or its affiliate, Fagron NV, a company registered and headquartered in the Netherlands. Dkt. 47 ¶ 13. The gravamen of Hope's claims is that defendants' drug compounding practices constitute unfair competition in violation of several states' unfair trade practice and consumer protection laws.

2. Hope and defendants sell competing drugs containing sodium thiosulfate as an active pharmaceutical ingredient ("API"). Sodium thiosulfate is hereinafter sometimes referred to as "STS". Defendants have been producing and selling their drug since 2011. Exhs. 540, 540A. Hope began selling its sodium thiosulfate drug in 2012, after the drug received FDA approval as a treatment for acute cyanide poisoning. Trial Testimony of Dr. Sherman. Defendants have not received FDA approval for their sodium thiosulfate drugs. Defendants' sodium thiosulfate drugs differ from Hope's sodium

thiosulfate drugs, because unlike Hope's drugs, defendants' drugs are compounded and do not contain potassium. *See* Dkt. 387 ("Final Pretrial Conf. Order") at 2:17-18. Defendants have produced their sodium thiosulfate drugs by two means: through compounding at pharmacies, referred to as 503A facilities, and through compounding at outsourcing facilities, referred to as 503B facilities, as described in greater detail below.

3. On November 12, 2019, Hope filed its operative amended complaint. Dkt. No. 47 ("FAC"). Hope asserted five claims, under (1) California's Unfair Competition Law ("UCL"), (2) Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"), (3) Tennessee's Consumer Protection Act ("TCPA"), (4) South Carolina's Unfair Trade Practices Act ("SCUTPA"), and (5) Connecticut's Unfair Trade Practices Act ("CUTPA"). *Id.* at ¶¶ 97–137. California, Florida, Tennessee, South Carolina, and Connecticut are hereinafter sometimes referred to as the "five states".

4. On June 1, 2020, Hope filed a motion for a preliminary injunction. Dkt. 105. Hope's motion was based in part on defendants' alleged production and sale of their sodium thiosulfate drugs without prescriber determinations required to exempt the drugs from premarket drug approval laws. *Id.* Defendants opposed the motion by arguing, among other grounds, that the Federal Food, Drug and Cosmetic Act ("FDCA") preempts Hope's claims. Dkt. 113. The FDCA requires compounded drugs to be approved by the FDA before they can be sold with two limited statutory exceptions: Section 503A, which

permits the sale of drugs compounded at pharmacies subject to specific limitations, and Section 503B, which permits the sale of drugs compounded at outsourcing facilities subject to specific limitations, as described in greater detail below.

5. This Court granted Hope's motion in part on July 7, 2020. Dkt. 141 ("Prelim. Inj."). The Court ordered as follows:

> a. Defendants and their officers, agents, servants, employees, attorneys and all those acting in concert with them, shall be preliminarily enjoined from directly or indirectly dispensing or distributing any compounded sodium thiosulfate product from a 503A facility into California, Connecticut, Florida, South Carolina, or Tennessee unless: (i) defendants are provided a valid prescription or order form for the product; (ii) the prescription or order form includes an attestation specifically indicating that defendants' compounded product, which does not contain potassium, will produce a significant difference for the intended patient; (iii) the attestation specifies that defendants' compounded product, rather than the comparable commercially available drug product, is "medically necessary" for the intended patient; and (iv) the attestation indicates that the attestation is made or approved by the intended patient's prescribing practitioner.
>
> b. Defendants and their officers, agents, servants, employees, attorneys and all those

> acting in concert with them, shall be preliminarily enjoined from directly or indirectly dispensing or distributing any compounded sodium thiosulfate product from a 503B facility into California, Connecticut, Florida, South Carolina, or Tennessee unless: (i) defendants are provided an order form for the product; (ii) the order form includes an attestation specifically indicating that defendants' compounded product, which does not contain potassium, will produce a clinical difference; (iii) the attestation specifies that defendants' compounded product, rather than the comparable commercially available drug product, is "medically necessary" for the patients to whom defendants' drug will be distributed or dispensed; and (iv) the attestation indicates that the attestation is made or approved by a prescribing practitioner.

Prelim. Inj. at 38–39.

6. On November 2, 2020, Hope moved for summary judgment. Dkt. 151. On the same day, Hope also moved for an order holding defendants in contempt for violating the preliminary injunction. Dkt. 153. Defendants opposed Hope's motion for contempt and asked the Court to reconsider the preliminary injunction, again arguing that the FDCA preempts Hope's claims. Dkt. 173 at 14–17. Defendants also moved for summary judgment. Dkt. 178.

7. On January 25, 2021, this Court denied both parties' summary judgment motions. Dkt. 226 at 43.

The Court reserved judgment on Hope's motion for contempt. *Id.* at 41. The Court denied defendants' motion for reconsideration of the preliminary injunction under Local Rule 7–18. *Id.* at 43.

8. Defendants filed a notice of appeal from the order denying their motion for reconsideration of the preliminary injunction. Dkt. 238. This appeal remains pending in the Ninth Circuit. *Id.* Defendants also moved the Court to certify for interlocutory appeal the order denying their motion for reconsideration. Dkt. 227. On March 15, 2021, this Court denied that motion. Dkt. 255.

9. On April 21, 2020, Hope served defendants with a declaration by Craig Sherman, Hope's co-founder and President, which stated that Hope waived all claims for damages. Dkt. 341-3. On June 28, 2021, Hope moved to strike defendants' jury demand. Dkt. 341. On July 12, 2021, this Court granted Hope's motion to strike the jury demand, finding that as a result of Hope's waiver of all claims for damages, neither the claims alleged nor the defenses raised give rise to a Seventh Amendment right to a jury trial. Dkt. 353.

10. On August 12, 2021, the parties submitted their Amended Proposed Final Pretrial Conference Order which included various stipulated facts to which all parties agreed. Final Pretrial Conf. Order at 2:5–5:1. This Court adopts all such stipulated facts as findings of facts whether or not restated herein.

11. On August 24, 2021, this matter came before the Court for a five-day bench trial. The parties called as witnesses Kalah Auchincloss, Jason McGuire,

Suzanne Heinemann, and Dennis David. Dkt. 413. Additionally, the Court received into evidence deposition testimony of Dr. George Aronoff, Dr. Jeffrey Hymes, Timothy Bresnahan, Tamekka Grant, Chris Kirkes, Keiola Peterson, Phu Pham, Shawn Trull, and Carl Woetzel. Dkts. 302, 322. The witnesses who were called at trial, the depositions of the foregoing witnesses, and the exhibits that were offered, admitted into evidence, and considered by the Court are identified in the witness and exhibit lists filed on September 2, 2021. Dkt. 413.

B. Regulatory Framework Governing Drug Compounding

12. At issue in this case are defendants' sales of their compounded sodium thiosulfate drugs. "Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). "Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product." *Id.*

13. In 1938, Congress enacted the FDCA "to regulate drug manufacturing, marketing, and distribution." *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388 (5th Cir. 2008). The FDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug." 21 U.S.C. § 355(a).

14. The FDCA defines "new drug" as "[a]ny new drug . . . the composition of which is such that such drug is not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof[.]" 21 U.S.C. § 321(p)(1). "The FDCA invests the Food and Drug Administration (FDA) with the power to enforce its requirements." *Thompson*, 535 U.S. at 362. To be deemed 'safe and effective' and thereby obtain FDA approval, a new drug must undergo an extensive application and approval process." *Med. Ctr. Pharmacy*, 536 F.3d at 388. The FDCA requires that any FDA finding that a drug is "'safe and effective' must be based on 'substantial evidence' of expert consensus." *Id.* "The 'test is rigorous,' requiring expensive and time-consuming clinical trials[.]" *Id.* at 388–389.

15. Drug compounding is an exception to the FDCA's premarket approval requirement. The federal government began regulating drug compounding "[i]n the early 1990's" when "the FDA became concerned that some pharmacies were purchasing bulk quantities of drug products, 'compounding' them into specific drug products before receiving individual prescriptions, and marketing those drugs to doctors and patients." *Med. Ctr. Pharmacy*, 536 F.3d at 389. The FDA ultimately concluded "that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Thompson*, 535 U.S. at 362.

16. Responding to concerns of regulation avoidance, in 2013, "Congress passed new legislation

that once again created federal regulatory power over compounding pharmacies." *Cruz v. Preferred Homecare*, No. 2:14-cv-00173-MMD, 2014 WL 4699531, at *3 (D. Nev. Sept. 22, 2014). This legislation—the Drug Quality and Security Act ("DQSA")—"amend[ed] FDCA Section 503A and add[ed] Section 503B." *Allergan USA Inc. v. Imprimis Pharm., Inc.*, No. 8:17-cv-01551-DOC(JDEx), 2017 WL 10526121 , at *2 (C.D. Cal. Nov. 14, 2017). The purpose of the DSQA was to improve overall quality and safety of compounded drugs following a 2012 incident in which a drug compounding center "produced contaminated injections that caused a meningitis outbreak, killing more than 60 people and infecting hundreds more." *Athenex Inc. v. Azar*, 397 F. Supp. 3d 56, 59 (D.D.C. 2019).

17. The FDA has issued the following guidance regarding the compounding of FDA approved drugs:

> "Although compounded drugs can serve an important need, they can also pose a higher risk to patients than FDA-approved drugs. Drug products compounded by outsourcing facilities in accordance with the conditions of section 503B are exempt from FDA drug approval requirements and the requirement to be labeled with adequate directions for use. There are greater assurances of quality when drugs are compounded by outsourcing facilities that meet the conditions of section 503B and CGMP requirements than there are for drugs compounded by entities that are not required to comply with CGMP requirements and are not routinely overseen by FDA.

> However, as with all compounded drugs, drugs compounded by outsourcing facilities have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process. Because they are subject to a lower regulatory standard, compounded drugs should only be distributed to health care facilities or dispensed to patients to fulfill the needs of patients whose medical needs cannot be met by an FDA-approved drug."

Dkt. No. 106–1, Exh. E (hereinafter, "FDA Guidance on 503B 'Essentially a Copy' Requirement").

FDA guidance documents—including the FDA Guidance on 503B "Essentially a Copy" Requirement—are "documents prepared for FDA staff, applicants/ sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue." *Figy v. Amy's Kitchen, Inc*, 37 F. Supp. 3d 1109, 1113 (N.D. Cal. 2014), *judgment set aside*, 2014 WL 3362178 (N.D. Cal. July 7, 2014) (citing 21 C.F.R § 10.115(b)(1)). "Although guidance documents do not legally bind [the] FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence." 21 C.F.R § 10.115(d)(3). Because FDA guidance documents "represent the agency's current thinking," courts have found them to be persuasive authority. *See, e.g., Ignacuinos v. Boehringer Ingelheim Pharms. Inc.*, 8 F.4th 98, 104 (2d Cir. 2021)

("Although the FDA's guidance is not binding on this Court, it fully comports with the plain meaning of the regulation, and we find it persuasive."). Here, because the FDA's guidance comports with the plain meaning of Sections 503A and 503B, the Court finds the FDA Guidance on 503A and 503B to be persuasive authority.

C. Section 503A of the FDCA

18. Section 503A of the FDCA regulates "pharmacy compounding." 21 U.S.C. § 353a. "Drug products compounded 'for an identified individual patient that are necessary for the identified patient' are exempted from normal-drug approval requirements under Section 503A when certain conditions are met." *Imprimis*, 2017 WL 10526121, at *2 (internal alterations omitted) (citing 21 U.S.C. § 353a(a)). Accordingly, "Section 503A allows pharmacy compounding in two scenarios: (1) drug compounding after the receipt of a prescription; and (2) drug compounding before the receipt of a prescription when the compounding is 'based on a history of receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between' the compounding pharmacy and the patient or prescribing physician." *Imprimis*, 2017 WL 10526121, at *2 (internal alterations omitted) (citing 21 U.S.C. § 353a(a)).

19. "In both scenarios, Section 503A also requires that the compounded drug is (1) compounded using approved drug products; (2) compounded using ingredients that comply with national standards; (3) not compounded 'regularly or in inordinate

amounts (as defined by the Secretary)' if the compounded drug is 'essentially a copy of a commercially available product'; (4) not a drug product whose safety or effectiveness may be adversely effected by compounding; and (5) compounded in a state that has entered into a Memorandum of Understanding ('MOU') with the FDA or, if no such MOU exists for that state, compounded by a pharmacy or individual that distributes less than '5 percent of its total prescription orders' to out-of-state patients." *Imprimis*, 2017 WL 10526121, at *2 (internal alterations omitted) (citing 21 U.S.C. § 353a(b)).

20. "[A]nticipatory mass compounding of standardized drugs in a 503A facility without identified individual patients based on valid prescription orders is clearly violative of the FDCA." *Allergan USA, Inc. v. Imprimis Pharm., Inc.*, 2019 WL 4545960, at *11 (C.D. Cal. Mar. 27, 2019).

21. As noted above, the FDCA does not permit compounded drugs to be sold or distributed under the 503A exception, a drug that is "compounded 'regularly or in inordinate amounts (as defined by the Secretary)' if the compounded drug is 'essentially a copy of a commercially available product.'" *Id.* (internal alterations omitted) (citing 21 U.S.C. § 353a(b)).

22. "This means that a compounded drug product is not eligible for the exemptions in Section 503A if it is (1) essentially a copy of a commercially available drug product, and (2) compounded regularly or in inordinate amounts." Dkt. 106-1, Exh. C (hereinafter, "FDA Guidance on 503A 'Essentially a Copy' Requirement").

23. A drug is compounded "regularly" if it is "compounded at regular times or intervals, usually or very often." FDA Guidance on 503A "Essentially a Copy" Requirement at 10. A drug is compounded in "inordinate amounts" if "it is compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances." *Id.*

24. A compounded drug may be "essentially a copy of a commercially available drug product" even if it is not an "exact cop[y]" of or "nearly identical" to "a commercially available drug product." *Id.* at 6. A drug is "essentially a copy of a commercially available drug product" if (a) the compounded drug and the commercially available drug have the same API, (b) the API has the same, a 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. *Id.* at 5–6.

25. The "term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product." 21 U.S.C. § 353a(b)(2). If a compounder intends to rely on such a significant difference statement, that determination is to be "documented on the prescription." FDA Guidance on 503A "Essentially a Copy" Requirement at 8. The determination is to be

made by "a prescriber . . . for the patient for whom [the compounded drug] is prescribed." *Id.* at 7; 21 U.S.C. §353a(b)(2).

26. The FDA's guidance indicates that the FDA "does not believe that a particular format is needed to document the determination, provided that the prescription makes clear that the prescriber identified the relevant change and the significant difference that the change will produce for the patient." FDA Guidance on 503A "Essentially a Copy" Requirement at 8. The FDA includes the following examples as sufficient to meet the documentation requirement:

> "No Dye X, patient allergy" (if the comparable drug contains the dye);
>
> "Liquid form, patient can't swallow tablet" (if the comparable drug is a tablet);
>
> "6 mg, patient needs higher dose" (if the comparable drug is only available in 5 mg dose).

Id. See also Trial Testimony of Kalah Auchincloss.

D. Section 503B of the FDCA

27. "Section 503B created a new category of drug maker called an 'outsourcing facility.'" *Athenex*, 397 F. Supp. 3d at 59 (citing 21 U.S.C. § 353b). "An outsourcing facility may compound drug products in large quantities without obtaining a prescription for 'an identified individual patient.'" *Id.* Accordingly, outsourcing facilities "are permitted to sell bulk compounded drug products to health care practitioners and hospitals as 'office stock,' for

providers to have available and to use on an as-needed basis." *Id.*

28. Pursuant to Section 503B, "[a]n outsourcing facility remains exempt from the FDCA's premarket approval requirements and certain labeling and supply-chain requirements, but only if it satisfies eleven statutory criteria." *Id.* These criteria include, inter alia, requirements that: "(1) the drug is not 'essentially a copy of one or more approved drugs;' (2) the drug is not sold wholesale; and (3) the 'drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with Section 503B.'" *Imprimis*, 2017 WL 10526121, at *2 (internal alterations omitted) (citing 21 U.S.C. § 353b(a)).

29. Section 503B "specifically limits the types of drugs that can be compounded at outsourcing facilities" to "compound bulk drug substances that appear on (1) a list established by the FDA identifying bulk drug substances for which there is a clinical need (hereinafter sometimes referred to as the "503B bulks list"); or (2) a drug shortage list established by the FDA." *Id.*

30. An additional limitation is that the compounded drug must not be "essentially a copy of one or more approved drugs." 21 U.S.C. § 353b(a). Similar to Section 503A, Section 503B defines "essentially a copy of an approved drug" as "a drug, a component of which is a bulk drug substance that is 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 drug." 21 U.S.C. § 353b(d)(2)(B). "If a component of the compounded drug is a bulk drug substance that is also a component of an approved drug, the compounded drug product is essentially a copy of an approved drug, and cannot be compounded under Section 503B, unless there is a prescriber determination of clinical difference[.]" FDA Guidance on 503B "Essentially a Copy" Requirement.

31. If a compounder intends to rely on a "clinical difference statement" to establish that a compounded drug is not essentially copy of an approved drug, the statement is to be "noted on the prescription or order (which may be a patient-specific prescription or a non-patient specific order) for the compounded drug." *Id.* at 8. The statement is to "specif[y] the change between the compounded drug and the comparable approved drug and indicate[] that the compounded drug will be administered or dispensed only to a patient for whom the change produces a clinical difference, as determined by the prescribing practitioner for that patient." *Id.* at 9; 21 U.S.C. § 353b(d)(2)(B).

E. Compounding of Sodium Thiosulfate

32. Hope manufactures and sells a Sodium Thiosulfate Injection, an FDA-approved intravenous solution with sodium thiosulfate as its API, in a concentration of 12.5g/50mL. Final Pretrial Conf. Order at 2:7–9. Hope's Sodium Thiosulfate Injection is the only FDA-approved drug with sodium thiosulfate as an API. *Id.* at 2:10–11.

33. In 2012, the FDA approved Hope's Sodium Thiosulfate Injection as a treatment for acute cyanide poisoning. *Id.* at 2:12–13.

34. Defendants also manufacture and sell drugs containing sodium thiosulfate as an API. Deposition Testimony of T.J. Bresnahan and Carl Woetzel. Defendants have always used the same formulation for their sodium thiosulfate drugs. *Id.* Defendants' sodium thiosulfate drugs contain the same API as Hope's Sodium Thiosulfate Injection, in the same concentration as in Hope's Sodium Thiosulfate Injection. *Id.*; Trial Testimony of Dr. Sherman.

35. Defendants have not applied for or received approval for their sodium thiosulfate drugs from the FDA, any state, or any state agency. Final Pretrial Conf. Order at 2:17–18; Trial Testimony of Jason McGuire.

36. Defendants claim to manufacture and sell their sodium thiosulfate drugs under the FDA regulations for compounding. The federal requirements for drug compounding are set forth in FDCA Sections 503A and 503B, as described above.

37. From September 2014 until the present, the 503B defendants operated two outsourcing facilities in Wichita, Kansas that prepared compounded sodium thiosulfate drugs which they claimed to be exempt from FDA approval under Section 503B. Deposition Testimony of Carl Woetzel. The 503B defendants compounded their sodium thiosulfate drugs in their outsourcing facilities after the enactment of Section 503B, 21 U.S.C. § 353b, and the 503B defendants' registration as outsourcing facilities. Final Pretrial Conf. Order at 3:11–12.

38. During the same time period, Anazao operated a "compounding pharmacy" in Tampa, Florida, that

prepared compound sodium thiosulfate drugs which it claimed to be exempt from FDA approval under Section 503A. Deposition Testimony of T.J. Bresnahan. The sodium thiosulfate drugs Anazao compounded in its Tampa pharmacy have not been approved by the FDA, any state, or any state agency. Final Pretrial Conf. Order at 2:21–22.

F. Sale of Sodium Thiosulfate

39. Dialysis clinics purchase medications containing sodium thiosulfate for use in treating calciphylaxis in dialysis patients. Trial Testimony of Dr. Sherman.

40. During the period from September 2014 to the present, Hope sold its Sodium Thiosulfate Injection to customers throughout the United States, including to dialysis clinics in the five states. Trial Testimony of Dr. Sherman; Exh. 683. Defendants' two largest customers of its sodium thiosulfate drug are dialysis providers Fresenius and DaVita. Final Pretrial Conf. Order at 2.

41. From November 2017 until at least November 2019, Anazao sold a sodium thiosulfate drug from its 503A compounding pharmacy in Tampa, Florida, to dialysis providers (including to dialysis companies located in each of the five states). Exhs. 582, 610.

42. During the period from September 2014 to the present, the 503B defendants sold sodium thiosulfate drugs to dialysis providers Fresenius and DaVita in each of the five states. Exhs. 540, 540A, 693, 693A.

43. Before September 2018, Fresenius ordered sodium thiosulfate drugs pursuant to a company-wide

policy that "[s]odium thiosulfate is ordered through JCB Laboratories." Exhs. 517–518.

44. Before September 2018, DaVita purchased all of its sodium thiosulfate drugs from defendants and did not purchase Hope's FDA-approved Sodium Thiosulfate Injection. Trial Testimony of Dr. Sherman; Exhs. 540, 540A.

45. During the period October 2018 to March 2019, the 503B defendants stopped selling compounded sodium thiosulfate drugs after defendants' compounded sodium thiosulfate failed quality inspections due to the presence of visible particulates in vials of the medication. Exhs. 540A, 867, 881, 887–888.

46. From October 2018 to March 2019, when the 503B defendants were not selling compounded sodium thiosulfate drugs, Fresenius and DaVita turned to Hope for their sodium thiosulfate drug needs to the extent those needs could not be met by Anazao. Trial Testimony of Dr. Sherman; Exhs. 610, 835, 870.

47. In October 2018, Fresenius's senior manager for pharmaceutical sourcing and analytics told defendants that Fresenius would "take a financial hit of $500K to $900K if [Fresenius had] to go through Hope Pharma and this situation [the unavailability of Defendants' compounded STS] goes 4 to 8 weeks." Exh. 528.

48. In November 2018, this same Fresenius executive wrote that if defendants "can't meet all our demands," certain Fresenius clinics would have to "order from Hope at significantly higher cost." Exh. 529. And in the same email chain, he wrote: "The

challenge we will have is if only a small portion of our demand can be met by Anazao (10%?) how I can juggle sending some clinics to Anazao and the remainder over to Hope Pharma . . ." *Id.*

49. In comparison with the seven-month period from September 2018 to March 2019, when the 503B defendants were largely out of the market for STS, and the seven-month period that preceded it, Hope's sales of sodium thiosulfate were 44% higher in California, 146% higher in Connecticut, 67% higher in Florida, 134% higher in South Carolina, and 118% higher in Tennessee. Exh. 883; Exh. 835; Trial Testimony of Dr. Sherman.

50. In September 2020, DaVita decided to "not us[e defendants'] product going forward." Deposition Testimony of Dr. George Aronoff.

51. Defendants' sodium thiosulfate drug has been out of stock at other times, including September 2020 and June 2021. Trial Testimony of Jason McGuire. During those times, Fresenius clinics have ordered sodium thiosulfate from Hope. Trial Testimony of Dr. Sherman.

52. Some purchasers of defendants' sodium thiosulfate drugs have confused defendants' sodium thiosulfate drugs with Hope's Sodium Thiosulfate Injection. In May 2019, an employee of a Tennessee medical facility sent faxes and emails to Hope, asking about the status of a late shipment of defendants' sodium thiosulfate drugs. Trial Testimony of Dr. Sherman; Exh. 853. The purchase order number indicated that this order had actually been placed with JCB, not with Hope. *Id.* Hope has also received orders

for defendants' compounded sodium thiosulfate drugs and inquiries about orders that had been placed with defendants. Trial Testimony of Dr. Sherman; Exhs. 852, 926.

G. Facts Relevant to Defendants' Violation of 503A

53. The sodium thiosulfate drug produced in Anazao's Tampa pharmacy has the same API, the same dosage strength (12.5gm/50mL), and the same route of administration (intravenous injection) as Hope's Sodium Thiosulfate Injection. Deposition Testimony of T.J. Bresnahan; Trial Testimony of Dr. Sherman; Exh. 617.

54. With respect to the 63 orders for DaVita filled by Anazao based on prescriptions, while a handful of prescriptions contain language that may indicate that the prescriber identified a preference for a compounded potassium-free product, the prescriptions do not specifically identify the relevant change nor the significant difference that change will produce for individual patients. Exh. 925. Moreover, the majority of the prescriptions did not contain any language suggesting that the prescriber had indicated any preference for potassium-free or compounded products. Exh. 925; Trial Testimony of Sue Heinemann.

55. The forms created by defendants for Fresenius contain the pre-printed statement: "By submitting this prescription, you acknowledge that you have evaluated commercially available drug product options and determined that this compounded preparation is clinically necessary for the patient

identified above." Exh. 588. Anazao filled 231 orders for Fresenius based on these forms. Exh. 582.

56. According to the testimony of Anazao's Rule 30(b)(6) designee and President, when the 503B defendants halted their production of sodium thiosulfate drugs in September 2018, Anazao began compounding a potassium-free product that Anazao claimed to be necessary for some patients "based on Fagron and JCB's historical volumes of sodium thiosulfate sales." Deposition Testimony of T.J. Bresnahan. Anazao "ramped up whatever [Anazao] could to satisfy their [Fagron's and JCB's] patient needs" during this time period. *Id.*

H. Facts Relevant to Defendant's Violation of 503B "Bulks List"

57. Bulk sodium thiosulfate has never appeared on the 503B bulks list, and Hope's Sodium Thiosulfate Injection has not appeared on the drug shortage list. 21 U.S.C. § 353b(a)(2)(A).

58. While developing the 503B bulks list, however, the FDA issued an interim policy stating that it "does not intend to take action against an outsourcing facility for compounding a drug using a bulk drug substance . . . if, among other conditions, the substance appears on a list of 'Category 1' substances that are currently under evaluation." Exh. 551; *Athenex Pharma Cols., LLC v. Par Pharm., Inc.*, 2019 WL 4511914, at *2 (W.D.N.Y. July 9, 2019). Sodium thiosulfate appeared on the FDA's Category 1 list from October 30, 2019 to July 31, 2020. Final Pretrial Conf. Order at 3:15–16.

59. From August 2019 until October 30, 2019, STS appeared on the Category 3 list, which includes substances nominated to the 503B bulks list without sufficient supporting information. Dkt. 151 at 16–17. There is no similar FDA exception for drugs listed on the Category 3 list as there is for drugs listed on the Category 1 list. *Id.*

60. On July 31, 2020, the FDA published a Notice in the Federal Register, proposing that sodium thiosulfate not be included on the 503B bulks list because it "f[ound] no basis to conclude that there is a clinical need for outsourcing facilities to compound drug products using . . . sodium thiosulfate." Exh. 570; 85 Fed. Reg. 46139, 46141 (July 31, 2020). The FDA rejected as "inaccurate" the claim that the potassium in "the FDA-approved product makes it medically unsuitable to treat patients with calciphylaxis." *Id.* at 46139.

I. Facts Relevant to Defendants' Violation of 503B "Essentially a Copy" Provision

61. In 2017, defendants became concerned that their sodium thiosulfate drug may be found to be "essentially a copy" of Hope's Sodium Thiosulfate Injection in violation of FDCA Sections 503A and 503B. Exh. 616. Defendants explored several approaches to justify selling their sodium thiosulfate compounded drug, including changing their sodium thiosulfate's formulation to be 10 percent different from Hope's drug; selling their drug in a 100 mL vial instead of the 50mL used by Hope, and asserting that Hope's drug might be dangerous because Hope offered its sodium thiosulfate drug in a package that also contained sodium nitrite. Exhs. 590, 616, 628, 860.

62. In September 2017, Jason McGuire, Fagron's Vice President of Quality and Regulatory, decided that Fagron could use the presence of potassium in Hope's product to justify the compounding and sale of defendants' drug to dialysis clinics. Defendants did not present evidence that any prescribing practitioner approached defendants requesting a potassium-free version of sodium thiosulfate. Trial Testimony of Jason McGuire.

63. However, upon discussions with defendants, business executives at the dialysis clinics operated by Fresenius and DaVita wrote to the FDA describing a professed need for a potassium-free sodium thiosulfate injection at their dialysis clinics. Exhs. 24, 26. One of these executives, Dr. George Aronoff, Vice President of Clinical Affairs at DaVita Kidney Care, is not a prescribing practitioner. Exh. 26; Deposition Transcript of Dr. George Aronoff. Similarly, the other executive, Dr. Jeffrey L. Hymes, the Senior Vice President for Fresenius Kidney Care, is also not a prescribing practitioner. Exh. 24; Deposition Testimony of Dr. Hymes.

64. Defendants never received any attestation form or other clinical difference statement signed by a prescribing practitioner or a person authorized to act on a practitioner's behalf at DaVita to support these sales. Deposition Testimony of Carl Woetzel; Trial Testimony of Jason McGuire and Sue Heinemann.

65. Defendants provided various attestation forms to Fresenius for Fresenius clinic personnel to sign beginning in September 2018. Exh. 923. No such forms existed at any time prior to September 2018. *Id.*

66. Defendants received two attestation forms from Fresenius clinic personnel in 2018. Neither attestation was signed by a prescribing practitioner or a person authorized to act on a practitioner's behalf. Exh. 923; Trial Testimony of Sue Heinemann.

67. Defendants received 42 attestation forms signed by Phu Pham, a Fresenius employee who works at a Fresenius finance center, dated between April 2, 2019 and October 22, 2019. *Id.*

68. In October 2019, defendants received four blanket attestation forms (forms which included attestations for multiple facilities) and one additional blanket attestation form dated December 30, 2019, signed by employees who work at Fresenius finance centers. *Id.*

69. In 2020, defendants received six more blanket attestation forms signed by employees who work at Fresenius finance centers. Exh. 923. These forms were signed by Phu Pham, Accounting Supervisor, and Keiola Peterson and Tamekka Grant, Accounting Representatives/IntelliOrder Coordinators. *Id.*; *see also* Exhs. 744, 745.

70. On July 9, 2020, Fagron requested from Fresenius three blanket attestations from each of Fresenius's East, West, and South Divisions. Exh. 702. In response, Fresenius sent the 503B defendants an attestation form dated July 7, 2020, on behalf of 422 Fresenius clinics in 20 states. Exh. 745. This attestation was signed by Keiola Peterson, a Fresenius Accounting Rep/Intelli-Order Coordinator. *Id.*

71. Starting in July 2020, after this Court issued its preliminary injunction, Fagron first received attestation forms from Fresenius signed by personnel on behalf of individual clinics: 177 between July 2020 and June 2021. Exh. 923; Trial Testimony of Sue Heinemann. With few exceptions, most of these personnel were not prescribing practitioners, nor was it apparent that they had the authority to act on behalf of a prescribing practitioner. After the preliminary injunction was issued, defendants also modified the language of their attestation forms to include additional statements regarding potassium and clinical difference, as described below. *See* Exh. 923.

72. Prior to the issuance of the preliminary injunction, defendants' attestation forms contained language such as: "By signing this document, the signatory hereby attests that he/she has the authority to speak on behalf of practitioners who will administer the compounded preparation(s) to which this attestation applies. Additionally, by signing this document, the signatory hereby attests that the compounded preparation(s) to which this attestation applies will only be administered to patients for whom the practitioner determines will produce a clinical difference from the comparable approved drug product, as described more fully in the applicable attestation below." Exhs. 695–696. The forms go on to state, for the drugs listed therein, including sodium thiosulfate, "in my professional judgment, this compounded product provides clinical and safety benefits relative to the comparable commercially available drug products, which is medically necessary for patients who require this compounded formulation." *Id.*

73. Prior to the issuance of the preliminary injunction, none of the attestation forms received by the 503B defendants were signed by a person whose title clearly indicates they had prescribing authority. Exh. 923–1 through 923–213; Trial Testimony of Sue Heinemann.

74. After the Court issued the preliminary injunction, Fagron modified its attestation forms. Defendants' modified attestation form V2020-03 states:

> "The compounded Sodium Thiosulfate injection solution is free of boric acid and potassium chloride compared to comparable commercially available drug products. In my professional judgement, this compounded product provides clinical and safety benefits relative to the comparable commercially available drug products, which is medically necessary for patients who require this compounded formula." Exh. 923-215.

Defendants modified the language of the attestation again in V2021-01 to include the phrase: "in the professional judgement of the prescriber . . ." Exh. 923–947.

Additionally, after the preliminary injunction, the majority of the clinic attestation forms were signed by registered nurses and clinical managers rather than accounting supervisors. *See* Exh. 923 at 229, 237, 253, 313, 329, 345, 353, 427.

III. CONCLUSIONS OF LAW

1. Hope bears the burden of proving by a preponderance of the evidence each element of its claims. *S. Cal. Gas Co. v. City of Santa Ana*, 336 F.3d 885, 888 (9th Cir. 2003). Defendants bear the burden of proving each element of their defenses. The Court finds and concludes that Hope has met its burden of proof with respect to its claim that defendants' distribution and sale of sodium thiosulfate drugs violated the FDCA and did not come within the exceptions provided by Sections 503A or 503B, and that defendants have not established any valid defenses.

B. Conclusions of Law Related to Section 503A

2. The Court finds and concludes that the prescription forms produced by Anazao do not contain qualifying significant difference statements because the forms do not reflect "a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product." 21 U.S.C. § 353a(b)(2).

3. With respect to the 63 orders by DaVita filled by Anazao between December 2017 and October 2019, while a few of the prescriptions contain language that appears to indicate that the prescriber identified a preference for a potassium-free or compounded product, the prescriptions do not explicitly state that the prescriber identified a change between the compounded drug and the comparable approved drug and the significant difference that the change will

produce for the patient. Exh. 925. Moreover, the majority of the DaVita prescriptions do not contain any language suggesting that the prescriber has indicated a preference for a potassium-free or compounded product. Exh. 925; Trial Testimony of Sue Heinemann.

4. The sodium thiosulfate drug manufactured and sold by Anazao's 503A pharmacy is "essentially a copy of" Hope's Sodium Thiosulfate Injection, "a commercially available product." 21 U.S.C. § 353a(b). Therefore, Anazao could not compound defendants' sodium thiosulfate drug consistent with Section 503A's essentially a copy prohibition unless "there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product." 21 U.S.C. § 353a(b)(2).

5. The Court finds and concludes that Anazao did not compound its sodium thiosulfate drug consistent with Section 503A's "essentially a copy" prohibition. Anazao fulfilled orders for Fresenius which contained generic statements in a pre-printed form stating that purchasers "acknowledge that [they] have evaluated commercially available drug product options and determined that this compounded preparation is clinically necessary for the patient identified above." Exh. 588. These statements do not reflect "a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable

commercially available drug product." 21 U.S.C. § 353a(b)(2).

6. The Court further finds and concludes that Anazao compounded its sodium thiosulfate drug "regularly or in inordinate amounts." 21 U.S.C. § 353a(b). Anazao compounded its sodium thiosulfate drug "regularly" because it did so "at regular times or intervals, usually or very often." FDA Guidance on 503A "Essentially a Copy" Requirement at 10. Anazao also compounded its sodium thiosulfate drug "in inordinate amounts" because it did so "more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances." *Id.*

7. Because Anazao compounded "regularly or in inordinate amounts" a drug that was "essentially a copy" of Hope's Sodium Thiosulfate Injection, Anazao's compounding of sodium thiosulfate was not exempted from the requirements for FDA premarket approval. 21 U.S.C. § 355.

8. Anazao's compounding of sodium thiosulfate was not exempt from FDA premarket approval under Section 503A because Anazao did not compound its sodium thiosulfate drug "based on a history of the licensed pharmacist . . . receiving valid prescription orders for the compounding of the drug product" based on an "established relationship" between the pharmacist and either the patient or the prescribing physician. 21 U.S.C. 353a(a)(2).

9. In September 2018, when the 503B defendants stopped manufacturing their sodium thiosulfate drug,

Anazao began compounding based on the 503B defendants' historical sales volume, not based on Anazao's pharmacists "receiving valid prescription orders . . . generated solely within an established relationship between" Anazao's pharmacists and the "individual patient for whom the prescription order will be provided" or "the physician or other licensed practitioner who will write such prescription order." 21 U.S.C. § 353a(a)(2)(B). Rather, Anazao "ramped up" as fast as it could "to satisfy [Fagron and JCB's] patient needs." Deposition Testimony of T.J. Bresnahan. These sales thus did not comply with Section 503A.

C. Conclusions of Law Related to Section 503B "Essentially a Copy" Provision

10. The Court concludes that the 503B defendants sold in the five states a sodium thiosulfate drug that has not received approval from the FDA, any state, or any state agency.

11. The Court concludes that the sodium thiosulfate drug manufactured and sold by the 503B defendants is "essentially a copy" of Hope's Sodium Thiosulfate Injection, an "approved drug[]." 21 U.S.C. § 353b(a).

12. The 503B defendants did not compound their sodium thiosulfate drug based upon prescriber determinations of clinical difference.

13. Defendants' blanket attestation forms do not take defendants' sodium thiosulfate drug outside of the prohibition against selling drugs that are essentially a copy of commercially available drugs. These forms were not signed or authorized by

prescribing practitioners for the patients, nor do they reflect that "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)(B).

14. The vast majority of attestations provided to 503B defendants from Fresenius were not made by patients' prescribing practitioner and thus do not take defendants' sodium thiosulfate drug outside the prohibition against selling drugs that are essentially a copy of commercially available drugs. Most of the attestations were signed by accounting supervisors without the authority to make medication-related decisions. Exh. 923. Even after defendants began obtaining attestations signed by clinical personnel, many were not signed by practitioners with prescribing authority, and many of those that were signed by clinic personnel did not sufficiently document that they had authority to speak on behalf of physicians who had prescribed sodium thiosulfate drugs for their patients. *Id.*

15. With respect to DaVita's purchases of the 503B defendants' sodium thiosulfate drugs, the 503B defendants received no determinations of clinical difference at all with respect to those purchases. As such, none of DaVita's purchases satisfied the "essentially a copy requirement" of 503B.

16. Defendants submitted evidence intended to show that their sodium thiosulfate drug has a clinical difference for at least some dialysis patients because defendants' STS drug does not include potassium, while Hope's Sodium Thiosulfate Injection includes

potassium as an excipient. Trial Testimony of Jason McGuire. Hope presented evidence that defendants explored several bases for avoiding the "essentially a copy" prohibition prior to arriving at their claimed absence of potassium approach. Exhs. 590, 616, 628, 860. The Court need not resolve whether the absence of potassium might make a clinical difference for some patients, because even if it did, defendants failed to prove that they produced and sold their sodium thiosulfate drug pursuant to a determination by a prescribing practitioner that there is "a change that produces for an individual patient a clinical difference . . . between the compounded drug and the comparable approved drug." 21 U.S.C. § 353b(d)(2)(B).

17. The relevant question under Section 503B is not whether defendants' sodium thiosulfate drug could have a clinical difference from Hope's Sodium Thiosulfate Injection for some patients, but rather whether the prescribing practitioner has made a determination of "a clinical difference . . . between the compounded drug and the comparable approved drug." *Id.* There is no such statement of clinical difference as determined by a prescribing practitioner submitted with most of Fresenius's attestation forms.

18. After this Court issued its preliminary injunction, defendants sought to obtain individual attestation forms instead of blanket attestations forms from Fresenius in order to comply with the injunction. Exh. 923. Additionally, defendants modified the language of their clinical difference statement for sodium thiosulfate on their template attestation forms to emphasize the necessity of an absence of potassium. *Id.* However, regardless of these

changes, only a small number of these forms signed after the preliminary injunction was issued were signed by a prescribing practitioner or someone who had the authority to act on behalf of a prescribing practitioner. *Id.*

C. Conclusions of Law Related to 503B "Bulks List"

19. Before the FDA added sodium thiosulfate to its Category 1 list on October 30, 2019, the compounded drugs produced in the 503B defendants' outsourcing facilities were not exempted from the premarket approval requirement, 21 U.S.C. § 355, because they were made in an outsourcing facility and used bulk drug substances for which the Secretary of Health and Human Services had not determined there is a clinical need for use in compounding. 21 U.S.C. § 353b(a)(2)(A).

20. The FDA's Interim Policy on Compounding states that "the FDA does not intend to take action against an outsourcing facility for compounding a drug using a bulk drug substance that does not appear on the 503B bulks list" if the drug meets certain conditions including that it appears on the 503B Category 1 List and "is compounded in compliance with all other provisions of section 503B." *Id.* at 8.

21. Regardless of whether defendants' compounding and sale of their sodium thiosulfate drugs between October 30, 2019 and July 31, 2020 while Sodium Thiosulfate was on the Category 1 List satisfied the Section 503B bulks list requirement, the defendants were in violation of the other provisions of Section 503B. Because almost all of the attestations

defendants' received failed to include a clinical difference statement signed or approved by a prescribing practitioner, defendants violated the "essentially a copy" provision of Section 503B during the period from September 2014 to the present, including the period from October 30, 2019 to July 31, 2020 when Sodium Thiosulfate was on the Category 1 List.

E. Conclusions of Law Related to California's UCL

22. Hope has satisfied its burden of proving by a preponderance of the evidence that defendants violated California's UCL, as alleged by Hope.

23. To succeed on its UCL claim, Hope must prove (1) defendants engaged in an unlawful, unfair, or fraudulent business act or practice, (2) Hope suffered a loss or deprivation of money, and (3) the economic injury was caused by the defendants' unlawful or unfair business practice. *Kwikset Corp. v. Superior Ct.*, 51 Cal. 4th 310, 322 (2011); *Lippitt v. Raymond James Fin. Servs., Inc.*, 340 F.3d 1033, 1043 (9th Cir. 2003).

24. The Court concludes that defendants' conduct was "unlawful" under the UCL because it violated California's Sherman Law. The UCL's "unlawful" prong incorporates and makes independently actionable violations of other state statutes, including the Sherman Law. *Allergan USA, Inc. v. Imprimis Pharm., Inc.*, 2017 WL 10526121, at *12 (C.D. Cal. Nov. 14, 2017).

25. The Sherman Law provides that "[n]o person shall sell, deliver, or give away any new drug" unless (1) "a new drug application has been approved for it

. . . under [FDCA] Section 505" or (2) California "has approved a new drug . . . application for that new drug." Cal. Health & Safety Code § 111550(a)-(b). Defendants violated the Sherman Law because, they sold in California their sodium thiosulfate drug, which has neither been approved by the FDA "under [FDCA] Section 505," nor by California. *Id.*

26. For the reasons given above, defendants violated the FDCA because their compounding and sale of their sodium thiosulfate drug were not made pursuant to an approved application or an exception to such approval.

27. Hope suffered a loss or deprivation of money caused by defendants' unlawful conduct. "When two competitors split a market, such that one's lost sales are likely the other's gains, . . . 'it is reasonable to presume that every dollar defendant makes has come directly out of plaintiff's pocket.'" *K&N Eng'g, Inc. v. Spectre Performance*, 2012 WL 12893797, at *6 (C.D. Cal. Aug. 2, 2012).

28. Here, because Hope and defendants were the only providers of sodium thiosulfate drugs, this presumption supports a finding that defendants' sales caused Hope to lose at least some sales that Hope would have made but for defendants' unlawful conduct. The Court thus finds that defendants caused Hope financial loss in the form of lost sales of Hope's Sodium Thiosulfate Injection.

29. The Court finds and concludes that defendants violated the UCL and plaintiffs are thus entitled to declaratory and equitable relief under the UCL. Notably, under the UCL, a plaintiff is not entitled to

damages or disgorgement when the profits realized by the defendants are not derived from property taken from the plaintiff. *Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal. 4th 1132 (2003) (holding that disgorgement of profits realized by a competitor is not a restitutionary remedy).

F. Conclusions of Law Related to FDUTPA

30. Hope has satisfied its burden of proving by a preponderance of the evidence that defendants violated FDUTPA, as alleged by Hope.

31. To succeed on its claim under FDUTPA, Hope must prove (1) that defendants engaged in unfair or deceptive practice, (2) causation, and (3) actual damages. *Glob. Tech Led, LLC v. Hilumz Int'l Corp.*, 2017 WL 588669, at *8 (M.D. Fla. Feb. 14, 2017); *Wright v. Emory*, 41 So. 3d 290, 292 (Fla. 4th DCA 2010)).

32. Defendants' conduct was "unfair" under FDUTPA. Under FDUTPA, a business practice is "unfair" if it "'offends [Florida's] established public policy.'" *State Farm Mut. Auto Ins. Co. v. Performance Orthopaedics & Neurosurgery, LLC*, 278 F. Supp. 3d 1307, 1326 (Fla. 4th DCA 2010). Here, that public policy is expressed in the Florida Drug and Cosmetic Act, which provides that "[a] person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the [FDCA] or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce." Fla Stat. § 499.023.

33. For the reasons given above, defendants violated the FDCA because their compounding and sale of their sodium thiosulfate drug were not made pursuant to an approved application or an exception to such approval.

34. Defendants argue that Hope must prove that defendants' conduct has caused harm to Florida consumers. Assuming that FDUTPA requires Hope to prove consumer harm, the Court finds that Hope has done so. Hope has proven that defendants' sales have caused at least some consumer confusion as to the source of defendants' sodium thiosulfate drugs. Consumer confusion qualifies as consumer harm under FDUTPA. *Wyndham Vacation Resorts, Inc. v. Timeshares Direct, Inc.*, 123 So. 3d 1149, 1152 (Fla. DCA 2012). In addition, the sale of a product that is unlawfully on the market qualifies as consumer harm under FDUTPA. *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019).

35. Hope is entitled to declaratory and equitable relief under the FDUTPA. However, because Hope chose to waive any claims for damages and only seeks equitable restitution of ill-gotten profits, Dkt. 341, and because damages were available as an adequate remedy at law under the FDUTPA, the Court finds and concludes that Hope is not entitled to equitable restitution under the FDUTPA. *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 845 (9th Cir. 2020).

G. Conclusions of Law Related to TCPA

36. Hope has satisfied its burden of proving by a preponderance of the evidence that defendants violated TCPA, as alleged by Hope.

37. To succeed on its TCPA claim, Hope must prove (1) defendants engaged in an unfair or deceptive act or practice declared unlawful by the TCPA and (2) defendants' conduct caused an "ascertainable loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value wherever situated." *Tucker v. Sierra Builders*, 180 S.W.3d 109, 115 (Tenn. Ct. App. 2005) (citing Tenn. Code Ann. § 47-18-109(a)(1)).

38. Defendants' conduct was "unfair" under TCPA. The TCPA provides that "advertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state" is unfair or deceptive. Tenn. Code Ann. § 47-18-104(b)(44)(C). The Court finds that defendants' sodium thiosulfate drug was "illegal or unlawful" to sell in Tennessee because the Tennessee Food, Drug and Cosmetic Act prohibits the sale of "any new drug unless an application with respect to the drug has become effective under § 505 of the [FDCA]." Tenn. Code Ann. § 53-1-110(a). Because defendants' sodium thiosulfate drug was not approved "under § 505," *id.*, the Court finds it was unlawful to sell those drugs in Tennessee under the Tennessee Food, Drug and Cosmetic Act.

39. For the reasons given above, defendants violated the FDCA because their compounding and sale of their sodium thiosulfate drug were not made pursuant to an approved application or an exception to such approval.

40. Defendants' conduct caused Hope an "ascertainable loss of money or property," *Tucker*, 180

S.W.3d at 115, in the form of lost sales as explained above.

41. Hope is entitled to declaratory and equitable relief under the TCPA. However, because Hope chose to waive any claims for damages and only seeks equitable restitution of defendants' ill-gotten profits, Dkt. 341, and because damages were available as an adequate remedy at law under the TCPA, the Court finds and concludes that Hope is not entitled to equitable restitution under the TCPA. *Sonner*, 971 F.3d at 845.

H. Conclusions of Law Related to SCUTPA

42. Hope has satisfied its burden of proving by a preponderance of the evidence that defendants violated SCUTPA, as alleged by Hope.

43. To succeed on its SCUTPA claim, Hope must prove that (1) defendants engaged in an unfair or deceptive trade practice, (2) Hope suffered actual, ascertainable losses as a result of the defendants' use of the unlawful trade practice, and (3) the unlawful trade practice engaged in by the defendants had an adverse impact on the public interest. *Williams v. Quest Diagnostics, Inc.*, 353 F. Supp. 3d 432, 450 (D.S.C. 2018).

44. Defendants' conduct was "unfair" under SCUTPA. Under SCUTPA, a business practice is "unfair" if it offends South Carolina's "public policy created by . . . legislative enactments." *Id.* Here, that public policy is expressed in the South Carolina Drug Act, which provides that "[n]o person shall introduce or deliver for introduction into intrastate commerce any new drug unless" the South Carolina

Commissioner of Health and Environmental Control has approved the drug or "an application with respect thereto has been approved . . . under Section 505 of the [FDCA]." S.C. Code § 39-23-70(a)-(b). Defendants violated the South Carolina Drug Act because they sold in South Carolina their sodium thiosulfate drug, which had not been approved by the Commissioner or by the FDA "under Section 505 of the [FDCA]." *Id.*

45. For the reasons given above, defendants violated the FDCA because their compounding and sale of their sodium thiosulfate drug were not made pursuant to an approved application or an exception to such approval.

46. The Court further finds that defendants' conduct caused Hope actual, ascertainable losses in the form of lost sales as explained above.

47. Finally, defendants' conduct had an adverse impact on the public interest. "An impact on the public interest may be shown if the acts or practices have the potential for repetition." *Williams*, 353 F. Supp. 3d at 450. "Potential for repetition may be demonstrated, among other ways, by showing that (1) the same kind of actions occurred in the past, thus making it likely they will continue to occur absent deterrence, and (2) the company's procedures create a potential for repetition of the unfair and deceptive acts." *Id.* In light of defendants' conduct following the issuance of the preliminary injunction, and defendants' prior conduct, the Court finds that there is a potential for repetitive, unfair, and deceptive action.

48. Hope is entitled to declaratory and equitable relief under the SCUTPA. However, because Hope

chose to waive any claim for damages and only seeks equitable restitution of ill-gotten profits, Dkt. 341, and because damages were available as an adequate remedy at law under the SCUTPA, the Court finds and concludes that Hope is not entitled to equitable restitution under the SCUTPA. *Sonner*, 971 F.3d at 845.

I. Conclusions of Law Related to CUTPA

49. Hope has satisfied its burden of proving by a preponderance of the evidence that defendants violated CUTPA as alleged by Hope.

50. To succeed on its CUTPA claim, Hope must prove that (1) defendants' conduct was in the course of their primary trade or commerce; (2) the conduct, "without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise," meaning that it (a) "is within at least the penumbra of some common law, statutory, or other established concept of unfairness"; (b) "is immoral, unethical, oppressive, or unscrupulous"; or (c) "causes substantial injury to consumers, [competitors or other businesspersons]"; and (3) Hope suffered "any ascertainable loss of money or property, real or personal, as a result of the use or employment of a [prohibited] method, act or practice." *Ulbrich v. Groth*, 310 Conn. 375, 409–10 (2013).

51. The Court finds defendants' conduct was in the course of their primary trade or commerce. Defendants' conduct "offend[ed] public policy as it has been established by statutes," *id.*, specifically Connecticut's Food, Drug and Cosmetic Act, which

provides that "[n]o 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 [FDCA]." Conn. Gen. Stat. § 21a-110. "Section 355 of the [FDCA]," as referenced in this statute, is Section 505 of the FDCA, and is codified at 21 U.S.C. § 355. Accordingly, defendants violated the Connecticut Food, Drug, and Cosmetic Act by selling in Connecticut their sodium thiosulfate drug, which has not been "approved under Section 355 of the [FDCA]." Conn. Gen. Stat. § 21a-110.

52. For the reasons given above, defendants violated the FDCA because their compounding and sale of their sodium thiosulfate drug were not made pursuant to an approved application or an exception to such approval.

53. Defendants' conduct caused Hope an "ascertainable loss of money or property," in the form of lost sales as explained above. *Ulbrich*, 310 Conn. at 409–10.

54. Hope is entitled to declaratory and equitable relief under the CUTPA. However, because Hope chose to waive any claim for damages and only seeks equitable restitution of ill-gotten profits, Dkt. 341, and because damages were available as an adequate remedy at law under the CUPTA, the Court finds and concludes that Hope is not entitled to equitable restitution under the CUPTA. *Sonner*, 971 F.3d at 845.

J. Conclusions of Law Related to Defendants' Defenses

55. Defendants pled eight affirmative defenses in their answer. Dkt. 35. Five of those claimed defenses, however, are not affirmative defenses. "[A] defense is an affirmative defense if it will defeat the plaintiff's claim even where the plaintiff has stated a prima facie case for recovery under the applicable law." *Quintana v. Baca*, 233 F.R.D. 562, 564 (C.D. Cal. 2005). If a defense "directly attacks the merits of the plaintiff's case," it is not an affirmative defense. *Id.* The Court concludes that the following defenses pleaded by defendants are not affirmative defenses:

(1) Third Defense: Failure to Mitigate;

(2) Fifth Defense: Acts of Plaintiff;

(3) Sixth Defense: Actions of Others;

(4) Seventh Defense: Lack of Standing; and

(5) Eighth Defense: FDA Authority.

See Vogel v. Huntington Oaks Delaware Partners, LLC, 291 F.R.D. 438, 442 (C.D. Cal. 2013) (lack of standing is not an affirmative defenses); *Microsoft Corp. v. Motorola, Inc.*, 963 F. Supp. 2d 1176, 1188-89 (W.D. Wash. 2013) (failure to mitigate is not an affirmative defense); *578539 B.C., Ltd. v. Kortz*, 2014 WL12572679, at *7–8 (C.D. Cal. Oct. 16, 2014) (lack of causation and failure to mitigate are not proper affirmative defenses); *Surface Supplied, Inc. v. Kirby Morgan Dive Sys., Inc.*, 2013 WL 5496961, at *3 (N.D. Cal. Oct. 3, 2013) (failure to mitigate is not an affirmative defense).

56. The Court finds that these five defenses, even if treated as affirmative defenses, are without merit. The Court has found that defendants' unlawful conduct caused Hope's injuries, and it therefore rejects defendants' "acts of plaintiff," "actions of others," and "lack of standing" defenses. Additionally, defendants fail to explain what conduct by Hope constitutes a failure to mitigate damages beyond stating that Hope did not seek to "obtain[] FDA approval for its Sodium Thiosulfate Injection to treat calciphylaxis." Dkt. 394. Defendants have provided no authority as to why Hope's failure to obtain approval for its Sodium Thiosulfate Injection for treating calciphylaxis has any bearing on Hope's ability to recover damages. The Court notes that during trial, counsel for Fagron admitted that the fact that Hope's Sodium Thiosulfate Injection was approved only for treating cyanide poisoning and the use for dialysis is an off-label use does not affect defendants' obligations under Sections 503A and 503B. Dkt. 397 at 53-54. However, because Hope has waived any claims for damages, it does not appear Hope is seeking any relief that is subject to a mitigation defense. Moreover, this Court has already rejected defendants' "FDA Authority" defense, which the Court treats as a defense of preemption. Dkt. 141.

57. The Court also finds that the defenses of waiver, acquiescence, and estoppel are also without merit. Waiver requires (1) intentional relinquishment of a known right, (2) knowledge of the known right's existence, and (3) intent to relinquish it. *United States v. King Features Enter., Inc.*, 843 F.2d 394, 399 (9th Cir. 1988). Estoppel requires that (1) Hope knew the facts, (2) Hope intended its conduct to be acted on by defendants or acted such that defendants had a right

to believe that Hope intended its conduct to be acted upon, (3) defendants were ignorant of the true facts, and (4) defendants relied on Hope's conduct to its injury. *Id.* With respect to waiver, the Court finds that defendants have not proved that Hope intended to relinquish any known right. As for estoppel, the Court finds that defendants have not proved that Hope committed any conduct on which defendants could reasonably rely, that Hope intended its conduct to be relied on, that defendants were ignorant of the facts, or that defendants relied on any of Hope's conduct to its detriment.

58. Nor has defendant established laches as a defense in this case. Laches requires proof that (1) Hope unreasonably delayed in filing suit based on when it knew or should have known about defendants' conduct and (2) the delay prejudiced defendants. *AirWair Int'l, Ltd. v. Schultz*, 84 F. Supp. 3d 943, 955 (N.D. Cal. 2015). The Court finds that defendants have not proved that Hope unreasonably delayed in filing suit or that defendants were prejudiced by any delay.

59. Likewise, the defense of unclean hands is not available. Unclean hands requires proof that (1) Hope's conduct was inequitable and (2) Hope's inequitable conduct relates to the subject matter of its claims. *Pom Wonderful LLC v. Coca Cola Co.*, 166 F. Supp. 3d 1085, 1092 (C.D. Cal 2016). Defendants' unclean hands defense rests on its claim that Hope illegally promoted its Sodium Thiosulfate Injection for the off-label use of treating calciphylaxis. The subject-matter of Hope's claims relates to the illegal sale of a drug that has not been approved by FDA for any

purpose, not the off-label promotion of an approved drug for unapproved purposes. Even if off-label promotion could relate to the subject-matter of Hope's claims, the Court finds that defendants have not proved that Hope engaged in any unlawful off-label promotion. 21 C.F.R. § 312.7.

K. Conclusions of Law Related to Remedies Sought by Plaintiff

60. Hope seeks declaratory relief and injunctive relief under the laws of the five states; disgorgement of defendants' profits under FDUTPA, TCPA, SCUTPA, and CUTPA; and attorneys' fees under the laws of California, Florida, Tennessee, South Carolina, and Connecticut. The Court finds Hope is entitled to declaratory and injunctive relief. The Court finds Hope is not entitled to disgorgement nor attorney's fees.

61. As described below, the Ninth Circuit has held that in federal court, federal law governs whether equitable relief such as equitable restitution can be granted. *Sonner*, 971 F.3d at 843-845; *See also Davilla v. Enable Midstream Partners L.P.*, 913 F.3d 959, 972–73 (10th Cir. 2019) ("The Supreme Court has concluded that 'State law cannot define the remedies which a federal court must give'. . . .Thus, the practice of borrowing state rules of decision does not apply with equal force to determining appropriate remedies, especially equitable remedies, as it does to defining actionable rights.") (quoting *York*, 326 U.S. at 105, 65 S. Ct. 1464).

62. The federal Declaratory Judgment Act governs the availability of declaratory relief in federal

court. *In re Adobe Sys., Inc. Privacy Litig.*, 66 F. Supp. 3d 1197, 1219–20 (N.D. Cal. 2014). The federal Declaratory Judgment Act authorizes "any court of the United States, upon the filing of an appropriate pleading" to "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such." 28 U.S.C.A. § 2201(a).

Under the Declaratory Judgment Act, declaratory relief is permitted when there is a "substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotation marks omitted); *see Adobe*, 66 F. Supp. at 1220-23 (permitting declaratory relief claim in a UCL case). Here, the Court finds that Hope has adequately alleged the existence of an actionable dispute for purposes of the Declaratory Judgment Act as described above.

63. Hope is thus entitled to a declaration that defendants' conduct violated the UCL, FDUTPA, TCPA, CUTPA, and SCUTPA.

64. Hope is also entitled to injunctive relief under both federal and state law. The UCL, FDUTPA, TCPA, and CUTPA expressly authorize injunctive relief. Cal. Bus. & Prof. Code § 17203; Fla. Stat. § 501.211; Tenn. Code. Ann. § 47-18-109(b); Conn. Gen. Stat. § 42-110g(d); *see Chowning v. Kohl's Dept. Stores, Inc.*, 735 F. App'x 924, 924 (9th Cir. 2018) ("[i]njunctions are the primary form of relief available under the UCL")

(internal quotation marks omitted) (quoting *Kwikset Corp. v. Super. Ct.*, 51 Cal. 4th 310 (2011))); *B.J.'s Wholesale Club, Inc. v. Bugliaro*, 2021 WL 1395602, at *4 (Fla. DCA Apr. 14, 2021) ("One of the remedies available under FDUTPA is an injunction."); *Roberson*, 2006 WL 287389, at *5 ("[A] party who has been or is 'affected by a violation' of the TCPA may bring an action for a declaratory judgment and injunctive relief."); *Artie's Auto Body, Inc. v. Hartford Fire Ins. Co.*, 317 Conn. 602, 623 (2015) ("[CUTPA] provides for . . . injunctive or other equitable relief."). SCUTPA does not expressly mention injunctive relief, but the Court finds that it authorizes such relief. SCUTPA provides that its remedies "shall be cumulative and supplementary to all . . . remedies otherwise provided by law," S.C. Code § 39-5-160, which this Court reads to incorporate the well-established remedy of injunctive relief.

65. Moreover, the Ninth Circuit has held that "a state statute does not change the nature of the federal courts' equitable powers." *Sonner*, 971 F.3d at 842 (quoting *Life Assurance Co. v. LaPeter*, 563 F.3d 837, 843 (9th Cir. 2009). Therefore, injunctive relief must also be available under federal law. "[T]he decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts." *See eBay Inc. v. MercExchange, LLC.*, 547 U.S. 388, 391 (2006).

66. "Permanent injunctive relief is appropriate where liability has been established and the plaintiff demonstrates '(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for

that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.'" *Allergan USA Inc. v. Imprimis Pharm., Inc.*, 2019 WL 3029114, at *1 (C.D. Cal. July 11, 2019) (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 156–57 (2010)).

67. The Court finds that Hope has suffered an irreparable injury. Defendants' unlawful conduct has cost Hope customers and sales and, in the absence of an injunction, will continue to do so. Hope and defendants are the only two suppliers of sodium thiosulfate drugs in the United States, which is "a substantial ground for granting an injunction because it creates an inference that an infringing sale amounts to a lost sale" with respect to the other market participant. *Open Text, S.A. v. Box, Inc.*, 36 F. Supp. 3d 885, 906 (N.D. Cal. 2014). These injuries—"lost profits and customers, as well as damage to goodwill and business reputation"—constitute "irreparable injury." *Sennheiser Elec. Corp. v. Eichler*, 2013 WL 3811775, at *10 (C.D. Cal. July 19, 2013); *see also Herb Reed Enters., LLC v. Fla. Entm't Mgmt., Inc.*, 736 F.3d 1239, 1250 (9th Cir. 2013).

68. Hope's irreparable injuries cannot adequately be compensated with legal remedies. *See Anhing Corp. v. Thuan Phong Co.*, 2015 WL 4517846, at *23 (C.D. Cal. July 24, 2015) ("The terms 'inadequate remedy at law' and 'irreparable harm' describe two sides of the same coin. If the harm being suffered by plaintiff . . . is 'irreparable,' then the remedy at law (monetary damages) is 'inadequate.'"). While defendants' past

conduct can be repaired through monetary damages in the form of lost profits, defendants' future conduct cannot be repaired through a remedy at law. Defendants' unlawful conduct has continued since at least the enactment of the 2013 Drug Quality and Security Act amendment to the FDCA (including the Compounding Quality Act), and it is likely to continue in the future absent an injunction. Such "[c]ontinuous" unlawful conduct "leaves no other adequate remedy for the [p]laintiff aside from injunctive relief." *Daimler AG v. A-Z Wheels LLC*, 498 F. Supp. 3d 1282, 1294 (S.D. Cal. 2020); *see also MAI Sys. Corp. v. Peak Computer, Inc.*, 991 F.2d 511, 520 (9th Cir. 1993) ("As a general rule, a permanent injunction will be granted when . . . there is a threat of continuing violations.").

69. The Court finds the balance of hardships tips in favor Hope. Defendants' unlawful conduct, if allowed to continue, would cause Hope substantial hardship in the form of lost sales with respect to one of Hope's only three products. Indeed, Fresenius and DaVita in fact began purchasing Hope's Sodium Thiosulfate Injections for their off-label treatment of calciphylaxis when defendants temporarily stopped selling their sodium thiosulfate drugs. In contrast to Hope's harm, defendants are not likely to suffer relevant hardship from an injunction. Although the injunction may cost defendants some sales of its sodium thiosulfate drugs, that will only be true for unlawful sales. Because the injunction will "enjoin only acts that have already been determined to be unlawful. . . the balance of hardships weighs in favor of issuing a permanent injunction." *Oracle USA, Inc. v. Rimini Street, Inc.*, 324 F. Supp. 3d 1157, 1166 (D. Nev. 2018), *vacated in part on other grounds*, 783 F.

App'x 707 (9th Cir. 2019); *see Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013) (holding that the government "cannot suffer harm from an injunction that merely ends an unlawful practice").

70. Finally, the Court finds that the public interest will not be disserved by a permanent injunction. "[T]here is a public interest in upholding the law and having parties abide by their legal duties." Judge Virginia A. Phillips & Judge Karen L. Stevenson, *Federal Civil Procedure Before Trial* § 13:76.1 (2019). The five states have "chosen to pass . . . law[s] that parallel[] federal approval of . . . new drugs" and to "provide[] a limited mechanism for protecting against their distribution and production." *Imprimis*, 2019 WL 3029114, at *13. The "public interest is not disserved by enforcing these guidelines . . . to protect patients from the sale and distribution of drugs that are not produced in accordance with applicable requirements." *Id.* Additionally, the purpose of the restrictions on the sale of compounded drugs is to protect the public from the risks of those drugs:

> "[D]rugs compounded by outsourcing facilities have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process. Because they are subject to a lower regulatory standard, compounded drugs should only be distributed to health care facilities or dispensed to patients to fulfill the needs of patients whose

> medical needs cannot be met by an FDA-approved drug."

FDA Guidance on 503B "Essentially a Copy" Requirement at 9.

The FDA Guidance emphasizes the public safety interest in enforcing the use of compounded drugs only when they are medically necessary. Accordingly, this factor weighs in favor of granting the permanent injunction.

71. The Court thus concludes that Hope is entitled to permanent injunctive relief under the UCL, FDUTPA, TCPA, CUTPA, and SCUTPA.

72. Hope seeks equitable disgorgement of defendants' profits derived from their unlawful sales of sodium thiosulfate drugs under CUTPA, FDUTPA, TCPA, and SCUTPA. Hope does not seek disgorgement of defendant's profits under the UCL.

73. The Court finds and concludes that Hope is not entitled to disgorgement of defendants' profits under the laws of the other four states. Hope is not entitled to disgorgement of defendants' ill-gotten profits because by abandoning its damages claims, Hope has waived its right to seek equitable restitution. *See Sonner*, 971 F.3d at 845. This is especially the case here where Hope's claim of injury and measure of restitution is based on the sales defendants made which Hope claims would have been made by it but for defendants' unlawful conduct. However, Hope, by waiving a claim for damages, relinquished its claim for recovery of its lost profits based on its own lost sales.

74. In *Sonner*, the Ninth Circuit held that in federal court, federal law governs whether equitable relief such as equitable restitution can be granted. *Id.* at 843–45. Thus, if a party has an adequate remedy at law such as a claim for damages, that party is not entitled to equitable relief for claims in which an adequate remedy at law exists. *Id.* This is true even where under applicable state law, equitable restitution can be awarded without showing that the plaintiff lacks an adequate remedy at law. *Id.*

75. In *Sonner*, plaintiff asserted claims under the Consumer Legal Remedies Act ("CLRA") and California's Unfair Competition Law ("UCL"). *Id.* at 838. The CLRA expressly provided a damages remedy. *Id.* The *Sonner* plaintiff abandoned her damages claim under the CLRA just prior to trial in an effort to avoid a jury trial. *Id.* In plaintiff's complaint in *Sonner*, plaintiff never alleged that she lacked an adequate remedy at law. *Id.* at 844. Thereafter, the trial court ruled that the plaintiff had an adequate remedy at law under federal equity principles and she would not be entitled to seek equitable restitution. *Id.* When plaintiff attempted to reverse field, and sought to reassert her CLRA claim, the court denied plaintiff's request. *Id.* The Ninth Circuit affirmed. *Id.* at 845.

76. Similarly, in the present case, Hope disclaimed any claim for damages for purposes of avoiding a jury trial. Dkt. 341. As in *Sonner*, plaintiff had an adequate remedy at law available under the CUTPA, FDUTPA, TCPA, and SCUTPA.[1] CUTPA

[1] Hope argues that the legal remedy of damages for its lost profits available under the four state statutes is not an adequate remedy at law because a claim for damages could not compensate

plaintiff for loss of goodwill. Hope relies on *Francois & Co., LLC v. Nadeau*, No. 5:18-cv-00843-DSF(PLAx), 2019 WL 994402, at *11 (C.D. Cal. Jan. 8, 2019), *motion for relief from judgment granted*, 334 F.R.D. 588 (C.D. Cal. 2020) for its proposition. In *Francois*, plaintiff sought a default judgment for, among other claims, a claim under the UCL, after defendant did not respond to plaintiff's complaint. When evaluating whether to grant a permanent injunction based on plaintiff's motion for default judgment, the *Francois* court stated that "plaintiffs have no adequate remedies at law, because monetary damages cannot rectify loss of customers or goodwill." *Id.* at *11.

Hope's reliance on *Francois* is misplaced. First, because it arose in the context of a default judgment, the issue was not litigated by the parties. Next, under the UCL—the claim asserted by the plaintiff in *Francois*—damages are not an available remedy, whereas here Hope is seeking equitable disgorgement under four state statutes which provide for a damages remedy. Further, the equitable disgorgement remedy Hope seeks is itself a monetary remedy, and while *Francois* states that a loss of goodwill cannot be compensated through money damages, the remedy sought by Hope—equitable restitution—would not relate to any prior loss of goodwill independent of any sales lost by Hope.

Accordingly, the Court finds and concludes that Hope's loss of goodwill could have been adequately compensated by the legal remedy of damages for lost profits under these states' statutes. Under these four state statutes, courts may consider a plaintiff's loss of goodwill as part of the damages calculation in determining lost profits. *Serv. Jewelry Repair, Inc. v. Cumulus Broad., LLC*, 145 F. Supp. 3d 737, 751 (M.D. Tenn. 2015) (discussing plaintiff's damages claims under the TCPA by evaluating loss of reputation, business goodwill, attorneys' fees, and lost revenue); *Collins Holding Corp. v. Defibaugh*, 373 S.C. 446, S.C.451, 646 S.E.2d 147, 149 (Ct. App. 2007) (explaining that under SCUTPA "recoverable damages include compensation for all injury to plaintiff's property or business . . .").

Indeed, plaintiff could have been compensated for its loss of goodwill in its damages calculation if it had not abandoned its damages claim.

§ 42-110g (providing for recovery of "actual damages"); Fla. Stat. § 501.211(1)-(2) (permitting recovery of "actual damages, plus attorney's fees, and court cost"); Tenn. Code § 47-18-109(a)(1) (providing a private right of action for recovery of "actual damages"); S.C. Code § 39-5-140(a) (permitting recovery of "actual damages").

77. Since the CUTPA, FDUTPA, TCPA, and SCUTPA provide actual damages as a remedy, and Hope chose to waive its damages claims when Hope moved to strike defendant's jury demand, Dkt. 341, Hope limited its remedies to those that are only equitable in nature.

78. Restitutionary disgorgement of a defendant's improper profits is an equitable remedy. "[D]isgorgement of improper profits . . . is a remedy only for restitution[.]" *Tull v. United States*, 481 U.S. 412, 424. And although "[t]he status of restitution as belonging to law or to equity has been ambiguous from the outset," Restatement (Third) of Restitution and Unjust Enrichment § 4(a) (2011), the Supreme Court has "invariably described restitutionary relief as 'equitable'" for Seventh Amendment purposes. *Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 229 (2002) (Ginsburg, J., dissenting) (listing cases). Indeed, "an action for disgorgement of improper profits" is "traditionally considered an equitable remedy." *Tull*, 481 U.S. at 424.

79. In Hope's motion to strike defendants' jury demand, Hope disavowed any claim for damages for its own lost sales and profits. Dkt. 341. Based on this waiver, the Court found that Hope may only seek

equitable remedies and that Hope's claims do not give rise to a Seventh Amendment right to a jury. *Id.*

80. Moreover, under *Sonner*, the Ninth Circuit held that, "when a plain, adequate, and complete remedy exists at law . . . federal courts rely on federal equitable principles before allowing equitable restitution in such circumstances. And because [plaintiff] fails to demonstrate that she lacks an adequate legal remedy in this case, we affirm the district court's order dismissing her claims for restitution." *Sonner*, 971 F.3d at 845.

81. Here, because Hope chose to seek disgorgement of improper profits as an equitable restitutionary remedy, when damages were available as an adequate remedy at law under the CUTPA, FDUTPA, TCPA, and SCUTPA, the Court finds and concludes that Hope is not entitled to disgorgement of defendants' ill-gotten profits. The Ninth Circuit's decision in *Sonner* does not affect Hope's claims for declaratory or injunctive relief because there is no adequate substitute at law for these remedies.

82. Hope is not entitled to recover attorneys' fees under California law. "The court may award attorneys' fees to a successful party against one or more opposing parties in any action which has resulted in the enforcement of an important right affecting the public interest if: (a) a significant benefit, whether pecuniary or nonpecuniary, has been conferred on the general public or a large class of persons, (b) the necessity and financial burden of private enforcement, or of enforcement by one public entity against another public entity, are such as to make the award appropriate, and (c) such fees should not in the

interest of justice be paid out of the recovery." Cal. Code Civ. Proc. § 1021.5. The Ninth Circuit has held that Cal. Code Civ. Pro. § 1021.5, is intended to encourage lawsuits serving a public interest that would not otherwise be brought. *See Unocal Corp. v. United States*, 222 F.3d 528, 543 (9th Cir. 2000). Even if the suit does serve a legitimate public interest, attorneys fees should not be granted if parties' "own interests are sufficient to motivate" the action. *Id.* Because Hope pursued this action against Fagron because Fagron's production of its sodium thiosulfate drugs was impacting Hope's sales, it had a sufficient motive to bring suit independent of any public benefit.

L. Conclusions of Law Related to the Court's Preliminary Injunction and Hope's Motion for Contempt

83. Hope claims that the 503B defendants violated this Court's preliminary injunction by continuing to sell their sodium thiosulfate drug without the clinical difference statements by prescribing practitioners required by the preliminary injunction.

84. "[C]ourts have inherent power to enforce compliance with their lawful orders through civil contempt." *Cal. Dep't of Soc. Servs. v. Leavitt*, 523 F.3d 1025, 1033 (9th Cir. 2008).

85. As relevant here, the Court preliminary enjoined defendants from "dispensing or distributing any compounded sodium thiosulfate product" from a 503A pharmacy or a 503B outsourcing facility into California, Connecticut, Florida, South Carolina, or Tennessee unless: "(i) defendants are provided an

order form for the product; (ii) the order form includes an attestation specifically indicating that defendants' compounded product, which does not contain potassium, will produce a clinical difference; (iii) the attestation specifies that defendants' compounded product, rather than the comparable commercially available drug product, is 'medically necessary' for the patients for whom defendants' drug will be distributed or dispensed; and (iv) the attestation indicates that the attestation is made or approved by a prescribing practitioner." Dkt. No. 141 at 38–39.

86. Thus, to comply with the injunction, defendants were required to follow 503B's "essentially a copy" provision. The FDA gives the following examples as acceptable statements of clinical difference:

a. "a physician who regularly treats patients with an allergy to an inactive ingredient in a particular approved injectable drug product could order a compounded version of the drug for office use from an outsourcing facility provided that he or she includes a statement on the order that removing the particular inactive ingredient produces a clinical difference for his or her individual patients and that he or she will provide the drug only to patients with that particular clinical need";

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

c. "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)";

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

FDA Guidance on 503B "Essentially a Copy" Requirement at 9.

Moreover, the guidelines explain what would be insufficient as a statement of clinical difference:

e. "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.

87. First, the Court finds that defendants' sales of its sodium thiosulfate drugs following the issuance of the preliminary injunction which were not made pursuant to orders with compliant attestations violated this Court's order. Defendants accepted and filled orders in at least July and August 2020 that were not accompanied by an attestation, provided defendants had in their files an existing, blanket ex ante attestation from the ordering clinic. As such, these sales were in violation of this Court's injunction.

88. Next, the Court finds that the blanket attestations signed by Fresenius accounting personnel

after the Court's preliminary injunction was issued do not qualify as clinical difference determinations required by the preliminary injunction, for at least two reasons. First, the preliminary injunction required that each attestation "indicate[] that the attestation is made or approved by a prescribing practitioner." *Id.* The blanket attestations were not made or approved by a prescribing practitioner. The Fresenius accounting personnel who signed the blanket attestations are not prescribing practitioners for the patients who were to receive the compounded drug, nor did defendants provide evidence that accounting personnel had authorization from the patients' prescribing practitioners to sign the attestations. Moreover, the attestations indicate that they were made on behalf of a practitioner who will administer the compounded drug, and not necessarily the prescribing practitioner. *E.g.* Exh. 745. Second, the preliminary injunction unambiguously required that each "prescription or order form include" an attestation of clinical difference. Dkt. No. 141 at 38–39. A blanket, uniform printed attestation form for multiple clinics did not satisfy this requirement, as these order forms were not accompanied by an attestation. Unlike the FDA's examples, defendants' attestation forms lack an explanation as to why there is a clinical difference or medical need for a potassium-free product in certain patients. *Id.*

89. However, the Court finds and concludes that defendants undertook steps to comply with the Court's preliminary injunction by (1) requesting attestation forms from individual clinics, (2) seeking to ensure attestations were approved by medical personnel, and (3) modifying the language of their attestation forms.

See Exhs. 864–65; 716; 923. Defendants' modified attestation form V2020-03 states in relation to a clinical difference statement:

> "The compounded Sodium Thiosulfate injection solution is free of boric acid and potassium chloride compared to comparable commercially available drug products. In my professional judgement, this compounded product provides clinical and safety benefits relative to the comparable commercially available drug products, which is medically necessary for patients who require this compounded formula." Exh. 923–215.

Defendants modified the language of the attestation again in V2021-01 to include the phrase: "in the professional judgement of the prescriber . . ." Exh. 923–947. Defendants testified that they believed that these modified attestation forms complied with the Court's preliminary injunction.

90. Hope has not provided sufficient evidence to show that defendants acted willfully and knowingly in violating the injunction. Moreover, defendants have provided evidence that they sought to comply with the Court's preliminary injunction. "The party alleging civil contempt must demonstrate that the alleged contemnor violated the court's order by 'clear and convincing evidence,' not merely a preponderance of the evidence." *In re Dual-Deck Video Cassette Recorder Antitrust Litigation*, 10 F.3d 693, 695 (9th Cir. 1993). "[A] person should not be held in contempt if his action 'appears to be based on a good faith and reasonable interpretation of the [court's order].'" *In re Dual-Deck*, 10 F.3d 693 at 695.

Hope argues that Fagron's conduct after the entry of the preliminary injunction shows that Fagron did not intend to comply with the order. For example, during trial, Hope relied on Exhibits 703-1, 703-2—an email exchange between Veronica Gwinup, Customer On-Boarding Specialist for Fagron, and Phu Pham, Supervisor of Accounting for Fresenius, dated July 9 and July 17, 2020—and on Exhibit 403—an email exchange between Gwinup and Pham, dated August 6, 2020. The Court finds that Gwinup's statement in Exhibit 704 that a corporate executive of Fresenius indicated that clinic physicians or managers need to sign the attestations instead of blanket attestations does not show, as Hope argues, that Fagron chose not to comply with the Court's orders for the first five weeks of the injunction and only took action based on their client's wishes. In Exhibit 703-2, written only a few days after the preliminary injunction was issued, Gwinup states that the Fagron's legal and compliance teams determined the attestations must be signed by someone with clinical authority. Read together, these exhibits show that Fagron was working to comply with the injunction shortly after it was issued. Moreover, the Court finds that Gwinup's statement that she hopes that Fagron "can identify an individual that can sign the attestation for each division so [Fagron doesn't] have to have each facility sign one" is expressing Gwinup's hope that she would not have to administer individual attestations and is not an example of Fagron executives' unwillingness to comply.

Because the Court finds that defendants attempted to comply with the injunction, and testified

that they believed they had done so, the Court declines to find defendants in contempt.

IV. CONCLUSION

In accordance with the foregoing, the Court orders as follows:

1. Judgment in favor of plaintiff is appropriate.

2. Plaintiff is entitled to declaratory relief that defendants violated the FDUTPA, UCL, CUTPA, SCUTPA, and TPCA.

3. The Court will ISSUE a permanent injunction as follows: Defendants and their officers, agents, servants, employees, attorneys and all those acting in concert with them, shall be permanently enjoined from directly or indirectly dispensing or distributing any compounded sodium thiosulfate product from a 503B 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 individual patients to whom defendants' drug will be distributed or dispensed; and

d. the attestation indicates that the attestation is made or approved by a prescribing practitioner of the specified patients; and

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

Plaintiff shall submit a proposed form of judgment in accordance with the foregoing and with the procedures set forth in the Local Rules of Court.

IT IS SO ORDERED.

Dated: October 26, 2021

Christina A. Snyder
UNITED STATES DISTRICT JUDGE

Appendix C

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

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

HOPE MEDICAL ENTERPRISES, INC.,

Plaintiff,

v.

FAGRON COMPOUNDING SERVICES, LLC; *et al.*,

Defendants.

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PROCEEDINGS: (IN CHAMBERS) – REDACTED PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION
(Dkt. [105], filed June 1, 2020)

The Honorable CHRISTINA A. SNYDER

I. INTRODUCTION

Plaintiff Hope Medical Enterprises, Inc. ("Hope") filed this action against defendants Fagron Compounding Services, LLC ("Fagron"), JCB Laboratories, LLC ("JCB"), AnazaoHealth Corporation ("AnazaoHealth"), and Coast Quality Pharmacy, LLC ("Coast") (collectively, "defendants") on September 6, 2019. Dkt. 1. The gravamen of Hope's claims is that defendants' drug compounding practices

constitute unfair competition in violation of several states' consumer protection laws.

On September 27, 2019, Hope filed a motion for a preliminary injunction. Dkt. 22. Hope subsequently filed a superseding amended motion for a preliminary injunction on October 21, 2019. Dkt. 38. On November 4, 2019, the parties filed a joint stipulation allowing Hope to withdraw its pending preliminary injunction motion. Dkt. 42. The Court entered the parties' joint stipulation on November 2019, allowing Hope to withdraw its pending preliminary injunction motion without prejudice and granting Hope leave to file a first amended complaint. Dkt. 46.

Hope thereafter filed the operative first amended complaint on November 12, 2019. Dkt. 47 ("FAC"). The FAC asserts claims for: (1) violation of California's Unfair Competition Law ("UCL"); (2) violation of Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"); (3) violation of Tennessee's Consumer Protection Act ("TCPA"); (4) violation of South Carolina's Unfair Trade Practices Act ("SCUTPA"); and (5) violation of Connecticut's Unfair Trade Practices Act ("CUTPA"). *See generally* FAC. Defendants filed their operative amended answer on January 27, 2020.[1] Dkt. 67.

Hope filed the present motion for a preliminary injunction on June 1, 2020. Dkt. 105 ("Mot.").

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[1] On January 13, 2020, the Court granted in part and denied in part Hope's motion to strike and for judgment on the pleadings as to affirmative defenses in defendants' prior answer to the FAC. Dkt. 66. Defendants thereafter filed their operative amended answer.

Defendants filed an opposition on June 8, 2020. Dkt. 113 ("Opp."). Hope filed a reply on June 15, 2020. Dkt. 122 ("Reply").

The Court held a hearing on June 29, 2020. Having carefully considered the parties' arguments, the Court finds and concludes as follows.

II. BACKGROUND

A. Regulatory Framework Governing Drug Compounding

At issue in this case are defendants' drug compounding practices. "Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). "Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product." *Id.* "Many States specifically regulate compounding practices as part of their regulation of pharmacies." *Id.*

The manner in which states and the federal government have regulated drug compounding has changed over time, and Hope's claims turn on the legality of defendants' drug compounding practices. Accordingly, the Court briefly sets forth both the regulatory framework governing drug compounding and its history.

1. Congress Enacts the Federal Food Drug and Cosmetic Act of 1938

In 1938, Congress enacted the Federal Food Drug and Cosmetic Act of 1938 ("FDCA") "to regulate drug manufacturing, marketing, and distribution." *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388 (5th Cir. 2008). The FDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application ... is effective with respect to such drug." 21 U.S.C.§ 355(a). The FDCA defines "new drug" as "[a]ny new drug ... the composition of which is such that such drug is not generally recognized ... as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof[.]" 21 U.S.C. § 321(p)(1). "The FDCA invests the Food and Drug Administration (FDA) with the power to enforce its requirements." *Thompson*, 535 U.S. at 362.

"To be deemed 'safe and effective' and thereby obtain FDA approval, a new drug must undergo an extensive application and approval process." *Med. Ctr. Pharmacy*, 536 F.3d at 388. The FDCA requires that any FDA finding of "'safe and effective' must be based on 'substantial evidence' of expert consensus." *Id.* "The 'test is rigorous,' requiring expensive and time-consuming clinical trials[.]" *Id.* at 388–389.

2. The FDA Historically Leaves Regulation of Compounding to the States

"For approximately the first 50 years after the enactment of the FDCA, the FDA generally left regulation of compounding to the States." *Thompson*, 535 U.S. at 362. Indeed, "the FDA as a matter of policy

has not historically brought enforcement actions against pharmacies engaged in traditional compounding." *Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592, 593 n.3 (5th Cir. 1995). During this period, "[p]harmacists continued to provide patients with compounded drugs without applying for FDA approval of those drugs." *Thompson*, 535 U.S. at 362. "In the early 1990's, however, the FDA became concerned that some pharmacies were purchasing bulk quantities of drug products, 'compounding' them into specific drug products before receiving individual prescriptions, and marketing those drugs to doctors and patients." *Med. Ctr. Pharmacy*, 536 F.3d at 389. The FDA ultimately came to believe "that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Thompson*, 535 U.S. at 362.

3. Congress Enacts the Drug Quality and Security Act in 2013

In 2013, "Congress passed new legislation that once again created federal regulatory power over compounding pharmacies."[2] *Cruz v. Preferred*

[2] In 1997, Congress passed the Food and Drug Administration Modernization Act ("FDAMA"), "which explicitly gave the FDA limited regulatory power over compounding pharmacies." *Cruz*, 2014 WL 4699531, at *3. In 2002, however, the United States Supreme Court in *Thompson* struck down particular provisions of the FDAMA as unconstitutional, and the FDA subsequently "took the position that all of the FDAMA is now invalid." *Med. Ctr. Pharmacy*, 536 F.3d at 391 (internal alteration omitted). "Thus, between 2002 and November 2013, there was no federal statute in effect that expressly provided for the FDA to regulate compounding pharmacies." *Cruz*, 2014 WL 4699531, at *3.

Homecare, No. 2:14-cv-00173-MMD, 2014 WL 4699531, at *3 (D. Nev. Sept. 22, 2014). This legislation—the Drug Quality and Security Act ("DQSA")—"amend[ed] FDCA Section 503A and add[ed] Section 503B."[3] *Allergan USA Inc. v. Imprimis Pharm., Inc.*, No. 8:17-cv-01551-DOC-JDE, 2017 WL 10526121, at *2 (C.D. Cal. Nov. 14, 2017).

a. Section 503A of the FDCA

Section 503A regulates "pharmacy compounding." *See* 21 U.S.C. § 353a. "Drug products compounded 'for an identified individual patient that are necessary for the identified patient' are exempted from normal-drug approval requirements under Section 503A when certain conditions are met." *Imprimis*, 2017 WL 10526121, at *2 (internal alterations omitted) (citing 21 U.S.C. § 353a(a)). Accordingly, "Section 503A allows pharmacy compounding in two scenarios: (1) drug compounding after the receipt of a prescription; and (2) drug compounding before the receipt of a prescription when the compounding is 'based on a history of receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between' the compounding pharmacy and the patient or prescribing physician." *Imprimis*, 2017 WL 10526121, at *2 (internal alterations omitted) (citing 21 U.S.C. § 353a(a)).

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[3] Congress enacted the DQSA following a 2012 incident wherein a drug compounding center "produced contaminated injections that caused a meningitis outbreak, killing more than 60 people and infecting hundreds more." *Athenex Inc. v. Azar*, 397 F. Supp. 3d 56, 59 (D.D.C. 2019).

"In both scenarios, Section 503A also requires that the compounded drug is (1) compounded using approved drug products; (2) compounded using ingredients that comply with national standards; (3) not compounded 'regularly or in inordinate amounts (as defined by the Secretary)' if the compounded drug is 'essentially a copy of a commercially available product'; (4) not a drug product whose safety or effectiveness may be adversely effected by compounding; and (5) compounded in a state that has entered into a 'Memorandum of Understanding' ('MOU') with the FDA or, if no such MOU exists for that state, compounded by a pharmacy or individual that distributes less than '5 percent of its total prescription orders' to out-of-state patients." *Imprimis*, 2017 WL 10526121, at *2 (internal alterations omitted) (citing 21 U.S.C. § 353a(b)).

b. Section 503B of the FDCA

"Section 503B created a new category of drug maker called an 'outsourcing facility.'" *Athenex*, 397 F. Supp. 3d at 59 (citing 21 U.S.C. § 353b). "An outsourcing facility may compound drug products in large quantities without obtaining a prescription for 'an identified individual patient.'" *Athenex*, 397 F. Supp. 3d at 59 (internal alteration omitted) (citing 21 U.S.C. § 353b). Accordingly, outsourcing facilities "are permitted to sell bulk compounded drug products to health care practitioners and hospitals as 'office stock,' for providers to have available and to use on an as needed basis." *Athenex*, 397 F. Supp. 3d at 59.

Pursuant to Section 503B. "[a]n outsourcing facility remains exempt from the FDCA's premarket approval requirements and certain labeling and

supply-chain requirements, but only if it satisfies eleven statutory criteria." *Athenex*, 397 F. Supp. 3d at 59 (internal citations omitted). These criteria include, inter alia, requirements that: "(1) the drug is not 'essentially a copy of one or more approved drugs;' (2) the drug is not sold wholesale; and (3) the 'drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with Section 503B.'" *Imprimis*, 2017 WL 10526121, at *2 (internal alterations omitted) (citing 21 U.S.C. § 353b(a)). In addition, Section 503B "specifically limits the types of drugs that can be compounded at outsourcing facilities" to those "compound bulk drug substances that appear on (1) a list established by the FDA identifying bulk drug substances for which there is a clinical need ('503b bulks list'); or (2) a drug shortage list established by the FDA." *Imprimis*, 2017 WL 10526121, at *2 (internal alterations omitted) (citing 21 U.S.C. § 353b(a)(2)(A)).

B. Hope's Sodium Thiosulfate Drugs

Hope is a pharmaceutical manufacturer that sells pharmaceutical products including a sodium thiosulfate injection and a sodium nitrite injection. FAC 26. Hope alleges that it "is the exclusive supplier of FDA-approved Sodium Thiosulfate Injection sold in the United States." *Id.* Similarly, "Hope is the only supplier of bulk sodium thiosulfate that has been approved by [the] FDA for use as an active ingredient in medications that are intended for administration to humans." *Id.* ¶ 43. Bulk sodium thiosulfate is the active ingredient in Hope's Sodium Thiosulfate Injection, and "Hope's Sodium Thiosulfate Injection has been approved by [the] FDA for the treatment of

acute cyanide poisoning that is judged to be serious or life-threatening." FAC ¶¶ 28, 38.

C. Defendants' Alleged Compounding Practices

Hope alleges that 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." FAC ¶ 13. According to Hope, defendants "are under common ownership and control and work closely together" in "creating, marketing, and selling unapproved new drugs for unapproved uses ... under the false guise of 'compounding.'" *Id.* ¶¶ 11, 13. In particular, Hope avers that defendants sell compounded sodium thiosulfate, which does not contain potassium, for the "off-label use" of treating "calciphylaxis, a painful condition suffered by some end stage renal disease patients." Mot. at 7 n.4.

Fagron, JCB, and AnazaoHealth own outsourcing facilities that purport to operate pursuant to Section 503B. FAC 14. Hope alleges that defendants' outsourcing facilities are engaged in compounding that violates Section 503B's eleven statutory criteria. *Id.* ¶¶ 71-72. Coast owns and operates a compounding pharmacy that "purports to operate" pursuant to Section 503A. FAC 14. According to Hope, however, Coast violates Section 503A because "Coast does not compound or dispense its compounded sodium thiosulfate 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 drugs." *Id.* ¶ 77. "Coast therefore does not comply with Section 503A's individual customization requirement." *Id.* Hope further alleges that Coast violates Section 503A in that Section 503A requires "that drug products that are essentially copies of a commercially available drug product must not be compounded regularly or in inordinate amounts." *Id.* ¶ 79. Nonetheless, "[d]efendants' compounded sodium thiosulfate drug product is essentially a copy of Hope's ... in that the two drugs have the same active pharmaceutical ingredient, in the identical dosage strength, with the same route of administration" and "[d]efendants are compounding their sodium thiosulfate drug products regularly and in inordinate amounts." *Id.*

III. LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). The Ninth Circuit summarized the Supreme Court's clarification of the standard for granting preliminary injunctions in *Winter* as follows: "[a] plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Am. Trucking Ass'n. Inc. v. City of Los Angeles*, 559 F.3d 1046, 1052 (9th Cir. 2009); *see also Cal. Pharms. Ass'n v. Maxwell-Jolly*, 563 F.3d 847, 849 (9th Cir. 2009). A preliminary injunction, moreover, may only be awarded "upon a clear

showing" of evidence that supports each relevant preliminary injunction factor. *Winter*, 555 U.S. at 22. Alternatively, "'serious questions going to the merits' and a hardship balance that tips sharply towards the plaintiff can support issuance of an injunction, so long as the plaintiff also shows a likelihood of irreparable injury and that the injunction is in the public interest." *Alliance for the Wild Rockies v. Cottrell*, 622 F.3d 1045, 1053 (9th Cir. 2010). Serious questions are those "which cannot be resolved one way or the other at the hearing on the injunction." *Bernhardt v. Los Angeles Cty.*, 339 F.3d 920, 926 (9th Cir. 2003) (citation omitted).

IV. DISCUSSION

A. Requests for Judicial Notice and Evidentiary Objections

The Court observes that each party has filed one or more requests for judicial notice, and the parties have lodged evidentiary objections to the documents that the parties submit in support of their respective briefs. *See, e.g.*, Dkts. 106 ("Hope RJN"), 114 ("D. RJN"), 114 ("D. Opp. to Hope RJN"), 123 ("Hope Supp. RJN"); 125 ("Hope Evidentiary Objections"). However, "[i]t is well established that trial courts may consider otherwise inadmissible evidence in preliminary injunction proceedings." *Garcia v. Green Fleet Sys., LLC*, No. 2:14-cv-06220-PSG-JEM, 2014 WL 5343814, at *5 (C.D. Cal. Oct. 10, 2014). "Indeed, district courts have considerable discretion to consider otherwise inadmissible evidence when ruling on the merits of an application for a preliminary injunction." *Id.*

The Court notes that "a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits." *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981); *accord Johnson v. Couturier*, 572 F.3d 1067, 1083 (9th Cir. 2009); *Flynt Distnb. Co. v. Harvey*, 734 F.2d 1389, 1394 (9th Cir. 1984). Accordingly, evidentiary objections to evidence submitted in connection with a motion for a preliminary injunction "properly go to weight, rather than admissibility." *Garcia*, 2014 WL 5343814, at *5. Similarly, even if evidence "do[es] not meet the requirements for judicial notice," the Court may consider the evidence "in the context of the preliminary injunction motion and give [the evidence] appropriate weight[.]" *Walker v. Woodford*, 454 F. Supp. 2d 1007, 1024 (S.D. Cal. 2006).

The Court has considered the parties' requests for judicial notice and the parties' evidentiary objections. To the extent that the parties' respective requests for judicial notice seek judicial notice of the *existence* of particular documents, the Court GRANTS the parties' requests for judicial notice. The Court DENIES the parties' requests for judicial notice in all other respects. In addition, where the Court has expressly relied on evidence that is subject to an evidentiary objection, the Court OVERRULES those objections.

B. Likelihood of Success

Hope's state-law consumer protection claims are predicated on defendants' alleged violations of Sections 503A and 503B. *See* Mot. at 15. Accordingly, to determine whether Hope is likely to succeed on the merits of Hope's claims, the Court first considers

Hope's arguments that defendants have violated Sections 503A and 503B. The Court next considers arguments specific to Hope's particular consumer protection claims.

1. Section 503A

Hope argues that "[d]efendants' compounding practices violate two separate provisions of section 503A: (1) the 'essentially a copy' provision"; and "(2) the 'individual prescription' requirement[.]" Mot. at 15. The Court addresses Hope's contention in turn.

a. "Essentially a Copy" Requirement

Pursuant to Section 503A, "[a] drug product may be compounded if the licensed pharmacist or licensed physician ... does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available product." 21 U.S.C. § 353a(b)(1)(D). "This means that a compounded drug product is not eligible for the exemptions in Section 503A if it is (1) essentially a copy of a commercially available drug product, and (2) compounded regularly or in inordinate amounts."[4] Dkt. 106-1, Exh. C, Food and Drug Administration, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section*

[4] A drug is compounded "regularly" if is "compounded at regular times or intervals, usually or very often." FDA Guidance on 503A "Essentially a Copy" Requirement at 10. A drug is compounded in "inordinate amounts" if "it is compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances." *Id.*

503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry (Jan. 2018) ("FDA Guidance on 503A 'Essentially a Copy' Requirement") at 4. "The term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient *a significant difference*, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product." 21 U.S.C. § 353a(b)(2) (emphasis added). "If a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription." FDA Guidance on 503A "Essentially a Copy" Requirement at 8.

Here, Hope first argues that defendants violate Section 503A's "essentially a copy" requirement because defendants' "compounded sodium thiosulfate drug is essentially a copy of Hope's" product since "it has the same API as Hope's Sodium Thiosulfate [injection], the identical dosage strength, and the same route of administration (intravenous injection)." Mot. at 16. In support of this argument, Hope submits the declaration of Dr. Craig Sherman, Hope's President, who attests to the characteristics of Hope's products, *see* Dkt. 105-3 ("Sherman Decl.") ¶ 9, as well as a copy of defendants' prescription order form, which indicates that defendants' sell sodium thiosulfate for intravenous use, *see* Dkt. 10-54, Exh. B.

In response, defendants argue that their compounded "product is not essentially a copy of

[Hope's] because [d]efendants' product does not contain potassium while [Hope's] does." Opp. at 12. According to defendants, "[t]his a very important distinction." *Id.* at 2. In support of defendants' argument that its compounded product is not essentially a copy of Hope's product, defendants submit letters from Dr. Jeffrey Hymes, the Chief Medical Officer of Fresenius Kidney Care and one of defendants' customers, who urges that there is a "significant difference between the JCB/Fagron and Hope preparations" of sodium thiosulfate. Dkt. 113-1, Exh. A. Dr. Hymes indicates that "the Hope Pharmaceuticals product contains 4 milligrams of potassium per milliliter ... [while] the Fagron product contains no potassium." *Id.* In another letter, Dr. Hymes explains that defendants' removal of potassium is "significant" because Fresenius Kidney Care uses defendants' compounded product for the off-label use of treating renal patients undergoing dialysis treatment who suffer from calciphylaxis, and for those patients suffering from renal failure, "control of potassium is a crucial function of dialysis" since exposure to potassium "can lead to cardiac arrythmia and death." *Id.* Similarly, defendants submit a letter from Dr. George Aronoff, the Vice President of Clinical Affairs for DaVita Kidney Care, another of defendants' customers, who indicates that "[o]ur preference from a clinical perspective is to use the STS compounded by JCB/Fagron because the commercially available 25 gram dose of STS provided by Hope Pharmaceuticals contains 880 mg of potassium." Dkt. 113-1, Exh. B.

Hope disputes that defendants' compounding of sodium thiosulfate without potassium is a "significant difference," pointing to evidence that defendants'

"customers purchase defendants' sodium thiosulfate drugs for purely financial reasons." Mot. at 7. For example, Dr. Sherman, Hope's President, attests that during a seven-month period between 2018 and 2019, Hope fulfilled orders from Fresenius and DaVita for Hope's sodium thiosulfate product, which contains potassium. Sherman Decl. ¶¶ 16–21. According to Hope, "[t]his establishes that [d]efendants' biggest customers believe that Hope's Sodium Thiosulfate Injection can satisfy their patients' medical needs, and that [d]efendants' compounded product does not produce a necessary or significant clinical difference." Mot. at 8. That is because these customers would not have purchased Hope's product if they "believed a compounded drug was medically necessary" and that "Hope's Sodium Thiosulfate Injection was inappropriate" for their patients. *Id.*

The FDA's guidance indicates that Section 503A's "essentially a copy" requirements—as set forth in 21 U.S.C. § 353a(b)(1)(D)—"apply to the compounding of drug products that are *essentially* copies of a commercially available drug product - not only to drugs that are exact copies or even to drugs that are nearly identical." FDA Guidance on 503A "Essentially a Copy" Requirement at 6 (emphasis in original). The FDA explains that "[t]his is to ensure that compounders do not evade the limits in this section by *making relatively small changes* to a compounded drug product and then offering the drug to the general public without regard to whether a prescribing practitioner has determined that the change produces for the patient a significant difference." FDA Guidance on 503A "Essentially a Copy" Requirement at 6 (emphasis added). The FDA further instructs that "for

some patients, a drug product that has the same API, strength, and route of administration may include a change that produces a significant difference for a particular patient." *Id.* "For example, a drug product compounded without a particular inactive ingredient may produce a significant difference for a patient who has an allergy to the inactive ingredient in the commercially available drug product." *Id.* "However, for other patients, this change may produce no difference at all. Congress did not intend for compounders to use ... the fact that some patients may have allergies as a basis to compound a drug without the inactive ingredient for other patients who do not have the allergy under the exemptions in section 503A[.] *Id.* Accordingly, the FDA "generally intend[s] to consider such a drug essentially a copy unless a prescriber determines that there is a change that will produce a significant difference for the patient for whom it is prescribed." *Id.* at 7.

The disputed record before the Court precludes the Court from determining, at this juncture, whether defendants' compounded sodium thiosulfate drug is "essentially a copy" of Hope's product, given that Hope's product contains potassium, while defendants' compounded product does not. However, the FDA's guidance indicates that "[i]f a compounder intends to rely on" a determination that its compounded drug contains a different formula from that of a commercially available drug product "to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription." FDA Guidance on 503A "Essentially a Copy" Requirement at 8. The parties

dispute whether defendants' compounded drugs contains the requisite "Significant Difference Statement."

Hope argues that defendants' "503A pharmacy fills prescriptions for compounded sodium thiosulfate drugs without requiring a Significant Difference Statement." Mot. at 11. Instead, defendants "simply ask doctors ordering through [d]efendants' website to certify that 'this compounded preparation is necessary for the patient(s) identified below.'" *Id.* Hope also points to a standard prescription form that defendants accept which contains a pre-printed statement that [REDACTED]. According to Hope, "[t]his 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 'clinically necessary language' does not satisfy Section 503A." Mot. at 11. Examples of defendants' website and [REDACTED] are pictured below:

Dkt. 105-4, Exh. E; [REDACTED].

In response, defendants argue that "[t]he FDA's Guidance under 503A regarding the 'Statement of Significant Difference' does not require a specific format to document the prescriber's determination." Opp. at 8. Defendants further assert that "[i]n response to discovery, [d]efendants have produced hundreds of individual prescriptions and orders containing attestations from medical providers for [d]efendants' potassium-free sodium thiosulfate for calciphylaxis patients, including order forms signed by pharmacy directors, registered nurses and clinical managers." *Id.* at 3; *see also* [REDACTED].

The FDA's guidance indicates that the FDA "does not believe that a particular format is needed to document the determination, provided that the prescription makes clear that the prescriber *identified the relevant change and the significant difference that the change will produce* for the patient." FDA Guidance on 503A "Essentially a Copy" Requirement at 8 (emphasis added). The FDA's guidance indicates that "the following would be sufficient:

- 'No Dye X, patient allergy' (if the comparable drug contains the dye)
- 'Liquid form, patient can't swallow tablet' (if the comparable drug is a tablet)
- '6 mg, patient needs higher dose' (if the comparable drug is only available in 5 mg dose)"

FDA Guidance on 503A "Essentially a Copy" Requirement at 8.

Accordingly, the pre-formulated, generic statements on defendants' website and standard prescription forms that defendants accept from prescribers appear to be inadequate in that these statements do not require the prescribers to "make clear that the prescriber made the determination required by section 503A(b)(2)." FDA Guidance on 503A "Essentially a Copy" Requirement at 9. And while the FDA's guidance states that the FDA "generally does not intend to question prescriber determinations that are documented in a prescription or notation," it also indicates that "*we do intend to consider whether a prescription* or notation relied upon by a compounder to establish that a drug is not

essentially a copy *documents that the determination was made*." *Id.* (emphases added).

In support of its argument that it is likely to succeed on the merits of its claim that defendants violated Section 503A's "essentially a copy" requirement, Hope relies on *Allergan USA Inc. v. Imprimis Pharm., Inc.*, No. 8:17-cv-01551-DOC-JDE, 2019 WL 3029114, (C.D. Cal. July 11, 2019). In that case, another court in the Central District of California issued a post-trial, permanent injunction in favor of Allergan, a pharmaceutical manufacturer, against Imprimis, a drug compounder, on the basis that Imprimis was engaged in unlawful compounding in violation of Sections 503A. *Id.* at *1. There, Imprimis used a "standard order form ... for Section 503A orders" and "required that every order shipped from a Section 503A facility be accompanied by a written confirmation from the doctor or hospital or surgery center that the order is 'necessary for an individual patient and subject to a valid prescription.'" *Id.* at *9. The court determined that the standard order form "does not adequately distinguish a Section 503A drug as medically necessary where a FDA-approved drug is medically appropriate for the patient." *Id.* at *10. The court concluded that "[a] limited permanent injunction is therefore proper to ensure compliance with ... Section 503A," explaining that Imprimis' standard "form would satisfy the injunction so long as it is adequately executed for an identified individual patient and specifies that (1) the *compounded* drug is medically necessary and (2) an

FDA-approved drug is not medically appropriate."[5] *Imprimis*, 2019 WL 3029114, at *11 (emphasis in original).

To the extent that Hope claims that defendants violate Section 503A's "essentially a copy" requirement because defendants fulfill orders for their compounded sodium thiosulfate products without sufficient, affirmative determinations by prescribers that defendants' compounded products—as opposed to Hope's FDA-approved products—are necessary, Hope raises a likelihood of success on the merits.

b. Individual Prescription Requirement

Alternatively, Hope argues that "[d]efendants' 503A pharmacy does not compound sodium thiosulfate drugs for 'identified individual patients' with 'valid prescription orders.'" Mot. at 16 (citing 21 U.S.C. § 353a(a)). In response, defendants assert that their "503A facility sells [their] potassium-free sodium thiosulfate product pursuant to individualized prescriptions from treating physicians." Opp. at 7.

In *Imprimis*, upon which Hope primarily relies, the court concluded, at the summary judgment stage, that "[u]nder the plain language of the statute,

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[5] Allergan requested a permanent injunction that would also "forbid a doctor from stating that a compounded medication is necessary by filling out an order form or a preprinted verification; and enjoin Imprimis from directly or indirectly advising a doctor as to how it completes a form documenting medical necessity of compounded medications." *Imprimis*, 2019 WL 3029114, at *11. The court rejected Allergan's proposed injunction as "representative of its aggressive approach to this litigation" and "stretche[d] beyond the requirements of the law." *Id.*

anticipatory mass compounding of standardized drugs in a 503A facility without identified individual patients based on valid prescription orders is clearly violative of the FDCA." *Allergan USA, Inc. v. Imprimis Pharm., Inc.*, No. 8:17-cv-01551-DOC-JDE, 2019 WL 4545960, at *11 (C.D. Cal. Mar. 27, 2019). There, Allergan challenged, *inter alia*, Imprimis' alleged practice of preparing compounded product "in advance" of actually having received a particular prescription tied to a specific patient. *Id.* The court noted that "[t]he parties dispute whether the formulations at the 503A facilities are generated pursuant to valid prescriptions from a practicing doctor for an identified individual patient," but concluded that "this dispute is not genuine." *Imprimis*, 2019 WL 4545960, at *11. That is because Allergan adduced evidence that "Imprimis has not matched orders with specific patients and customized prescriptions." *Id.* For example, rather than disburse compounded product to a customer to fill a particular patient's needs, Imprimis appeared to "'pick 3 names' in order to ship[.]" *Id.* Similarly, instead of fulfilling orders based on a valid prescription, "Imprimis has allowed customers to provide a surgery schedule or list of patients to obtain drug orders from the 503A facility." *Id.*

As evidence that they are complying with Section 503A's individual prescription requirement, defendants submit a declaration from TJ Bresnahan, AnazaoHealth's President. *See* Dkt. 113-2 ("Bresnahan Decl."). Bresnahan attests that Coast, the 503A facility at issue in this case, "dispenses its products pursuant to individualized prescriptions from treating physicians." *Id.* ¶ 6. Indeed, the record

before the Court appears to include instances where defendants have fulfilled written prescriptions—issued by licensed physicians and tied to particular patients—for defendants' compounded sodium thiosulfate. *See, e.g.*, Dkt. 111-12, Exh. P (prescription written by physician tied to patient whose identity is redacted); Dkt. 111-12, Exh. Q (purchase order listing "Dr. [REDACTED]" as "Prescriber"). Moreover, Section 503A provides that a compounding facility may fulfill an order *prior to* receiving a valid prescription in certain circumstances. *See Imprimis*, 2017 WL 10526121, at *2 (indicating that "Section 503A allows ... drug compounding before the receipt of a prescription when the compounding is based on a history of receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between the compounding pharmacy and the patient or prescribing physician.").

Because of the disputed record presently before the Court, the Court cannot determine, at this juncture, whether Hope is likely to succeed on the merits of its claim that defendants have violated Section 503A's "individual prescription" requirement.

2. Section 503B

Hope also argues that defendants' "outsourcing facilities" violate Section 503B because defendants' "drug is 'essentially a copy' of Hope's FDA-approved Sodium Thiosulfate Injection, and because [d]efendants are illegally selling their sodium thiosulfate drug through a wholesaler/distributor, AmerisourceBergen Corporation." Mot. at 1. The Court addresses Hope's contentions in turn.

a. "Essentially a Copy" Requirement

"Section 503B regulates drug products compounded by an 'outsourcing facility.'" *Athenex Pharma Sols., LLC v. Par Pharm., Inc.*, No. l:18-cv-896, 2019 WL 4511914, at * 1 (W.D.N.Y. July 9, 2019). "Under certain conditions, drugs compounded by a registered outsourcing facility are exempt from certain FDA drug approval requirements[.]" *Id.* "One condition is that the outsourcing facility may only compound products using bulk drug substances included on either (1) a list established by the FDA identifying bulk drug substances for which there is a clinical need"; or "(2) the FDA's drug shortage list."[6] *Id.* (citing 21 U.S.C. § 353b(a)(2) (internal alterations omitted). "Another condition is that the compounded drug cannot be 'essentially a copy' of a drug approved

[6] Although bulk sodium thiosulfate appears on neither the FDA's bulks list nor the FDA's drug shortage list, Hope does not contend that defendants' outsourcing facilities violate these requirements. That is because "[t]he FDA is currently developing the bulks list" but has, "[i]n the meantime, ... issued an industry guidance document that describes interim regulatory policies[.]" *Par*, 2019 WL 4511914, at *2. The FDA's interim policy explains "that the FDA 'does not intend to take action against an outsourcing facility for compounding a drug using a bulk drug substance ... if, among other conditions, the substance appears on a list of 'Category 1' substances that are currently under evaluation." *Id.* And, Hope acknowledges that "on October 30, 2019," the FDA "moved bulk sodium thiosulfate," the bulk ingredient in defendants' compounded products, onto the FDA's Category 1 list[.]" Reply at 6. Indeed, the FDA's moving of bulk sodium thiosulfate onto the FDA's Category 1 list prompted Hope to withdraw its previous preliminary injunction motion. *See* Dkt. 42 at 1–2.

by the FDA." *Par*, 2019 WL 4511914, at *1 (citing 21 U.S.C. § 353b(a)(5)).

Section 503B defines "essentially a copy of an approved drug" as "a drug, a component of which is a bulk drug substance that is 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 drug." 21 U.S.C. § 353b(d)(2)(B). The FDA has issued an advisory document which "explain[s] how [the FDA] intend[s] to apply the definition of *essentially a copy of an approved drug* in section 503B(d)(2) when the compounded drug is compared to an approved drug[.]" Dkt. 106-1, Exh. E, Food and Drug Administration, *Compounded Drug Products That Are Essentially Copies of a Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry* (Jan. 2018) ("FDA Guidance on 503B 'Essentially a Copy' Requirement") at 6 (emphasis in original). The FDA's guidance indicates that "[i]f a component of the compounded drug is a bulk drug substance that is also a component of an approved drug, the compounded drug product is essentially a copy of an approved drug, and cannot be compounded under Section 503B, unless there is a prescriber determination of clinical difference[.]" *Id.* at 8.

The parties dispute whether defendants' compounded bulk sodium thiosulfate products are "essentially a copy" of Hope's FDA-approved product. Hope maintains that because defendants compounded sodium thiosulfate drug contains "sodium thiosulfate,

the same 'bulk drug substance' that is in Hope's product," that "makes [d]efendant's drug essentially a copy of Hope's[.]" Mot. at 17. Defendants, on the other hand, aver that the omission of potassium in defendants' compounded products renders defendants' products clinically different from Hope's products, defeating Hope's claim that defendant's products are "essentially a copy." Opp. at 2. As the Court discussed above with respect to Hope's claim that defendants' compounding facilities violated Section 503A's "essentially a copy" requirement, the disputed record regarding the omission of potassium in defendants' compounded product precludes the Court from determining, at this juncture, whether defendants' compounded product are "essentially a copy" of Hope's product for the purposes of Section 503B.

The FDA's guidance indicates that "[i]f an outsourcing facility intends to rely on" a determination that there is a clinical difference "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 (which may be a patient-specific prescription or a non-patient specific order) for the compounded drug." FDA Guidance on 503B "Essentially a Copy" Requirement at 8. The parties dispute whether defendants' outsourcing facilities fulfill orders only where an order provides the requisite "Clinical Difference" statement.

The FDA's guidance document acknowledges that the 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

individual patients who will receive the compounded drug at the time of the order." FDA Guidance on 503B "Essentially a Copy" Requirement at 9. The FDA's document advises, however, that "[i]n 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 change produces a clinical difference, as determined by the prescribing practitioner for that patient." FDA Guidance on 503B "Essentially a Copy" Requirement at 9. The FDA further indicates that "[s]uch assurances should be provided by the health care practitioner or a person able to make the representation for the health care practitioner." *Id.*

Hope argues that defendants fail to satisfy these requirements for several reasons. First, Hope points to defendants' standard order forms, which do not specify the change between defendants' compounded drug and Hope's approved drug—the removal of potassium—but instead generically require the customer to attest that "the use of the below indicated compound drug preparations that have one or more variations in: active ingredient(s), route of administration, dosage form, dosage strength, and excipient(s) from comparable manufactured drug products provides clinical and safety benefits for patients who require these formulations." *See, e.g.*, Dkt. 121, Exh. C at 3. Hope also emphasizes that the seven order forms that defendants submit in support of their opposition brief are signed by the Director of Pharmacy, Clinical Manager, or Facility Administrator of defendants' customers, and that

"[n]one of these people treat patients or have prescribing authority," nor the authority "to make this representation on behalf of the physicians who actually treat patients and prescribe drugs for patients." Reply at 14.

In response, defendants argue that Hope "cannot hold [d]efendants responsible for not using specific language or having a particular person's signature on the documents the medical providers use to order [d]efendants' [outsourcing facilities] products." Opp. at 3. Defendants further rely on language in the FDA's guidance document which indicates that "[a]t this time, [the FDA] generally does not intend to question the determinations of clinical difference that are documented in a prescription or order[.]" FDA Guidance on 503B "Essentially a Copy" Requirement at 11.

The Court does not find defendants' argument availing. Defendants appear to conflate the FDA's statement that it does not intend to question "the determination of clinical difference"—in other words, a healthcare provider's determination regarding whether a specified change in formula is required—with whether a healthcare provider has adequately documented that such a change is necessary. Indeed, the very next sentence in the FDA's guidance document indicates that "we do intend to consider *whether a* prescription or *order relied upon* by an outsourcing facility to establish that a drug is not essentially a copy *documents* that *the determination* was made." FDA Guidance on 503B "Essentially a Copy" Requirement at 11 (emphases added). Moreover, the FDA expressly contemplated that some

prescribers' documentation of their determinations, on the outsourcing facility's order forms, could be insufficient to satisfy Section 503B. *See Id.* at 10 ("An order that only identifies the product formulation, without more information, would not be sufficient ... "). Presumably, that is why the FDA provides for a follow-up procedure that allows the outsourcing facility to "contact the prescriber or health care facility" to confirm whether there is a clinical need and "make a notation on the ... order that the prescriber has determined that the compounded product contains a change that produces a clinical difference for patient(s)." *Id.* at 11.

The FDA sets forth the following examples of notations on a non-patient-specific order form that "would be sufficient" to satisfy Section 503B's "clinical difference" requirement:

- 'Liquid form, compounded drug will be prescribed to patients who can't swallow tablet' (if the comparable drug is a tablet)
- '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)
- '1 mg, pediatric patients need lower dose' (if the comparable drug is only available in 25 mg doses).

FDA Guidance on 503B "Essentially a Copy" Requirement at 10. Unlike these examples, which specify the change as between the FDA-approved

product and the desired compounded product, defendants' forms do not appear to specify that Hope's product contains potassium, while defendants' do not. Nor do defendants' forms appear to make clear that this change is "clinically" significant for patients suffering from calciphylaxis, to whom the presence of potassium would pose a health risk.

In accordance with the foregoing, Hope appears likely to succeed on the merits of its claim that defendants' outsourcing facilities violate Section 503B's "essentially a copy" requirement.

b. Prohibition on Wholesaling

Section 503B also contains a prohibition on wholesaling. The statute provides that a drug, compounded in an outsourcing facility, "will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug." 21 U.S.C. § 353b(a)(8). The parties dispute whether defendants' outsourcing facilities are engaged in unlawful wholesaling.

Hope asserts that defendants "are illegally selling their sodium thiosulfate drug through a wholesaler/distributor, AmerisourceBergen Corporation." Mot. at 1. In support of this contention, Hope offers the declaration of its Dr. Craig Sherman, Hope's President, who attests that "[i]n September 2018, I received a phone call from a representative of a drug distributor, ASD Healthcare (which I know to be affiliated with the drug distributor AmerisourceBergen from visiting ASD's website ...), who inquired about purchasing Hope's Sodium Thiosulfate Injection." Sherman Decl. ¶ 15. Dr.

Sherman further attests that "[t]he representative informed me that the distributor she represented distributed [d]efendants' compounded sodium thiosulfate drug product," but that defendants' "compounded drug product was abruptly unavailable." *Id.*

In addition, Hope submits webpages from AmerisourceBergen's Integrated Nephrology Network "INN" website. *See* Dkt. 105-2, Exh. T. The INN website, which display's AmerisourceBergen's name and logo, indicates that INN "is the largest specialty nephrology Group Purchasing Organization dedicated exclusively to dialysis providers and nephrology practices[.]" *Id.* at 289. A portion of INN's website, entitled "Manufacturer Partners," indicates that "[b]y creating collaborative and receptive opportunities for manufacturer-provider communication, [INN] allows manufacturers to present themselves as partners in renal care" and that manufacturers can "[r]ely on INN for solutions that deliver your product's key messages through channels that garner a response." *Id.* at 290. Under the "Pharmaceutical Manufacturer Partners" heading, the page displays "JCB Laboratories" and its logo. *Id.* A different page on INN's website, entitled "Service Contracts," indicates that "INN offers its members a wide variety of contracted services to help control costs, streamline business and enhance quality care. These service contracts are available to all INN members, and prove very valuable in positively affecting the bottom line of business." Dkt. 105-2, Exh. T at 292. Under a heading entitled "Compounding Pharmacy," the page lists "JCB Laboratories (now Fagron Sterile Services)." *Id.* And, an order form that an AnazaoHealth employee sent to a prospective

customer—which lists "Sodium Thiosulfate 25% SDV PF (250mg/mL in 50mL vial)" as a product available for purchase—displays the logos for "Fagron Sterile Services," "JCB Laboratories," and "INN Amerisource Bergen Speciality Group." Dkt. 105-4, Exh. B.

In response to Hope's claim that defendants "sell their potassium-free products through" wholesalers, defendants aver that Hope has "provided nothing to substantiate this claim other than second hand hearsay and images and information, none of which support [Hope's] factually incorrect claim." Opp. at 13. In support of their argument, defendants rely on the declaration of TJ Bresnahan, AnazaoHealth's President, who attests that "Coast does not distribute its products through wholesalers." Bresnahan Decl. ¶ 6. Similarly, defendants submit a declaration from Carl Woetzel, the President of Fagron and JCB, who attests that Fagron and JCB "do not distribute any products, including potassium-free sodium thiosulfate, through wholesalers" but instead "distribute products directly to end-user facilities." Dkt. 113-3 ("Woetzel Decl.") ¶ 7. According to Woetzel, any "listing with General Purchasing Organization such as INN, and the inclusion of the INN logo on any consumer forms have no relationship whatsoever to how [Fagron] and JCB distribute products. [Fagron] and JCB do not distribute their products through any wholesalers, including AmerisourceBergen Corporation." *Id.* ¶ 8.

Section 503B provides that any drug compounded in an outsourcing facility "will not be *sold* or *transferred* by any entity other than the outsourcing facility that compounded such drug." 21 U.S.C.

§ 353b(a)(8) (emphases added). Based on the record before the Court, the Court cannot determine whether Amerisource is engaged in the direct sale or transfer of defendants' compounded sodium thiosulfate product.[7]

3. Private Enforcement of the FDCA

As discussed above, Hope's state-law consumer protection claims are predicated on defendants' alleged FDCA violations. Even assuming Hope has raised a serious question regarding its claims that defendants have violated one or more of the FDCA's provisions, defendants argue that Hope "has no private right of action under the FDCA."[8] Opp. at 11. In reply, Hope asserts that defendants' argument "is beside the point because Hope is not suing under the FDCA. Hope is suing under state consumer-protection laws, which incorporate state-law prohibitions on the sale of unapproved drugs." Reply at 17. According to Hope, then, its "claims rely on those state laws, not the FDCA." *Id.*

The FDCA provides that "all such proceedings for the enforcement, or to restrain violations, of this

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[7] During the hearing, defendants' counsel argued that AmerisourceBergen neither sells nor transfers defendants' compounded sodium thiosulfate product. Instead, defendants' counsel indicated that members of AmerisourceBergen's INN purchasing network received discounts on defendants' product.

[8] Defendants specifically raise this argument with respect to Hope's Tennessee, South Carolina, and Connecticut consumer protection claims. Opp. at 14–15. It is unclear whether defendants also challenge Hope's ability to vindicate defendants' alleged failure to comply with FDCA Sections 503A and 503B as violations of California and Florida law.

chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). "Courts have generally interpreted this provision to mean that no private right of action exists to redress alleged violations of the FDCA." *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 305 (C.D. Cal. 1996). Accordingly, some courts have determined that "plaintiffs may not use other federal statutes or state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA." *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290–91 (C.D. Cal. 2008); *see also Goldsmith v. Allergan, Inc.*, No. 2:09-cv-07088-PSG-E, 2011 WL 147714, at *2 (C.D. Cal. Jan. 13, 2011) ("A purported state-law claim does not exist where the claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist") (internal citation omitted); *accord Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) ("a private litigant cannot bring a state-law claim against a defendant ... when the state claim would not exist if the FDCA did not exist.").

The United States Court of Appeals for the Federal Circuit addressed the scope of the FDCA's preemption clause in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013). In that case, a pharmaceutical manufacturer, Allergan, sued a cosmetics company, Athena, based on Athena's marketing, distributing, and selling, without regulatory approval, products that qualify as drugs. *Id.* at 1352. Allergan sold an FDA-approved prescription drug used for the treatment of a condition that affects eyelash growth, and Athena sold, without

FDA-approval, a product that contained the same active ingredient. *Id.* at 1353. Allergan asserted a UCL claim against Athena—premised on Athena's alleged violation of Cal. Health & Safety Code § 111550 ("the Sherman Law") as the predicate "unlawful" act—based on allegations that Athena "market[ed], s[old], and distribut[ed] its hair and/or eyelash growth products without a new drug application by the FDA or California State Department of Health Services." *Id.* (internal alterations omitted). Athena challenged the district court's denial of Athena's motion for judgment on the pleadings that the FDCA pre-empted Allergan's UCL claim. *Allergan*, 738 F.3d at 1353.

On appeal, the Federal Circuit concluded "that the FDCA does not impliedly preempt [Allergan's] UCL claim."[9] *Allergan*, 738 F.3d at 1355. The Federal Circuit reasoned that the Sherman Law "incorporates various provisions of the FDCA, which does not itself allow a private right of action." *Id.* at 1354. The Federal Circuit explained that "'[t]he purpose of Congress is the ultimate touchstone in every pre-emption case.'" *Id.* at 1355 (citing *Wyeth v. Levine*, 555 U.S. 555, 565 (2009)). With this principle in mind, the Federal Circuit "d[id] not find a clear purpose by Congress to preempt" the Sherman Law, "the state law claim at issue." *Allergan*, 738 F.3d at 1355. The Federal Circuit determined that the Sherman Law "is not an obstacle to realizing federal objectives. To the contrary, it contains the provisions that parallel the

[9] The Federal Circuit had jurisdiction because Allergan previously asserted a claim for patent infringement.

FDCA, such that the statutes have consistent goals." *Id.* at 1356.

In *Imprimis*, another court in the Central District of California subsequently determined, based on the Federal Circuit's decision in *Allergan*, that "[t]he Sherman Law remains a valid mechanism for private enforcement of FDCA violations" through the UCL's unlawful prong. *Imprimis*, 2019 WL 4545960, at *8. After the court determined, at the summary judgment stage, "that as a matter of law there had been instances where Imprimis had" violated Sections 503A and 503B, the case proceeded to trial, and the court entered a posttrial permanent injunction. *Imprimis*, 2019 WL 4545960, at *1. The court noted that "Imprimis has not complied with the requirements set forth in Section 503A or Section 503B," and "[t]he Sherman Law forbids the sale of any drug that has not been approved by the California Department of Human Services or the FDA. It follows that failure to comply with the FDCA ... affronts California's parallel prohibition." *Id.* at *6.

Consistent with *Allergan* and *Imprimis*, then, it appears that the FDCA does not preempt state-law, consumer protection claims based on alleged violations of the FDCA where there is a parallel state law that renders the same noncompliant conduct independently unlawful. *See, e.g., Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1091 n.13, 1094 (2008) (determining that "in California, an unlawful business practice, *including violations of the Sherman law*, may be redressed by a UCL private action" and reasoning "[t]hat the Sherman law imposes obligations identical to those imposed by the FDCA ...

does not substantively transform plaintiffs' action into one seeking to enforce federal law.") (emphasis in original). Because Hope's claims arise under California, Florida, South Carolina, Connecticut, and Tennessee law, the Court looks to those states' laws to determine whether the FDCA preempts Hope's claims.

a. California

California's Sherman law provides that "'no person shall sell, deliver, or give away any new drug' that has not been approved by the California Department of Human Services or the FDA." *Imprimis*, 2019 WL 3029114, at *6 (citing Cal. Health & Safety Code § 111550(a)–(b)). And, "[i]t follows that failure to comply with the FDCA ... affronts" the Sherman Law. *Imprimis*, 2019 WL 3029114, at *6. Here, Hope alleges that defendants are selling compounded products in violation of FDCA Sections 503A and 503B, that California's Sherman Law "prohibit[s] the sale of drugs not approved by the FDA," and that defendants "have violated the UCL by ... marketing, selling, and distributing their products in violation of the California Sherman Law." FAC ¶ 15, 102. It does not appear, then, that the FDCA preempts Hope's UCL claim, which is predicated on Hope's allegations that defendants violated California's Sherman Law by failing to comply with the FDCA.

b. Florida

The Florida Drug and Cosmetic Act provides that "[a] person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any

new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce." Fla. Stat. § 499.023. Accordingly, the Florida Drug and Cosmetic Act imposes on drug manufacturers independent statutory obligations that parallel those in the FDCA. *See* Fla. Stat. § 499.002(1)(b) (describing Florida Drug and Cosmetic Act "as intended to ... [p]rovide uniform legislation to be administered so far as practicable in conformity with the provisions of ... the Federal Food, Drug, and Cosmetic Act").

Here, Hope alleges that defendants' compounding practices violate Sections 503A and 503B, and thus the Florida Drug and Cosmetic Act, and Hope's FDUTPA claim is based on these underlying violations. *See* FAC ¶ 116. "FDUTPA requires that its provisions 'be construed liberally' to ... 'protect 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.'" *State Farm Mut. Auto. Ins. Co. v. Performance Orthopaedics & Neurosurgery, LLC*, 278 F. Supp. 3d 1307, 1324 (S.D. Fla. 2017) (citing Fla. Stat. § 501.202(2)). Accordingly, because Florida law appears to impose a separate, parallel obligation on drug manufacturers to adhere to the FDCA, the Court cannot say, at this juncture, that the FDCA bars Hope's FDUTPA claim.

c. Tennessee

The Tennessee Food, Drug and Cosmetic Act provides that "[n]o 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."[10] Tenn. Code § 53-1-110. The TCPA makes "unlawful" the "[a]dvertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state[.]" Tenn. Code § 47-18-104 (b)(43)(C).

Defendants cite *Autin v. Solvay Pharm., Inc.*, for the proposition that "courts have held that plaintiffs may not use other laws to enforce violations of the FDCA indirectly." Opp. at 15 (citing No. 05-2213-MA-AN, 2006 WL 889423, at *3 (W.D. Tenn. Mar. 31, 2006)). In that case, however, plaintiffs directly challenged, as a TCPA violation, a drug manufacturer's sale of a drug in contravention of applicable FDA regulations. *Autin*, 2006 WL 889423, at *3. By contrast, Hope avers that defendants' sales contravene the Tennessee Food, Drug and Cosmetic Act because they violate FDCA Sections 503A and

[10] Although the Tennessee Food, Drug, and Cosmetic Act appears to vest the Tennessee Department of Agriculture with primary enforcement authority, *see* Tenn. Code Arm. § 53-1-101, Tennessee courts have concluded that private litigants may assert claims predicated on underlying violations of the Tennessee Food, Drug, and Cosmetic Act. *See Bissinger v. New Country Buffet*, No. 2011-M-02183-COA-R9CV, 2014 WL 2568413, at *19 (Tenn. Ct. App. June 6, 2014) (allowing decedent's estate to pursue negligence claim against restaurant based on restaurant's alleged sale of oysters in violation of Tennessee Food, Drug, and Cosmetic Act).

503B, which Hope asserts gives rise to a TCPA claim. *See* FAC ¶ 52.

Federal law impliedly preempts a state law only where "compliance with both federal and state regulations is a physical impossibility ... or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress[.]" *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). Because the Tennessee Food, Drug and Cosmetic Act simply creates an independent state law duty that mirrors the FDCA, the FDCA does not preclude Hope's TCPA claim based on defendants' alleged violation of the Tennessee Food, Drug, and Cosmetic Act.

d. Connecticut

The Connecticut Food, Drug, and Cosmetic Act provides that "[n]o 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[.]" Conn. Gen. Stat. § 21a-110(a). CUTPA, Connecticut's consumer protection statute, states that "[n]o person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110b(a). "In determining whether a practice violates CUTPA, courts have used the 'cigarette rule' adopted by the Federal Trade Commission, which looks to" factors including, *inter alia*, "[w]hether the practice ... offends public policy as it has been established by statutes, the common law, or otherwise[.]" *Bentley v. Greensky Trade Credit, LLC*, 156 F. Supp. 3d 274, 288-89 (D. Conn. 2015) (internal citation omitted).

In arguing that the FDCA preempts Hope's CUTPA claim, defendants rely on *Patane v. Nestle Waters N. Am., Inc. See* Opp. at 15 (citing 314 F. Supp. 3d 375 (D. Conn. 2018)). In that case, consumers asserted a CUTPA claim against a manufacturer, alleging that the manufacturer mislabeled its spring water in violation of the FDCA. *Patane*, 314 F. Supp. 3d at 378. The court dismissed the plaintiffs' CUTPA claim on preemption grounds, explaining that "[i]n order to survive preemption, a state law claim must rely on an independent state law duty that parallels or mirrors the FDCA's requirement[.]" *Id.* at 386. The plaintiffs' CUTPA claim failed to meet that standard, however, because the claim was "wholly FDCA-dependent." *Id.* at 387.

Defendants' reliance on *Patane* is unavailing because the court explicitly concluded that "a State can impose the *identical* requirement or requirements, and by doing so be enabled to enforce a violation of the FDCA as a violation of state law." 314 F. Supp. 3d at 386 (emphasis in original) (internal citation omitted). That is Hope's theory here, as Hope alleges that the Connecticut Food, Drug, and Cosmetic Act imposes independent requirements that mirror those of the FDCA and that defendants violated these requirements in failing to adhere to Sections 503A and 503B, giving rise to a CUTPA claim. *See* FAC ¶¶ 15, 131–32. Accordingly, the Court rejects defendants' argument that the FDCA preempts Hope's CUTPA claim.

e. South Carolina

The South Carolina Drug Act provides that "[n]o person shall introduce or deliver for introduction into

intrastate commerce any new drug unless an application ... 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 § 39-23-70(a). SCUTPA makes unlawful "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce[.]" S.C. Code § 39-5-20(a). "In order to bring an action under [SCUTPA], the plaintiff must demonstrate," among other things, that the defendant engaged in an unlawful trade practice[.]" *Havird Oil Co. v. Marathon Oil Co.*, 149 F.3d 283, 291 (4th Cir. 1998).

Defendants cite *Bean v. Upsher-Smith Pharm., Inc.* for the proposition that "[t]he FDCA does not provide a private right of action for a defendant's violation of its provisions." Opp. at 15 (citing No. 4:16-cv-01696-RBH, 2017 WL 4348330, at *6 (D.S.C. Sept. 29, 2017)). In that case, the court determined that a plaintiff's state-law negligence claims "based on the alleged 'off-label' promotion of amiodarone [were] impliedly preempted ... because the duties [p]laintiff alleges [d]efendants breached regarding 'offlabel' promotions exist solely under the FDCA." *Id.* at *7. The court noted that "[p]laintiff has not directed the Court to any S.C. state law causes of action that parallel the federal safety requirements [.]" *Bean*, 2017 WL 4348330, at *7.

Here, by contrast, Hope's SCUTPA claim is based on defendants' alleged violation of the South Carolina Drug Law, *see* FAC ¶¶ 9,126, which independently imposes on drug makers requirements that mirror those set forth in the FDCA. The Court therefore finds

unavailing defendants' preemption argument regarding Hope's SCUTPA claim.

4. Other Miscellaneous Arguments

Assuming that Hope has demonstrated a likelihood of success on the merits of its claims that defendants violate state law by failing to adhere to FDCA Sections 503A and 503B and that the FDCA does not pre-empt Hope's state-law claims, defendants offer several additional arguments as to why Hope's claims nonetheless fail. For example, defendants argue that Hope "has produced no evidence either in discovery or in its Motion that it lost sales because of [d]efendants allegedly illegal conduct." Opp. at 13. According to defendants, then, Hope "therefore has not made the requisite evidentiary showing of economic injury, and therefore has not established a likelihood of success on the merits." Opp. at 13 (internal citations omitted).

As an initial matter, the cases upon which defendants rely are wholly inapt. As an example, defendants rely on the Court's denial of a motion for a preliminary injunction in *Essence Imaging Inc. v. Icing Images LLC*, No. 2:13-cv-5449-CAS, 2014 WL 1384028, (C.D. Cal. Apr. 9, 2014). In that case, the Court denied a printing product manufacturer's motion for a preliminary injunction, determining that the manufacturer failed to show a likelihood of success on the merits of its California False Advertising Law ("FAL") claim. *Id.* at *2. The Court noted that the manufacturer "contends in its memorandum in support of its motion for a preliminary injunction that it is 'losing sales to Defendants' falsely advertised claims,'" but concluded "that this contention is

unsupported by any evidence" and was therefore insufficient to establish "statutory standing to bring an FAL claim." *Id.* Hope does not assert a FAL claim—which contains unique statutory standing requirements—here.

And, contrary to defendants' assertion, Hope does submit evidence that it has lost sales to defendants because of defendants' alleged misconduct.[11] The parties agree that Hope and defendants are the only two suppliers of sodium thiosulfate products. Opp. at 20; Reply at 14. Dr. Sherman, Hope's President, attests that: (1) defendants severely limited their sales of compounded sodium thiosulfate during a seven-month period between September 2018 and March 2019; (2) during this time, defendants' customers, including DaVita and Fresenius, began buying from Hope instead; (3) Hope's sales then increased by 44% in California, 146% in Connecticut, 67% in Florida, 134% in South Carolina, and 20% in Tennessee during this period; and (4) Hope's sales decreased once defendants resumed selling their compounded products, allegedly in violation of Sections 503A and

[11] Defendants cite *Tseng v. Home Depot USA, Inc.*, for the proposition that "arguments of counsel and conclusory factual statements are improper in support of a motion for preliminary injunction." Opp. at 13 (citing No. 05-cv-0908-RSM, 2006 WL 521723, at *3 (W.D. Wash. Mar. 2, 2006)). In that case, the court determined that a declaration from the plaintiff's counsel regarding the infringement of the plaintiff's patent was "improper" because "it contains conclusory attorney argument that 'masquerades as expert opinion[.]'" *Tseng*, 2006 WL 521723, at *3. While Hope submits a declaration from its counsel, dkt. 111-1, the declaration merely describes the exhibits that Hope offers in support of its motion, including defendants' sales data.

503B. Sherman Decl. ¶¶ 14–21. Accordingly, the Court concludes that Hope has set forth sufficient evidence of its own harm because "[w]hen two competitors split a market, such that one's lost sales are likely the other's gains, ... 'it is reasonable to presume that every dollar defendant makes has come directly out of plaintiff's pocket.'" *K&N Eng'g, Inc. v. Spectre Performance*, No. 5:09-cv-01900-VAP-DTB, 2012 WL 12893797, at *6 (C.D. Cal. Aug. 2, 2012) (citing *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 831 (9th Cir. 2011)) (internal alterations omitted).

Defendants further assert that Hope's claims fail because "[a]ll of the state statutes also require a showing of harm to ... a consumer." Opp. at 13. According to defendants, Hope "cannot make that showing here ... because [Hope] provided no evidence of any consumer injury, which is fatal to its claims." *Id.* Assuming *arguendo* that Hope's consumer protection claims require harm to consumers, rather than to simply Hope itself, Hope adduces evidence of such harm to consumers here. For example, Hope submits evidence that consumers are confused about the source of defendants' sodium thiosulfate drug, blaming Hope for defendants' allegedly deficient shipping practices and causing Hope to suffer a loss in Hope's reputation and goodwill. *See* Sherman Decl. ¶¶ 10–12; Dkt. 105-4, Exhs. C–D. Each of the consumer protection statutes that form the bases for Hope's claims appear to recognize consumer confusion as a form of consumer harm. *See Xerox Corp. v. Apple Computer, Inc.*, 734 F. Supp. 1542, 1550 (N.D. Cal. 1990) (noting that competitor could state UCL claim where "there is a likelihood of consumer confusion as

to source or sponsorship"); *Wyndham Vacation Resorts. Inc. v. Timeshares Direct, Inc.*, 123 So. 3d 1149, 1152 (Fla. Dist. Ct. App. 2012) (determining that "conduct [that] could create consumer confusion and damage [competitor's] goodwill ... is actionable under FDUTPA"); *Suisman, Shapiro, Wool, Brennan, Gray, & Greenberg, P.C. v. Suisman*, No. 3:04-CV-745-JCH, 2006 WL 387289, at *13 (D. Conn. Feb. 15, 2006) ("evidence of actual consumer confusion supports the inference that the plaintiff ... has suffered an ascertainable loss entitling it to relief under CUTPA."): *Sinclair & Assocs. of Greenville. LLC v. Crescom Bank*. No. 2:16-cv-00465-DCN, 2016 WL 6804326, at *3 (D.S.C. Nov. 17, 2016) (noting that SCUTPA allows a plaintiff "to show that an unfair or deceptive act or practice adversely affects the public interest by demonstrating a potential for repetition" such as repeated "public confusion"); *Kaldy v. Urshow.tv, Inc.*, No. 2:16-cv-00054, 2017 WL 104148, at *4 (E.D. Tenn. Jan. 10, 2017) (finding that "likelihood of confusion among consumers" can give rise to "claims under the TCPA.").

In addition, Hope argues that "because [d]efendants' [sic] cannot legally sell their drugs, consumers are necessarily injured by buying an illegal product." Reply at 16. That is because, according to Hope, "there is no market value for an unlawful product." Reply at 16. The consumer protection statutes upon which Hope's claims are based each recognize that, in particular circumstances, the sale of an illegal product can itself give rise to a claim. *See Gitson v. Trader Joe's Co.*, No. 13-CV-01333-WHO, 2013 WL 5513711, at *10 (N.D. Cal. Oct. 4, 2013) (finding that plaintiffs could state a UCL claim

predicated on violation of the Sherman Law based on defendant's alleged failure to comply with FDA's regulations); *Morris v. Viking Pools Ne., Inc.*, 492 F. Supp. 2d 90, 94 (D. Conn. 2007) (determining that plaintiff could state CUTPA claim against pool installer where installer unlawfully installed pool without a license and recognizing that unlawful installation would cause redressable "financial injury" in form of higher price); *In re StarLink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d 828, 835, 852 (N.D. Ill. 2002) (determining that manufacturers' sale of genetically modified corn that failed to comply with Environmental Protection Agency's requirements gave rise to TCPA claim); *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019) (determining that plaintiffs could state FDUTPA claim based on purchase of dietary supplements unlawfully adulterated in violation of the FDCA because "a dietary supplement that is deemed adulterated and cannot lawfully be sold has no value."): *Jones v. Ram Med., Inc.*, 807 F. Supp. 2d 501, 510(D.S.C. 2011) (determining that pharmaceutical device manufacturers' sale of surgical mesh gave rise to SCUTPA claim based on allegations that manufacturers' product was a counterfeit that violated FDA regulations and reasoning that plaintiffs "have alleged that [d]efendants have acted in a manner which is clearly not permitted under FDA regulations.").

C. Irreparable Harm

Having determined that Hope has at least raised "serious questions" regarding the merits of its claims, the Court next determines where Hope has

demonstrated that it would suffer irreparable harm in the absence of a preliminary injunction. On this point, Hope bears the burden of demonstrating "that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in original). "Irreparable harm is traditionally defined as harm for which there is no adequate legal remedy, such as an award of damages." *Arizona Dream Act Coal, v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014). Stated differently, "economic harm is not generally considered irreparable." *E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1280 (9th Cir. 2020). As such, "a party is not entitled to a preliminary injunction unless he or she can demonstrate more than simply damages of a pecuniary nature." *Regents of Univ. of California v. Am. Broad. Companies, Inc.*, 747 F.2d 511, 519 (9th Cir. 1984).

1. Loss of Customers, Market Share, and Goodwill

Here, Hope avers that without a preliminary injunction, it will suffer several forms of irreparable harm. For example, Hope argues that its lost sales are not compensable by money damages because its consumer protection claims do not allow for recovery of money damages, and "[l]ost profits that are *not* compensable through monetary damages are irreparable harm." Reply at 21 (emphasis in original).

Hope also argues that absent an injunction, it will "los[e] customers, market share, reputation, and goodwill due to [d]efendants' conduct." Mot. at 22. Courts have recognized that, in some circumstances, the likelihood of loss of customers, market share, and goodwill can support the issuance of a preliminary

injunction. *See, e.g., Herb Reed Enterprises, LLC v. Fla. Entm't Mgmt., Inc.*, 736 F.3d 1239, 1250 (9th Cir. 2013) ("Evidence of loss of control over business reputation and damage to goodwill could constitute irreparable harm."); *Bird-B-Gone, Inc. v. Bird Barrier Am., Inc.*, No. 8:12-cv-00178-AG-RNB, 2013 WL 11730662, at *2 (C.D. Cal. Mar. 20, 2013) ("Lost market share can constitute irreparable harm[.]"); *see also Car-Freshner Corp. v. Valio, LLC*, No. 2:14-cv-01471 -RFB-GWF, 2016 WL 7246073, at *8 (D. Nev. Dec. 15, 2016) ("Damage to reputation and loss of customers are intangible harms not adequately compensable through monetary damages."). However, any finding of irreparable harm "cannot be grounded in platitudes rather than evidence." *Cutera, Inc. v. Lutronic Aesthetics. Inc.*, No. 2:20-cv-00235-KJM-DB, 2020 WL 1234551, at *6 (E.D. Cal. Mar. 13, 2020) (citing *Herb*, 2-2-W; 1234551, at *6).

Hope submits evidence that on two separate occasions, it received inquiries for sodium thiosulfate products that were apparently intended for defendants. *See* Sherman Decl. ¶¶ 11–12. On one of these occasions, one of defendants' customers appeared to blame Hope for defendants' tardy shipment of defendants' products. *See* Dkt. 105-4, Exh. D. Hope further urges that "confused customers may associate the many FDA warning letters [d]efendants have received with Hope, misleading customers into thinking that Hope's drugs, like [d]efendants', are unsafe." Mot. at 22 (internal citations omitted). And, after defendants resumed selling their compounded sodium thiosulfate products, Hope lost two customers, DaVita and Fresenius, to defendants. Sherman Decl. ¶¶ 14–21.

That two of defendants' customers previously confused Hope with defendants, and that Hope lost to defendants two specific customers, DaVita and Fresenius, who were originally defendants' customers, does not, itself, appear to demonstrate the type of irreparable harm that would warrant a preliminary injunction. *See Open Text, S.A. v. Box, Inc.*, 36 F. Supp. 3d 885, 906 (N.D. Cal. 2014) ("Although the 'quantum of evidence' required to prove irreparable harm is unclear, case law is clear that the *potential* for loss of market share is insufficient. Open Text has not provided to the Court, with any level of specificity, what sales have been lost to Box, what Open Text's market share is in relevant market, or any evidence of actual lost customers going to Box.") (emphasis in original). Hope does not, for example, point to specific customers that it fears it may lose to defendants should defendants continue to sell their compounded products. *Cf. Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 841 (9th Cir. 2001) (determining that safe manufacturer had shown irreparable harm warranting preliminary injunction enjoining manufacturer's competitor from using the United States Customs Service to seize manufacturer's safes where safes were "earmarked" for particular customers such that, without injunction, seizure would cause manufacturer "to lose its newfound customers and accompanying goodwill and revenue."). On the other hand, Hope and defendants are the only two suppliers of sodium thiosulfate products in the United States, and "[t]he existence of a two-player market may well serve as a substantial ground for granting an injunction because it creates an inference that an infringing sale amounts to a lost

sale" with respect to the other market participant. *Open Text*, 36 F. Supp. at 906.

On balance, Hope has demonstrated a likelihood of irreparable harm based on loss of customers, market share, and goodwill, especially since Hope and defendants are the only two participants in the market for sodium thiosulfate in the United States. The unavailability of monetary damages, with respect to at least several of Hope's claims, further bolsters the Court's finding of irreparable harm.[12]

2. Delay

In addition, "[d]elay in seeking a remedy is an important factor bearing on the need for a preliminary injunction[.]" *Open Text*, 36 F. Supp. 3d at 909. The Ninth Circuit has stated that a "long delay before seeking a preliminary injunction implies a lack of urgency and irreparable harm." *Oakland Tribune. Inc. v. Chronicle Pub. Co.*, 762 F.2d 1374, 1377 (9th Cir. 1985). Defendants argue that even assuming Hope has demonstrated defendants' conduct has harmed Hope, Hope's delay in filing the present motion for a preliminary undermines that harm.

Here, Carl Woetzel, the President of Fagron and JCB, attests that "JCB has been producing and distributing potassium-free sodium thiosulfate since

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[12] For example, the California Supreme Court has explained that "[w]hile the scope of conduct covered by the UCL is broad, its remedies are limited." *Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal. 4th 1134, 1144 (2003). Accordingly, "damages cannot be recovered." *Id.* Similarly, with respect to Hope's FDUTPA claim, defendants themselves argue that "lost profits are not recoverable under the Act." Opp. at 15.

2011." Woetzel Decl. ¶ 5. By contrast, Hope only received approval from the FDA to sell its sodium thiosulfate injection, as a treatment for acute cyanide poisoning, in 2012. *See* Mot. at 6. Hope sent defendants a cease and desist letter on August 17, 2018, notifying defendants that Hope "manufactures the only FDA-approved sodium thiosulfate drug approved in the United States" and indicating that JCB "distributes compounded sodium thiosulfate in violation of" Section 503B of the FDCA. *See* Dkt. 27-1, Exh. B. JCB responded on September 7, 2018, indicating that "JCB will not cease compounding and dispensing Sodium Thiosulfate" because, *inter alia*, JCB "believes that it is in compliance with [the] FDA's expectations under the FDCA[.]" Dkt. 113-1, Exh. B. More than one year after sending its cease and desist letter, Hope filed this action on September 6, 2019. Dkt. 1. While Hope originally moved for a preliminary injunction on September 27, 2019, it withdrew that motion, filing the present preliminary injunction motion on June 1, 2020. Dkts. 22, 46, 105. That Hope knew of defendants' alleged unlawful conduct in August of 2018 but did not file the present motion until June of 2020 tends to undermine Hope's claim that defendants' conduct will irreparably harm Hope unless the Court grants Hope's request for injunctive relief.

In reply, Hope claims it did not unreasonably delay in filing the present motion for injunctive relief. Hope points out that "[d]efendants stopped selling their compounded sodium thiosulfate drugs shortly after Hope sent its letter," such that during the time when defendants were no longer selling their compounded product, "Hope had no reason to seek ...

an injunction against conduct that was not occurring." Reply at 18. After defendants resumed "their illegal drug sales in April 2019," and after another court in *Imprimis* entered a permanent injunction in July of 2019, which "clarif[ied] the law of sections 503A and 503B," Hope asserts that it "then promptly filed this lawsuit in September 2019." *Id.* Hope explains that it withdrew its prior preliminary injunction motion because that motion challenged defendants' practice of compounding bulk sodium thiosulfate even though bulk sodium thiosulfate did not then appear on the FDA's "bulks list," but after Hope filed the motion, the FDA subsequently added bulk sodium thiosulfate to its Category 1 list, mooting Hope's motion. Reply at 19. Hope attributes its further delay in filing the present motion to defendants' alleged refusal to produce certain discovery that would form the basis for the present motion, requiring Hope to bring a motion to compel discovery responses. *Id.* Pursuant to an order granting in part Hope's motion to compel, defendants "produced 150,000 pages of documents" to Hope on March 25, 2020. *Id.*; *see also* Dkt. 76 (order granting in part Hope's motion to compel defendants' discovery responses).

While "a party requesting a preliminary injunction must generally show reasonable diligence," *Benisek v. Lamone*, 138 S. Ct. 1942, 1944-45 (2018), "delay is only one factor among the many that we consider in evaluating whether a plaintiff is likely to suffer irreparable harm absent interim relief," and "by itself is not a determinative factor in whether the grant of interim relief is just and proper." *Cuviello v. City of Vallejo*, 944 F.3d 816, 833 (9th Cir. 2019) (citations omitted). In accordance with the foregoing,

the Court concludes that Hope did not unreasonably delay in filing the present motion for a preliminary injunction.

D. Balance of Hardships

"In each case, a court must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Amoco Prod. Co. v. Vill. of Gambell, AK*, 480 U.S. 531, 542 (1987). Here, Hope argues that "[t]he balance of hardships weighs strongly in Hope's favor." Mot. at 23. Dr. Sherman, Hope's President, attests that Hope's "Sodium Thiosulfate Injection is one of three products sold by Hope[.]" Sherman Decl. ¶ 21. According to Hope, then, allowing defendants to continue to sell their compounded products would cause Hope substantial hardship in the form of lost sales and goodwill with respect to one of Hope's only three products. Mot. at 23-24. Hope further asserts that "[t]he extent to which [d]efendants' business depends on the sale of illegal sodium thiosulfate drugs is not precisely known, but [is] likely quite small when compared to their total revenues." *Id.* at 23–24 n. 9.

Defendants, in turn, argue that "the balance of hardships strongly favors" them. Opp. at 19. Defendants urge that they "have been in the business of compounding and selling their potassium-free sodium thiosulfate for years" and that "[g]ranting the injunction would require [d]efendants to shut down a significant portion of [their] business [that] has taken years to develop and grow[.]" Opp. at 19. Defendants also assert that they primarily sell their compounded sodium thiosulfate products for the off-label use of treating renal patients suffering from calciphylaxis, so

it is unlikely that allowing them to continue selling their compounded products will cause substantial harm to Hope since Hope is "still ... unable to market its sodium thiosulfate to treat calciphylaxis without FDA approval[.]" *Id.*

Neither party has provided any evidence from which the Court can determine the extent to which the parties' businesses depend on the sale of the parties' respective sodium thiosulfate products. However, a limited injunction that would allow defendants to continue operating so long as defendants comply with the "essentially a copy" requirements of Sections 503A and 503B would not unduly burden defendants' business. By contrast, without an injunction, Hope faces additional lost sales and goodwill. For these reasons, the Court concludes that the balance of hardships favors Hope.

E. Public Interest

Finally, the Court considers "whether the public interest will be advanced by granting preliminary relief." *Preminger v. Principi*, 422 F.3d 815, 823 (9th Cir. 2005). The parties dispute whether a preliminary injunction would advance the public interest.

Defendants urge that "granting the injunction would deprive a population of dialysis patients of access to treatment for calciphylaxis." Opp. at 19. Indeed, defendants provide a May 30, 2018 letter from one of defendants' customers, Dr. Jeffrey Hymes, the Chief Medical Officer of Fresenius Kidney Care, "urg[ing] the FDA to continue to allow compounding of sodium thiosulfate by JCB/Fagron" because of the clinical value defendants' products, rather than

Hope's, provide renal patients suffering from calciphylaxis. Dkt. 113-1, Exh. A. In an October 7, 2019 letter, Dr. Hymes opposes Hope's efforts to enjoin defendants, indicating that he "ha[s] grave concerns about this action." *Id.* Dr. Hymes explains that, "[a]t any given time 400-500 patients may be" receiving treatment from Fresenius using defendants' compounded sodium thiosulfate product, and "[t]he arbitrary elimination of one of the two major suppliers of this compound places our patients at the risk of product unavailability." *Id.* Dr. Hymes further contends that, "[a]dditionally, a monopoly on thiosulfate by one company creates potential financial jeopardy for [Fresenius], which treats approximately 200,000 patients, 80% of whom are Medicare beneficiaries." *Id.* Similarly, defendants submit a letter from another of defendants' customers, Dr. George Aronoff, the Vice President of Clinical Affairs for DaVita Kidney Care, to the FDA "strongly urg[ing] the FDA to continue to allow compounding ... by JCB/Fagron" and nothing that defendants' products can be used to treat DaVita's patients that suffer from [c]alciphylaxis." Dkt. 113-1, Exh. B. Dr. Aronoff indicates that "[c]alciphylaxis occurs in about 4% of dialysis patients ... for DaVita this equates to approximately 6,000 patients." *Id.*

Hope asserts that "[t]he public interest favors an injunction for the simple reason that [d]efendants are seeking to gain a competitive advantage by violating the law." Reply at 21. Thus, "[g]ranting 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." Mot. at 24. Hope moreover argues that an injunction "would

also ensure the safety and effectiveness of the sodium thiosulfate drug on the market." *Id.* at 25. Hope submits warning letters, inspection reports, and recall notices that the FDA appears to have issued to defendants.[13] *See* Dkt. 106-1, Exhs. I–K, M–U. One release by the FDA, dated August 26, 2013, indicates that JCB voluntarily recalled products, including sodium thiosulfate, "due to concerns of sterility assurance following a recent inspection[.]" Dkt. 106-1, Exh. K. In a September 14, 2018 inspection report, the FDA noted that "[y]our firm lacked valid analytical and stability data to support the ... expiration date assigned to all of your products such as Vancomycin, Sodium Thiosulfate, and Ephedrine Sulfate." Dkt. 106-1, Exh. J at 157. The FDA's inspection report further noted that JCB's compounded sodium thiosulfate has "no method validation for potency, sterility, and endotoxin." *Id.* at 158. And, in a December 18, 2018 email chain, JCB and Fagron employees discussed having [REDACTED].

[T]here is a public interest in upholding the law and having parties abide by their legal duties." Judge Virginia A. Phillips & Judge Karen L. Stevenson, *Federal Civil Procedure Before Trial*, § 13:76.1 (The Rutter Group 2019). And, in *Imprimis*, another court in the Central District of California issued a post-trial permanent injunction, determining that the public interest favored enjoining a drug compounder that had violated Sections 503A and 503B. 2019 WL

[13] Defendants characterize these materials as "hearsay," "old press releases," "old FDA inspection reports," and "recalls of products other than [d]efendants' potassium-free sodium thiosulfate[.]" Opp. at 5, 14.

3029114, at *13. The court explained that "some compounders have taken advantage of the Section 503A exception in order to distribute drugs without individualized prescriptions, or have compounded drugs in 503B facilities using ingredients that are not undergoing FDA evaluation." *Imprimis*, 2019 WL 3029114, at *13. The court reasoned that "the State of California has chosen to pass a law that parallels federal approval of such new drugs; and ... this provides a limited mechanism for protecting against their distribution and production in California." *Id.* Accordingly, the Court concluded that "[t]he public interest is not disserved by enforcing these guidelines in California to protect patients from the sale and distribution of drugs that are not produced in accordance with applicable requirements." *Id.*

California, Florida, Connecticut, South Carolina, and Tennessee each provide for limited mechanisms to protect against the distribution and production of drugs that do not conform with their various statutory requirements, which parallel those set forth in the FDCA. On balance, the Court therefore concludes that the public interest factor favors the entry of a preliminary injunction.

F. Appropriate Bond

Rule 65(c) provides that the Court "may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c). "Rule 65(c) invests the district court with discretion as to the amount of security required, *if*

any." *Jorgensen v. Cassiday*, 320 F.3d 906, 919 (9th Cir. 2003) (emphasis in original) (internal citation omitted). "In particular, the district court may dispense with the filing of a bond when it concludes there is no realistic likelihood of harm to the defendant from enjoining his or her conduct." *Johnson*, 572 F.3d at 1086 (internal citation and alteration omitted).

During the hearing, defendants' counsel indicated defendants' position that no bond would be necessary to the extent that any preliminary injunction entered by the Court allowed defendants to continue operating so long as defendants' 503A and 503B facilities required more specific attestations from customers regarding the clinical need for defendants' products. Accordingly, the Court concludes that Hope need not post a bond.

V. CONCLUSION

For the foregoing reasons, the Court orders as follows:

1. To the extent that the parties' respective requests for judicial notice seek judicial notice of the existence of particular documents, dkts. 106, 114, 123, the Court GRANTS the parties' requests for judicial notice. The Court DENIES the parties' requests for judicial notice in all other respects.

2. The Court OVERRULES the parties' evidentiary objections.

3. The Court GRANTS in part Hope's motion for a preliminary injunction as follows[14]:

a. Defendants and their officers, agents, servants, employees, attorneys and all those acting in concert with them, shall be preliminarily enjoined from directly or indirectly dispensing or distributing any compounded sodium thiosulfate product from a 503A facility into California, Connecticut, Florida, South Carolina, or Tennessee unless: (i) defendants are provided a valid prescription or order form for the product; (ii) the prescription or order form includes an attestation specifically indicating that defendants' compounded product, which does not contain potassium, will produce a significant difference for the intended patient; (iii) the attestation specifies that defendants' compounded product, rather than the comparable commercially available drug product, is "medically necessary" for the intended patient; and (iv) the attestation indicates that the attestation is made or approved by the intended patient's prescribing practitioner.

b. Defendants and their officers, agents, servants, employees, attorneys and all those acting in concert with them, shall be preliminarily enjoined from directly or indirectly dispensing or distributing any compounded sodium thiosulfate product from a 503B facility into California, Connecticut, Florida, South Carolina, or Tennessee unless: (i) defendants are provided an order form for the product; (ii) the order

[14] To the extent necessary, each of the foregoing findings of fact may deemed a conclusion of law, and each of the foregoing conclusions of law may be deemed a finding of fact.

form includes an attestation specifically indicating that defendants' compounded product, which does not contain potassium, will produce a clinical difference; (iii) the attestation specifies that defendants' compounded product, rather than the comparable commercially available drug product, is "medically necessary" for the patients to whom defendants' drug will be distributed or dispensed; and (iv) the attestation indicates that the attestation is made or approved by a prescribing practitioner.

c. The Court DENIES Hope's motion for a preliminary injunction in all other respects.

IT IS SO ORDERED.

Appendix D

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 22-55173

HOPE MEDICAL ENTERPRISES, INC.,
DBA Hope Pharmaceuticals,

Plaintiff-Appellee,

v.

FAGRON COMPOUNDING SERVICES, LLC; *et al.*,

Defendants-Appellants.

Appeal from the United States District Court
for the Central District of California, Los Angeles
D.C. No. 2:19-cv-07748-CAS-PLA

Filed October 2, 2023
Document No. 73

ORDER

Before: S.R. THOMAS, NGUYEN, and FORREST, Circuit Judges.

The full court has been advised of the petition for rehearing en banc, and no judge of the court has requested a vote on the petition for rehearing en banc. Fed. R. App. P. 35(b).

The appellee's petition for rehearing en banc is DENIED.

Appendix E

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 22-55173

HOPE MEDICAL ENTERPRISES, INC.,
DBA Hope Pharmaceuticals,

Plaintiff-Appellee,

v.

FAGRON COMPOUNDING SERVICES, LLC; *et al.*,

Defendants-Appellants.

Appeal from the United States District Court
for the Central District of California, Los Angeles
D.C. No. 2:19-cv-07748-CAS-PLA

Filed October 27, 2023
Document No. 79

ORDER

Before: S.R. THOMAS, NGUYEN, and FORREST, Circuit Judges.

Appellee's Motion to Stay the Mandate (Dkt. No. 74) is GRANTED. Pursuant to Rule 41(d) of the Federal Rules of Appellate Procedure, the mandate is stayed for 90 days to permit the filing of a petition for writ of certiorari in the Supreme Court. Appellee must notify the Court in writing that the petition has been filed, in which case the stay will continue until the

Supreme Court resolves the petition. *See* Fed. R. App. P. 41(d)(2)(B)(ii). Should the Supreme Court grant certiorari, the mandate will be stayed pending disposition of the case. Should the Supreme Court deny certiorari, the mandate will issue immediately. The parties shall advise this Court immediately upon the Supreme Court's decision.

Appendix F

Relevant Constitutional Provisions and Statutes

U.S. Const., art. VI, cl. 2 (U.S. Supremacy Clause)

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 U.S.C. § 337

Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)--

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the

informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

21 U.S.C. § 353a

Pharmacy compounding

(a) In general

Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding--

(1) is by--

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid

prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between--

(i) the licensed pharmacist or licensed physician; and

(ii)(I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician--

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations--

(i) that--

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are

components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product

A drug product may be compounded under subsection (a) only if--

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State--

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints

relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

(c) Regulations

(1) In general

The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(2) Limiting compounding

The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(d) Application

This section shall not apply to--

(1) compounded positron emission tomography drugs as defined in section 321(ii) of this title; or

(2) radiopharmaceuticals.

(e) "Compounding" defined

As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(f) Redesignated (e)

21 U.S.C. § 353b

Outsourcing facilities

(a) In general

Sections 352(f)(1), 355, and 360eee-1 of this title shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

(1) Registration and reporting

The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

(2) Bulk drug substances

The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless--

(A)(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by--

(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing;

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

(C) the bulk drug substances are each manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

(3) Ingredients (other than bulk drug substances)

If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

(4) Drugs withdrawn or removed because unsafe or not effective

The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or

components of such drugs have been found to be unsafe or not effective.

(5) Essentially a copy of an approved drug

The drug is not essentially a copy of one or more approved drugs.

(6) Drugs presenting demonstrable difficulties for compounding

The drug--

(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

(7) Elements to assure safe use

In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 355-1 of this title, or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such

facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

(8) Prohibition on wholesaling

The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 353(b)(1) of this title.

(9) Fees

The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 379j-62 of this title.

(10) Labeling of drugs

(A) Label

The label of the drug includes--

(i) the statement "This is a compounded drug." or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

(ii) the name, address, and phone number of the applicable outsourcing facility; and

(iii) with respect to the drug--

(I) the lot or batch number;

(II) the established name of the drug;

(III) the dosage form and strength;

(IV) the statement of quantity or volume, as appropriate;

(V) the date that the drug was compounded;

(VI) the expiration date;

(VII) storage and handling instructions;

(VIII) the National Drug Code number, if available;

(IX) the statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"; and

(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

(B) Container

The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include--

(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

(ii) the following information to facilitate adverse event reporting: www.fda.gov/ medwatch and 1-800-FDA-1088 (or any

successor Internet Web site or phone number); and

(iii) directions for use, including, as appropriate, dosage and administration.

(C) Additional information

The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

(11) Outsourcing facility requirement

The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

(b) Registration of outsourcing facilities and reporting of drugs

(1) Registration of outsourcing facilities

(A) Annual registration

Upon electing and in order to become an outsourcing facility, and during the period beginning on October 1 and ending on December 31 of each year thereafter, a facility--

(i) shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 360 of this title), and a point of contact email address; and

(ii) shall indicate whether the outsourcing facility intends to compound a drug that

appears on the list in effect under section 356e of this title during the subsequent calendar year.

(B) Availability of registration for inspection; list

(i) Registrations

The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this paragraph.

(ii) List

The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the name of each facility registered under this subsection as an outsourcing facility, the State in which each such facility is located, whether the facility compounds from bulk drug substances, and whether any such compounding from bulk drug substances is for sterile or nonsterile drugs.

(2) Drug reporting by outsourcing facilities

(A) In general

Upon initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report--

(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

(B) Form

Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

(C) Confidentiality

Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(B)(i), unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health.

(3) Electronic registration and reporting

Registrations and drug reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of

electronic means is not reasonable for the person requesting waiver.

(4) Risk-based inspection frequency

(A) In general

Outsourcing facilities--

(i) shall be subject to inspection pursuant to section 374 of this title; and

(ii) shall not be eligible for the exemption under section 374(a)(2)(A) of this title.

(B) Risk-based schedule

The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

(C) Risk factors

In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

(i) The compliance history of the outsourcing facility.

(ii) The record, history, and nature of recalls linked to the outsourcing facility.

(iii) The inherent risk of the drugs compounded at the outsourcing facility.

(iv) The inspection frequency and history of the outsourcing facility, including whether

the outsourcing facility has been inspected pursuant to section 374 of this title within the last 4 years.

(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 356e of this title.

(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) Adverse event reporting

Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

(c) Regulations

(1) In general

The Secretary shall implement the list described in subsection (a)(6) through regulations.

(2) Advisory committee on compounding

Before issuing regulations to implement subsection (a)(6), the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding,

physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

(3) Interim list

(A) In general

Before the effective date of the regulations finalized to implement subsection (a)(6), the Secretary may designate drugs, categories of drugs, or conditions as described such1 subsection by--

(i) publishing a notice of such substances, drugs, categories of drugs, or conditions proposed for designation, including the rationale for such designation, in the Federal Register;

(ii) providing a period of not less than 60 calendar days for comment on the notice; and

(iii) publishing a notice in the Federal Register designating such drugs, categories of drugs, or conditions.

(B) Sunset of notice

Any notice provided under subparagraph (A) shall not be effective after the earlier of--

(i) the date that is 5 years after November 27, 2013; or

(ii) the effective date of the final regulations issued to implement subsection (a)(6).

(4) Updates

The Secretary shall review, and update as necessary, the regulations containing the lists of drugs, categories of drugs, or conditions described in subsection (a)(6) regularly, but not less than once every 4 years. Nothing in the previous sentence prohibits submissions to the Secretary, before or during any 4-year period described in such sentence, requesting updates to such lists.

(d) Definitions

In this section:

(1) The term "compounding" includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(2) The term "essentially a copy of an approved drug" means--

(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 353(b) of this title and not subject to approval in an application submitted under section 355 of this title, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing; or

(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 353(b) of this title and not subject to approval in an application submitted

under section 355 of this title, 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.

(3) The term "approved drug" means a drug that is approved under section 355 of this title and does not appear on the list described in subsection (a)(4) of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

(4)(A) The term "outsourcing facility" means a facility at one geographic location or address that--

(i) is engaged in the compounding of sterile drugs;

(ii) has elected to register as an outsourcing facility; and

(iii) complies with all of the requirements of this section.

(B) An outsourcing facility is not required to be a licensed pharmacy.

(C) An outsourcing facility may or may not obtain prescriptions for identified individual patients.

(5) The term "sterile drug" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.

(d) Obligation to pay fees

Payment of the fee under section 379j-62 of this title, as described in subsection (a)(9), shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees.

21 U.S.C. § 355

New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) Filing application; contents

(1)(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application--

(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

(ii) a full list of the articles used as components of such drug;

(iii) a full statement of the composition of such drug;

(iv) a full description of the methods used in, and the facilities and controls used for, the

manufacture, processing, and packing of such drug;

(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

(vi) specimens of the labeling proposed to be used for such drug;

(vii) any assessments required under section 355c of this title; and

(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that--

(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

(II) claims a method of using such drug for which approval is sought or has been granted in the application.

(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the patent number and expiration date.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include--

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)--

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a

statement that the method of use patent does not claim such a use.

(3) Notice of opinion that patent is invalid or will not be infringed

(A) Agreement to give notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) Timing of notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph--

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) Recipients of notice

An applicant required under this paragraph to give notice shall give notice to--

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) Contents of notice

A notice required under this paragraph shall-

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(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of Title 42, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of Title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size--

(i)(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

(II) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

(ii) with respect to an application for approval of a biological product under section 262(k) of Title 42, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except--

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not

directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of Title 42 (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 282(j)(5)(B) of Title 42. Such certification shall not be considered an element of such application.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either--

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) Not later than 30 days after the date of approval of an application submitted under subsection (b), the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. If a patent described in subsection (b)(1)(A)(viii) is issued after the date of approval of an application submitted under subsection (b), the holder of the approved application shall, not later than 30 days after the date of issuance of the patent, file the patent number and the expiration date of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use

has been granted in the application. If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii). If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) because no patent of the type for which information is required to be submitted in subsection (b)(1)(A)(viii) had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it. Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

> (i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or

invalidity), the approval shall be made effective on--

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed--

(I) if the judgment of the district court is appealed, the approval shall be made effective on--

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a

court order under section 271(e)(4)(A) of Title 35;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28 by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the

certification referred to in subparagraph (C) unless--

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the

applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to

access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection

(b) or this subsection on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)(i) Repealed. Pub. L. 117-9, § 1(b)(1)(A), Apr. 23, 2021, 135 Stat. 258

(ii) If an application submitted under subsection (b) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not

conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such

application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailabilty1 studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application

were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination

that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

(B) A supplemental application is eligible for review as described in subparagraph (A) only if--

(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually--

(i) the number of applications reviewed solely under subparagraph (A) or section 262(a)(2)(E) of Title 42;

(ii) the average time for completion of review under subparagraph (A) or section 262(a)(2)(E) of Title 42;

(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 262(a)(2)(E) of Title 42; and

(iv) the number of applications reviewed under subparagraph (A) or section 262(a)(2)(E) of Title 42 for which the Secretary made use of full data sets in addition to the qualified data summary.

(D) In this paragraph--

(i) the term "qualified indication" means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

(ii) the term "qualified data summary" means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

(4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation

and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the

conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: Provided, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying

or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 355-1(g)(2)(D) of this title.

(f) Revocation of order refusing, withdrawing or suspending approval of application

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall

approve such application or reinstate such approval, as may be appropriate.

(g) Service of orders

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) Appeal from order

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of Title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary

or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and

effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon--

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of nonclinical tests of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation

of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including--

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from nonclinical tests or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that--

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best

interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 282 of Title 42.

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain--

> (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");
>
> (ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage

form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (ii) through (vi) of subsection (b)(1)(A);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the

applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)--

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that

the applicant will give notice as required by this subparagraph.

(ii) Timing of notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph--

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice

An applicant required under this subparagraph to give notice shall give notice to--

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice

A notice required under this subparagraph shall--

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety

days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds--

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of

bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except--

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the

drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds--

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show--

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet

the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed

pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of

subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination

that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on--

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed--

(aa) if the judgment of the district court is appealed, the approval shall be made effective on--

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a

court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such

a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application"

means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(v) 180-day exclusivity period for competitive generic therapies

(I) Effectiveness of application

Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(II) Limitation

The exclusivity period under subclause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

(III) Definitions

In this clause and subparagraph (D)(iv):

(aa) The term "competitive generic therapy" means a drug--

(AA) that is designated as a competitive generic therapy under section 356h of this title; and

(BB) for which there are no unexpired patents or exclusivities on the list of products described in section 355(j)(7)(A) of this title at the time of submission.

(bb) The term "first approved applicant" means any applicant that has submitted an application that--

(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28 by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless--

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc)

is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered

terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of--

(aa) the earlier of the date that is--

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval

The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant

If all first applicants forfeit the 180-day exclusivity period under clause (ii)--

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(iv) Special forfeiture rule for competitive generic therapy

The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be

conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) Repealed. Pub. L. 117-9, § 1(b)(1)(B), Apr. 23, 2021, 135 Stat. 258

(ii) If an application submitted under subsection (b) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in

subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application

submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended--

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public--

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (c) respecting a drug

included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(iv) For each drug included on the list, the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which such period has not yet expired, under--

(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E);

(II) clause (iv) or (v) of paragraph (5)(B);

(III) clause (ii), (iii), or (iv) of paragraph (5)(F);

(IV) section 355a of this title;

(V) section 355f of this title;

(VI) section 360cc(a) of this title; or

(VII) subsection (u).

(v)(I) With respect to an application submitted pursuant to subsection (b)(2) for a drug that is subject to section 353(b) of this title for which the sole difference from a listed drug relied upon in the application is a difference in inactive ingredients not permitted under clause (iii) or (iv) of section 314.94(a)(9) of title 21, Code of Federal Regulations (or any successor regulations), the Secretary shall make an evaluation with respect to whether such drug is a therapeutic

equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) to another approved drug product in the prescription drug product section of the list under this paragraph as follows:

(aa) With respect to such an application submitted after December 29, 2022, the evaluation shall be made with respect to a listed drug relied upon in the application pursuant to subsection (b)(2) that is a pharmaceutical equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) to the drug in the application pursuant to subsection (b)(2) at the time of approval of such application or not later than 180 days after the date of such approval, provided that the request for such an evaluation is made in the original application (or in a resubmission to a complete response letter), and all necessary data and information are submitted in the original application (or in a resubmission in response to a complete response letter) for the therapeutic equivalence evaluation, including information to demonstrate bioequivalence, in a form and manner prescribed by the Secretary.

(bb) With respect to such an application approved prior to or on December 29, 2022, the evaluation shall

be made not later than 180 days after receipt of a request for a therapeutic equivalence evaluation submitted as part of a supplement to such application; or with respect to an application that was submitted prior to December 29, 2022, but not approved as of December 29, 2022, the evaluation shall be made not later than 180 days after the date of approval of such application if a request for such evaluation is submitted as an amendment to the application, provided that--

(AA) such request for a therapeutic equivalence evaluation is being sought with respect to a listed drug relied upon in the application, and the relied upon listed drug is in the prescription drug product section of the list under this paragraph and is a pharmaceutical equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) to the drug for which a therapeutic equivalence evaluation is sought; and

(BB) the amendment or supplement, as applicable, containing such request, or the relevant application, includes all necessary data and information for the therapeutic equivalence evaluation, including information to demonstrate

bioequivalence, in a form and manner prescribed by the Secretary.

(II) When the Secretary makes an evaluation under subclause (I), the Secretary shall, in revisions made to the list pursuant to clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list--

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the

withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(D) In the case of a listed drug for which the list under subparagraph (A)(i) includes a patent for such drug, and any claim of the patent has been cancelled or invalidated pursuant to a final decision issued by the Patent Trial and Appeal Board of the United States Patent and Trademark Office or by a court, from which no appeal has been, or can be, taken, if the holder of the applicable application approved under subsection (c) determines that a patent for such drug, or any patent information for such drug, no longer meets the listing requirements under this section--

(i) the holder of such approved application shall notify the Secretary, in writing, within 14 days of such decision of such cancellation or invalidation and request that such patent or patent information, as applicable, be amended or withdrawn in accordance with the decision issued by the Patent Trial and Appeal Board or a court;

(ii) the holder of such approved application shall include in any notification under clause (i) information related to such patent cancellation or invalidation decision and submit such information, including a copy of such decision, to the Secretary; and

(iii) the Secretary shall, in response to a notification under clause (i), amend or remove

patent or patent information in accordance with the relevant decision from the Patent Trial and Appeals Board or court, as applicable, except that the Secretary shall not remove from the list any patent or patent information before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV).

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if--

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of--

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and shall not be considered misbranded under section 352 of this title if--

(i) a revision to the labeling of the listed drug has been approved by the Secretary within 90 days of when the application is otherwise eligible for approval under this subsection;

(ii) the sponsor of the application agrees to submit revised labeling for the drug that is the subject of the application not later than 60 days after approval under this subsection of the application;

(iii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

(11)(A) Subject to subparagraph (B), the Secretary shall prioritize the review of, and act within 8 months of the date of the submission of, an original abbreviated new drug application submitted for review under this subsection that is for a drug--

(i) for which there are not more than 3 approved drug products listed under paragraph (7) and for which there are no blocking patents and exclusivities; or

(ii) that has been included on the list under section 356e of this title.

(B) To qualify for priority review under this paragraph, not later than 60 days prior to the submission of an application described in subparagraph (A) or that the Secretary may prioritize pursuant to subparagraph (D), the applicant shall provide complete, accurate information regarding facilities involved in manufacturing processes and testing of the drug that is the subject of the application, including

facilities in corresponding Type II active pharmaceutical ingredients drug master files referenced in an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, to enable the Secretary to make a determination regarding whether an inspection of a facility is necessary. Such information shall include the relevant (as determined by the Secretary) sections of such application, which shall be unchanged relative to the date of the submission of such application, except to the extent that a change is made to such information to exclude a facility that was not used to generate data to meet any application requirements for such submission and that is not the only facility intended to conduct one or more unit operations in commercial production. Information provided by an applicant under this subparagraph shall not be considered the submission of an application under this subsection.

(C) The Secretary may expedite an inspection or reinspection under section 374 of this title of an establishment that proposes to manufacture a drug described in subparagraph (A).

(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

(12) The Secretary shall publish on the internet website of the Food and Drug Administration, and update at least once every 6 months, a list of all drugs approved under subsection (c) for which all patents

and periods of exclusivity under this chapter have expired and for which no application has been approved under this subsection.

(13) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall, as appropriate, provide review status updates indicating the categorical status of the applications by each relevant review discipline.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e). Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) Active postmarket risk identification

(A) Definition

In this paragraph, the term "data" refers to information with respect to a drug approved under this section or under section 262 of Title 42, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) Development of postmarket risk identification and analysis methods

The Secretary shall, not later than 2 years after September 27, 2007, in collaboration with public, academic, and private entities--

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate--

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012; and

(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

(C) Establishment of the postmarket risk identification and analysis system

(i) In general

The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures--

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 355-1(b) of this title) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary

determines appropriate, which may include data on comparative national adverse event trends; and

(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(ii) Timeliness of reporting

The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(iii) Private sector resources

To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(iv) Complementary approaches

To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop,

support, and participate in complementary approaches to gather and analyze such data and information, including--

(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(v) Authority for contracts

The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(4) Advanced analysis of drug safety data

(A) Purpose

The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 299b-1 of Title 42, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to--

(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(B) Privacy

Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

(C) Public process for priority questions

At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on--

(i) priority drug safety questions; and

(ii) mechanisms for answering such questions, including through--

(I) active risk identification under paragraph (3); and

(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

(D) Procedures for the development of drug safety collaborations

(i) In general

Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to--

(I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

(II) allow for prompt investigation of priority drug safety questions, including--

(aa) unresolved safety questions for drugs or classes of drugs; and

(bb) for a newly-approved drugs,2 safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

(III) perform advanced research and analysis on identified drug safety risks;

(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety

signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

(ii) Request for specific methodology

The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(E) Use of analyses

The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

(F) Qualified entities

(i) In general

The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(ii) Qualification

The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has a significant presence in the United States and

has one or more of the following qualifications:

(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

(G) Contract requirements

Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

(i) Ensuring privacy

The qualified entity shall ensure that the entity will not use data under this subsection in a manner that--

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

(II) violates sections 552 or 552a of Title 5 with regard to the privacy of individually-identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

(ii) Component of another organization

If a qualified entity is a component of another organization--

(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

(iii) Termination or nonrenewal

If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

(I) Confidentiality and privacy protections

The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

(II) Disposition of data

The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(H) Competitive procedures

The Secretary shall use competitive procedures (as defined in section 132 of Title 41) to enter into contracts under subparagraph (G).

(I) Review of contract in the event of a merger or acquisition

The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

(J) Coordination

In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.

(5) The Secretary shall--

(A) conduct regular screenings of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse3 Event Reporting System within the last quarter; and4

(B) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments; and

(C) make available on the Internet website of the Food and Drug Administration—

(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

(ii) criteria for public posting of adverse event signals.

(l) Public disclosure of safety and effectiveness data and action package

(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown--

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(2) Action package for approval

(A) Action package

The Secretary shall publish the action package for approval of an application under

subsection (b) or section 262 of Title 42 on the Internet Web site of the Food and Drug Administration--

(i) not later than 30 days after the date of approval of such applications--

(I) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

(II) for a biological product, no active ingredient of which has been approved in any other application under section 262 of Title 42; and

(ii) not later than 30 days after the third request for such action package for approval received under section 552 of Title 5 for any other drug or biological product.

(B) Immediate publication of summary review

Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

(C) Contents

An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

(i) Documents generated by the Food and Drug Administration related to review of the application.

(ii) Documents pertaining to the format and content of the application generated during drug development.

(iii) Labeling submitted by the applicant.

(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

(v) The Division Director and Office Director's decision document which includes--

(I) a brief statement of concurrence with the summary review;

(II) a separate review or addendum to the review if disagreeing with the summary review; and

(III) a separate review or addendum to the review to add further analysis.

(vi) Identification by name of each officer or employee of the Food and Drug Administration who--

(I) participated in the decision to approve the application; and

(II) consents to have his or her name included in the package.

(D) Review

A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(E) Confidential information

This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of Title 5.

(m) "Patent" defined

For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n) Scientific advisory panels

(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under this section or section 262 of Title 42, the Secretary shall establish panels of experts or use panels of experts established before November 21, 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 394 of this title to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of--

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this chapter and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(5) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of Title 5, for persons in the Government service employed intermittently.

(6) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(7) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the

affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

(o) Postmarket studies and clinical trials; labeling

(1) In general

A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

(2) Definitions

For purposes of this subsection:

(A) Responsible person

The term "responsible person" means a person who--

(i) has submitted to the Secretary a covered application that is pending; or

(ii) is the holder of an approved covered application.

(B) Covered application

The term "covered application" means--

(i) an application under subsection (b) for a drug that is subject to section 353(b) of this title; and

(ii) an application under section 262 of Title 42.

(C) New safety information; serious risk

The terms "new safety information", "serious risk", and "signal of a serious risk" have the meanings given such terms in section 355-1(b) of this title.

(3) Studies and clinical trials

(A) In general

For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

(B) Purposes of study or clinical trial

The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

(i) To assess a known serious risk related to the use of the drug involved.

(ii) To assess signals of serious risk related to the use of the drug.

(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

(C) Establishment of requirement after approval of covered application

The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.

(D) Determination by Secretary

(i) Postapproval studies

The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

(ii) Postapproval clinical trials

The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

(E) Notification; timetables; periodic reports

(i) Notification

The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for

communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(ii) Timetable; periodic reports

For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the

requirements under section 282(j) of Title 42. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

(F) Dispute resolution

The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

(4) Safety labeling changes requested by Secretary

(A) New safety or new effectiveness information

If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under subsection (b) is not currently marketed, the holder of an approved application under subsection (j).

(B) Response to notification

Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under subsection (j) shall within 30 days--

(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions, or new effectiveness information; or

(ii) notify the Secretary that the responsible person or the holder of the approved application under subsection (j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(C) Review

Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety or new effectiveness information, and if so, the contents of such labeling changes.

(D) Discussions

Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

(E) Order

Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under subsection (j) to make such a labeling change as the Secretary deems appropriate to address the new safety or new effectiveness information. Within 15 days of such an order, the responsible person or the holder of the approved application under subsection (j) shall submit a supplement containing the labeling change.

(F) Dispute resolution

Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under subsection (j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(G) Violation

If the responsible person or the holder of the approved application under subsection (j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution

proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

(H) Public health threat

Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

(I) Rule of construction

This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under subsection (j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(5) Non-delegation

Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(p) Risk evaluation and mitigation strategy

(1) In general

A person may not introduce or deliver for introduction into interstate commerce a new drug if--

(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 353(b) of this title; or

(ii) the application for such drug is approved under section 262 of Title 42; and

(B) a risk evaluation and mitigation strategy is required under section 355-1 of this title with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 355-1 of this title, including requirements regarding assessments of approved strategies.

(2) Certain postmarket studies

The failure to conduct a postmarket study under section 356 of this title, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).

(q) Petitions and civil actions regarding approval of certain applications

(1) In general

(A) Determination

The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 262(k) of Title 42 because of any request to take any form of

action relating to the application, either before or during consideration of the request, unless--

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Consideration of the petition shall be separate and apart from review and approval of any application.

(B) Notification

If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

(i) Notification of the fact that a determination under subparagraph (A) has been made.

(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

(C) Format

The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary--

(i) a document; or

(ii) a meeting with the applicant involved.

(D) Public disclosure

Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

(E) Denial based on intent to delay

If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(F) Final agency action

The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted. The Secretary

shall not extend such period for any reason, including--

(i) any determination made under subparagraph (A);

(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

(iii) the consent of the petitioner.

(G) Extension of 30-month period

If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(H) Certification

The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: "I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to

the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(I) Verification

The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: "I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive

payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(2) Exhaustion of administrative remedies

(A) Final agency action within 150 days

The Secretary shall be considered to have taken final agency action on a petition if--

(i) during the 150-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(ii) such period expires without the Secretary having made such a final decision.

(B) Dismissal of certain civil actions

If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(C) Administrative record

For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include--

(i) the petition filed under paragraph (1) and any supplements and comments thereto;

(ii) the Secretary's response to such petition, if issued; and

(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(3) Annual report on delays in approvals per petitions

The Secretary shall annually submit to the Congress a report that specifies--

(A) the number of applications that were approved during the preceding 12-month period;

(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

(C) the number of days by which such applications were so delayed; and

(D) the number of such petitions that were submitted during such period.

(4) Exceptions

(A) This subsection does not apply to--

(i) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

(ii) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 262(k) of Title 42.

(5) Definitions

(A) Application

For purposes of this subsection, the term "application" means an application submitted under subsection (b)(2) or (j) of this section or section 262(k) of Title 42.

(B) Petition

For purposes of this subsection, other than paragraph (1)(A)(i), the term "petition" means a request described in paragraph (1)(A)(i).

(r) Postmarket drug safety information for patients and providers

(1) Establishment

Not later than 1 year after September 27, 2007, the Secretary shall improve the transparency of

information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that--

(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 262 of Title 42; and

(B) improves communication of drug safety information to patients and providers.

(2) Internet Web site

The Secretary shall carry out paragraph (1) by--

(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate--

(i) patient labeling and patient packaging inserts;

(ii) a link to a list of each drug, whether approved under this section or licensed under such section 262, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 282 of Title 42;

(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

(vi) guidance documents and regulations related to drug safety; and

(vii) other material determined appropriate by the Secretary;

(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 262;

(D) preparing and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 262 of Title 42;

(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

(3) Posting of drug labeling

The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 262 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(4) Private sector resources

To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(5) Authority for contracts

The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

(6) Review

The Advisory Committee on Risk Communication under section 360bbb-6 of this title shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information

provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(s) Referral to advisory committee

The Secretary shall--

(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the approval of such drug or biological if it is--

(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

(B) a biological product, no active ingredient of which has been approved in any other application under section 262 of Title 42; or

(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.

(t) Database for authorized generic drugs

(1) In general

(A) Publication

The Commissioner shall--

(i) not later than 9 months after September 27, 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(B) Notification

The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

(2) Inclusion

The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the

Secretary by the sponsor of a listed drug after January 1, 1999.

(3) Authorized generic drug

In this section, the term "authorized generic drug" means a listed drug (as that term is used in subsection (j)) that--

(A) has been approved under subsection (c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

(u) Certain drugs containing single enantiomers

(1) In general

For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active moiety as that contained in the approved racemic drug, if--

(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

(ii) the application submitted under subsection (b) for such non-racemic drug--

(I) includes full reports of new clinical investigations (other than bioavailability studies)--

(aa) necessary for the approval of the application under subsections (c) and (d); and

(bb) conducted or sponsored by the applicant; and

(II) does not rely on any clinical investigations (other than bioavailability studies) that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use--

(i) in a therapeutic category in which the approved racemic drug has been approved; or

(ii) for which any other enantiomer of the racemic drug has been approved.

(2) Limitation

(A) No approval in certain therapeutic categories

Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) Labeling

If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(3) Definition

(A) In general

For purposes of this subsection, the term "therapeutic category" means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1395w-104(b)(3)(C)(ii) of Title 42 and as in effect on September 27, 2007.

(B) Publication by Secretary

The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

(4) Availability

The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after September 27, 2007, and before October 1, 2027.

(v) Antibiotic drugs submitted before November 21, 1997

(1) Antibiotic drugs approved before November 21, 1997

(A) In general

Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

(B) Application; antibiotic drug described

(i) Application

An application described in this clause is an application for marketing submitted under this section after October 8, 2008, in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) Antibiotic drug

An antibiotic drug described in this clause is an antibiotic drug that was the

subject of an application approved by the Secretary under section 357 of this title (as in effect before November 21, 1997).

(2) Antibiotic drugs submitted before November 21, 1997, but not approved

(A) In general

Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug--

(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

(ii) a patent term extension under section 156 of Title 35, subject to the requirements of such section.

(B) Application; antibiotic drug described

(i) Application

An application described in this clause is an application for marketing submitted under this section after October 8, 2008, in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) Antibiotic drug

An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 357 of this title (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

(3) Limitations

(A) Exclusivities and extensions

Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs5 (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

(B) Conditions of use

Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before October 8, 2008.

(4) Application of certain provisions

Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

(w) Deadline for determination on certain petitions

The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

(x) Date of approval in the case of recommended controls under the CSA

(1) In general

In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) Date of approval

For purposes of this section, with respect to an application described in paragraph (1), the term "date of approval" shall mean the later of--

(A) the date an application under subsection (b) is approved under subsection (c); or

(B) the date of issuance of the interim final rule controlling the drug.

(y) Contrast agents intended for use with applicable medical imaging devices

(1) In general

The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking approval for a new use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 360j(p)(1) of this title.

(2) Review of supplement

In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may--

(A) consult with the center charged with the premarket review of devices; and

(B) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 360e, 360(k), or 360c(f)(2) of this title so long as the sponsor of such applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference.

(3) Definitions

For purposes of this subsection--

(A) the term "new use" means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 360j(p) of this title, but that is not described in the approved labeling of the contrast agent; and

(B) the terms "applicable medical imaging device" and "contrast agent" have the meanings given such terms in section 360j(p) of this title.

(z) Nonclinical test defined

For purposes of this section, the term "nonclinical test" means a test conducted in vitro, in silico, or in chemico, or a nonhuman in vivo test, that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug. Such test may include the following:

(1) Cell-based assays.

(2) Organ chips and microphysiological systems.

(3) Computer modeling.

(4) Other nonhuman or human biology-based test methods, such as bioprinting.

(5) Animal tests.

(z) Diversity action plan for clinical studies

(1) With respect to a clinical investigation of a new drug that is a phase 3 study, as defined in section 312.21(c) of title 21, Code of Federal Regulations (or successor regulations), or, as appropriate, another

pivotal study of a new drug (other than bioavailability or bioequivalence studies), the sponsor of such drug shall submit to the Secretary a diversity action plan.

(2) Such diversity action plan shall include--

(A) the sponsor's goals for enrollment in such clinical study;

(B) the sponsor's rationale for such goals; and

(C) an explanation of how the sponsor intends to meet such goals.

(3) The sponsor shall submit to the Secretary such diversity action plan, in the form and manner specified by the Secretary in guidance, as soon as practicable but not later than the date on which the sponsor submits the protocol to the Secretary for such a phase 3 study or other pivotal study of the drug. The sponsor may submit modifications to the diversity action plan. Any such modifications shall be in the form and manner specified by the Secretary in guidance.

(4)(A) On the initiative of the Secretary or at the request of a sponsor, the Secretary may waive any requirement in paragraph (1), (2), or (3) if the Secretary determines that a waiver is necessary based on what is known or what can be determined about the prevalence or incidence of the disease or condition for which the new drug is under investigation (including in terms of the patient population that may use the drug), if conducting a clinical investigation in accordance with a diversity action plan would otherwise be impracticable, or if such waiver is

necessary to protect public health during a public health emergency.

(B) The Secretary shall issue a written response granting or denying a request from a sponsor for a waiver within 60 days of receiving such request.

(5) No diversity action plan shall be required for a submission described in section 360bbb of this title.

Cal. Bus. & Prof. Code § 17200

Unfair competition; prohibited activities

As used in this chapter, unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1 (commencing with Section 17500) of Part 3 of Division 7 of the Business and Professions Code.

Cal. Health & Safety Code § 111550

Sale, delivery, or gift of new drug or device; requirements; new drug or device application; contents

No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is one of the following:

(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

(2) A new biologic product for which a license has been issued as required by the federal Public Health Service Act (42 U.S.C. Sec. 262).

(3) A device that is reported under Section 510(k) of the federal act (21 U.S.C. Sec. 360(k)), or is a device exempted pursuant to subsection (l) or (m) of Section 360 of Title 21 of the United States Code, or it is a new device for which a premarket approval application has been approved, and that approval has not been

withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).

(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:

(1) Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.

(2) A full list of the articles used as components of the new drug or device.

(3) A full statement of the composition of the new drug or device.

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug, or in the case of a new device, a full statement of its composition, properties, and construction, and the principles of its operation.

(5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.

(6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

Conn. Gen. Stat. § 21a-110

New drugs

(a) 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 of the federal act or (2), when not subject to the federal act, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the commissioner an application setting forth (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the commissioner may require; and (F) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subdivision (2) of subsection (a) shall become effective on the one hundred eightieth day after the filing thereof, except that, if the commissioner finds, after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof, he shall, prior to the

effective date of the application, issue an order refusing to permit the application to become effective.

(c) This section shall not apply: (1) To a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug shall be plainly labeled in compliance with regulations issued under Section 355(i) or 357(d) of the federal act; or (2) to a drug sold in this state at any time prior to the enactment of this chapter or introduced into interstate commerce at any time prior to the enactment of the federal act; or (3) to any drug which is licensed under Title 42 USC 262; or (4) to any drug subject to subsection (o) of section 21a-106.

(d) An order refusing to permit an application under this section to become effective may be revoked by the commissioner.

Conn. Gen. Stat. § 42-110b

Unfair trade practices prohibited. Legislative intent

(a) No person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.

(b) It is the intent of the legislature that in construing subsection (a) of this section, the commissioner and the courts of this state shall be guided by interpretations given by the Federal Trade Commission and the federal courts to Section 5(a)(1) of the Federal Trade Commission Act (15 USC 45(a)(1)), as from time to time amended.

(c) The commissioner may, in accordance with chapter 54, establish by regulation acts, practices or methods

which shall be deemed to be unfair or deceptive in violation of subsection (a) of this section. Such regulations shall not be inconsistent with the rules, regulations and decisions of the federal trade commission and the federal courts in interpreting the provisions of the Federal Trade Commission Act.

(d) It is the intention of the legislature that this chapter be remedial and be so construed.

Fla. Stat. § 499.023

New drugs; sale, manufacture, repackaging, distribution

A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce.

Fla. Stat. § 501.203

Definitions

As used in this chapter, unless the context otherwise requires, the term:

(1) "Final judgment" means a judgment, including any supporting opinion, that determines the rights of the parties and concerning which appellate remedies have been exhausted or the time for appeal has expired.

(2) "Enforcing authority" means the office of the state attorney if a violation of this part occurs in or affects the judicial circuit under the office's jurisdiction. "Enforcing authority" means the Department of Legal Affairs if the violation occurs in or affects more than one judicial circuit or if the office of the state attorney defers to the department in writing, or fails to act upon a violation within 90 days after a written complaint has been filed with the state attorney.

(3) "Violation of this part" means any violation of this act or the rules adopted under this act and may be based upon any of the following as of July 1, 2017:

(a) Any rules promulgated pursuant to the Federal Trade Commission Act, 15 U.S.C. ss. 41 et seq.;

(b) The standards of unfairness and deception set forth and interpreted by the Federal Trade Commission or the federal courts; or

(c) Any law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices.

(4) "Department" means the Department of Legal Affairs.

(5) "Order" means a cease and desist order issued by the enforcing authority as set forth in s. 501.208.

(6) "Interested party or person" means any person affected by a violation of this part or any person affected by an order of the enforcing authority.

(7) "Consumer" means an individual; child, by and through its parent or legal guardian; business; firm; association; joint venture; partnership; estate; trust; business trust; syndicate; fiduciary; corporation; any commercial entity, however denominated; or any other group or combination.

(8) "Trade or commerce" means the advertising, soliciting, providing, offering, or distributing, whether by sale, rental, or otherwise, of any good or service, or any property, whether tangible or intangible, or any other article, commodity, or thing of value, wherever situated. "Trade or commerce" shall include the conduct of any trade or commerce, however denominated, including any nonprofit or not-for-profit person or activity.

(9) "Thing of value" may include, without limitation, any moneys, donation, membership, credential, certificate, prize, award, benefit, license, interest, professional opportunity, or chance of winning.

Fla. Stat. § 501.204

Unlawful acts and practices

(1) Unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.

(2) It is the intent of the Legislature that, in construing subsection (1), due consideration and great weight shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to s. 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. s. 45(a)(1) as of July 1, 2017.

Fla. Stat. § 501.211

Other individual remedies

(1) Without regard to any other remedy or relief to which a person is entitled, anyone aggrieved by a violation of this part may bring an action to obtain a declaratory judgment that an act or practice violates this part and to enjoin a person who has violated, is violating, or is otherwise likely to violate this part.

(2) In any action brought by a person who has suffered a loss as a result of a violation of this part, such person may recover actual damages, plus attorney's fees and court costs as provided in s. 501.2105. However, damages, fees, or costs are not recoverable under this section against a retailer who has, in good faith,

engaged in the dissemination of claims of a manufacturer or wholesaler without actual knowledge that it violated this part.

(3) In any action brought under this section, upon motion of the party against whom such action is filed alleging that the action is frivolous, without legal or factual merit, or brought for the purpose of harassment, the court may, after hearing evidence as to the necessity therefor, require the party instituting the action to post a bond in the amount which the court finds reasonable to indemnify the defendant for any damages incurred, including reasonable attorney's fees. This subsection shall not apply to any action initiated by the enforcing authority.

S.C. Code Ann. § 39-5-20

Unfair methods of competition and unfair or deceptive acts or practices unlawful; application of federal act.

(a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.

(b) It is the intent of the legislature that in construing paragraph (a) of this section the courts will be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to Section 5(a) (1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), as from time to time amended.

S.C. Code Ann. § 39-23-70

Intrastate commerce, introduction of new drugs.

(a) 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 Section 505 of the Federal act.

(b) Any person may file with the Director of Health and Environmental Control an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Director of Health and Environmental Control as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the

methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Director of Health and Environmental Control may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) An application provided for in subsection (b) shall become effective on the one hundred eightieth day after the filing thereof, except that if the Director of Health and Environmental Control finds, after due notice to the applicant and giving him an opportunity for a hearing, (1), that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof; or (2) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drugs are inadequate to preserve its identity, strength, quality, and purity; or (3) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(d) If the Director of Health and Environmental Control finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Director pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such

drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Director of Health and Environmental Control be suspended if the Director finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Director of Health and Environmental Control finds that the facts so require.

(g) Orders of the Director of Health and Environmental Control issued under this section shall

be served (1) in person by an officer or employee of the Department of Health and Environmental Control designated by the Director or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last known address in the records of the Director.

(h) An appeal may be taken by the applicant from an order of the Director of Health and Environmental Control refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the circuit court within any circuit wherein such applicant resides or has his principal place of business, within sixty days after the entry of such order, a written petition praying that the order of the Director be set aside. A copy of such petition shall be forthwith served upon the Director or upon any officer designated by him for that purpose, and thereupon the Director shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Director shall be considered by the court unless such objection shall have been argued before the Director or unless there were reasonable grounds for failure so to do. The findings of the Director as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Director, the court may order such additional evidence

to be taken before the Director and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Director may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Director shall be final, subject to review as provided by statute. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Director's orders.

(i) The Director of Health and Environmental Control shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

Tenn. Code Ann. § 47-18-104

Unfair or deceptive acts or practices

(a) Unfair or deceptive acts or practices affecting the conduct of any trade or commerce constitute unlawful acts or practices and are Class B misdemeanors.

(b) The following unfair or deceptive acts or practices affecting the conduct of any trade or commerce are declared to be unlawful and in violation of this part:

(1) Falsely passing off goods or services as those of another;

(2) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services. This subdivision (b)(2) does not prohibit the private labeling of goods and services;

(3) Causing likelihood of confusion or misunderstanding as to affiliation, connection or association with, or certification by, another. This subdivision (b)(3) does not prohibit the private labeling of goods or services;

(4) Using deceptive representations or designations of geographic origin in connection with goods or services;

(5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship approval, status, affiliation or connection that such person does not have;

(6) Representing that goods are original or new if they are deteriorated, altered to the point of decreasing the value, reconditioned, reclaimed, used or secondhand;

(7) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;

(8) Disparaging the goods, services or business of another by false or misleading representations of fact;

(9) Advertising goods or services with intent not to sell them as advertised;

(10) Advertising goods or services with intent not to supply reasonably expectable public demand, unless the advertisement discloses a limitation of quantity;

(11) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;

(12) Representing that a consumer transaction confers or involves rights, remedies or obligations that it does not have or involve or which are prohibited by law;

(13) Representing that a service, replacement or repair is needed when it is not;

(14) Causing confusion or misunderstanding with respect to the authority of a salesperson, representative or agent to negotiate the final terms of a consumer transaction;

(15) Failing to disclose that a charge for the servicing of any goods in whole or in part is based on

a predetermined rate or charge, or guarantee or warranty, instead of the value of the services actually performed;

(16) Disconnecting, turning back, or resetting the odometer of any motor vehicle so as to reduce the number of miles indicated on the odometer gauge, except as provided for in § 39-14-132(b);

(17) Advertising of any sale by falsely representing that a person is going out of business;

(18) Using or employing a chain referral sales plan in connection with the sale or offer to sell of goods, merchandise, or anything of value, which uses the sales technique, plan, arrangement or agreement in which the buyer or prospective buyer is offered the opportunity to purchase goods or services and, in connection with the purchase, receives the seller's promise or representation that the buyer shall have the right to receive compensation or consideration in any form for furnishing to the seller the names of other prospective buyers if the receipt of compensation or consideration is contingent upon the occurrence of an event subsequent to the time the buyer purchases the merchandise or goods;

(19) Representing that a guarantee or warranty confers or involves rights or remedies which it does not have or involve; provided, that nothing in this subdivision (b)(19) shall be construed to alter the implied warranty of merchantability as defined in § 47-2-314;

(20) Selling or offering to sell, either directly or associated with the sale of goods or services, a right of participation in a pyramid distributorship. As used in

this subdivision (b)(20), a "pyramid distributorship" means any sales plan or operation for the sale or distribution of goods, services or other property wherein a person for a consideration acquires the opportunity to receive a pecuniary benefit, which is not primarily contingent on the volume or quantity of goods, services or other property sold or delivered to consumers, and is based upon the inducement of additional persons, by such person or others, regardless of number, to participate in the same plan or operation;

(21) Using statements or illustrations in any advertisement which create a false impression of the grade, quality, quantity, make, value, age, size, color, usability or origin of the goods or services offered, or which may otherwise misrepresent the goods or services in such a manner that later, on disclosure of the true facts, there is a likelihood that the buyer may be switched from the advertised goods or services to other goods or services;

(22) Using any advertisement containing an offer to sell goods or services when the offer is not a bona fide effort to sell the advertised goods or services. An offer is not bona fide, even though the true facts are subsequently made known to the buyer, if the first contact or interview is secured by deception;

(23) Representing in any advertisement a false impression that the offer of goods has been occasioned by a financial or natural catastrophe when such is not true, or misrepresenting the former price, savings, quality or ownership of any goods sold;

(24) Assessing a penalty for the prepayment or early payment of a fee or charge for services by a utility or company which has been issued a franchise license by a municipal governing body to provide services. Nothing in this subdivision (b)(24) shall be construed to prohibit a discount from being offered for early payment of the applicable fee or charge for services. This subdivision (b)(24) does not apply to a utility or company whose billing statement reflects charges both for service previously rendered and in advance of services provided;

(25) Discriminating against any disabled individual, as defined by §§ 47-18-802(b) and 55-21-102(3), in violation of the Tennessee Equal Consumer Credit Act of 1974, compiled in part 8 of this chapter. This subdivision (b)(25) does not apply to any creditor or credit card issuer regulated by the department of financial institutions. The attorney general shall refer any complaint against such a creditor or credit card issuer involving the Equal Consumer Credit Act to such department for investigation and disposition;

(26) Violating § 65-5-106;

(27) Engaging in any other act or practice which is deceptive to the consumer or to any other person; provided, however, that enforcement of this subdivision (b)(27) is vested exclusively in the office of the attorney general and reporter;

(28)(A)(i) Failing of a motor vehicle repair facility to return to a customer any parts which were removed from the motor vehicle and replaced during the process of repair if the customer, at the time repair work was authorized, requested return of such parts;

provided, that any part retained by the motor vehicle repair facility as part of a trade-in agreement or core charge agreement for a reconditioned part need not be returned to the customer unless the customer agrees to pay the facility the additional core charge or other trade-in fee; and provided further, that any part required to be returned to a manufacturer or distributor under a warranty agreement or any part required by any federal or state statute or rule or regulation to be disposed of by the facility need not be returned to the customer; or

(ii) Failing of a motor vehicle repair facility to permit inspection of any parts retained by the repair facility if the customer, at the time repair work was authorized, expressed the customer's desire to inspect such parts; provided, that if, after inspection, the customer requests return of such parts, the restrictions set forth in subdivision (b)(28)(A)(i) shall apply;

(B)(i) Failing of a motor vehicle repair facility to post in a prominent location notice of the provisions of this subdivision (b)(28); or

(ii) Failing of a motor vehicle repair facility to print on the repair contract notice of the provisions of this subdivision (b)(28);

(C) The motor vehicle repair facility need not retain any parts not returned to the customer after the motor vehicle has been returned to the customer;

(29) Advertising that a business is "going out of business" more than ninety (90) days before such business ceases to operate;

(30) Failing to comply with §§ 6-55-401 -- 6-55-413, where a municipality has adopted the regulations of liquidation sales pursuant to § 6-55-413;

(31) Offering lottery winnings in exchange for making a purchase or incurring a monetary obligation pursuant to § 47-18-120;

(32)(A) The act of misrepresenting the geographic location of a person through a business name or listing in a local telephone directory or on the Internet is an unfair or deceptive act or practice affecting the conduct of trade or commerce, if:

(i) The name misrepresents the person's geographic location; or

(ii) The listing fails to clearly and conspicuously identify the locality and state of the person's business;

(iii) Calls to the listed telephone number are routinely forwarded or otherwise transferred to a person's business location that is outside the calling area covered by the local telephone directory, or that is outside the local calling area for the telephone number that is listed on the Internet;

(iv) The person's business location is located in a county that is not contiguous to a county in the calling area covered by the local telephone directory, or is located in a county that is not contiguous to a county in the local

calling area for the telephone number that is listed on the Internet; and

(v) The person does not have a business location or branch, or an affiliate or subsidiary of the person does not have a business location or branch, in the calling area or county contiguous to the local calling area.

(B) This subdivision (b)(32) shall not apply:

(i) To a telecommunications service provider, an Internet service provider, or to the publisher or distributor of a local telephone directory unless the act is on behalf of the Internet or telecommunications service provider or on behalf of the publisher or distributor of the local telephone directory; or

(ii) To the act of listing a number for a call center. For purposes of this subdivision (b)(32)(B)(ii), "call center" means a location that utilizes telecommunication services for activities related to an existing customer relationship, including, but not limited to, customer services, reactivating dormant accounts or receiving reservations.

(C) Notwithstanding any other law to the contrary, and without limiting the scope of § 47-18-104, a violation of this subdivision (b)(32) shall be punishable by a nonremedial civil penalty of a minimum of one thousand dollars ($1,000) to a maximum of five thousand dollars ($5,000) per violation. Civil penalties assessed under this subdivision (b)(32) are separate and apart from

the remedial civil penalties authorized in § 47-18-108(b)(3).

(D) This subdivision (b)(32) applies only to information supplied to a telephone directory published after July 1, 2008, information that is published on the Internet after July 1, 2008, or to information supplied for entry into a directory assistance database after July 1, 2008;

(33) Advertising that a person is an electrician for hire when such person has not been licensed by a local jurisdiction to perform electrical work within such jurisdiction or by the state as a limited licensed electrician or contractor, as appropriate or, if no such licenses are then available, such person is not registered with the state;

(34) Unreasonably raising prices or unreasonably restricting supplies of essential goods, commodities or services in direct response to a crime, act of terrorism, war, or natural disaster, regardless of whether such crime, act of terrorism, war, or natural disaster occurred in the state of Tennessee;

(35) Representing that a person is a licensed contractor when such person has not been licensed as required by § 62-6-103 or § 62-6-502; or, acting in the capacity of a contractor as defined in § 62-6-102(4)(A), § 62-6-102(7) or § 62-6-501, and related rules and regulations of the state of Tennessee, or any similar statutes, rules and regulations of another state, while not licensed;

(36)(A) Using any advertisement for a workshop, seminar, conference, or other meeting that contains a reference to a living trust or a revocable living trust,

or that otherwise offers advice or counsel on estate taxation unless such advertisement also includes the information required in this subdivision (b)(36);

(B) An advertisement as provided in this subdivision (b)(36) shall, at a minimum, include the following:

(i) The maximum exclusion for federal estate tax purposes and the maximum exemption for state inheritance tax purposes for the year in which the advertisement appears;

(ii) Includes a statement that certain property, including real property, insurance proceeds, deposit accounts, stocks and retirement fund, may be taxable or not taxable, depending on how legal title is held or beneficiary designation is made, or both;

(iii) Includes a statement that certain property may be transferred through several different means including, but not limited to, joint ownership of property with rights of survivorship, joint deposit accounts, beneficiary designations or elections permitted under retirement plans, insurance policies, trusts, or wills; and

(iv) A statement that before creating any transfer through a living trust, revocable living trust, or otherwise, the individual should seek advice from an attorney, accountant or other tax professional to determine the true tax impact and ensure

that assets are properly transferred into any trust;

(C) The disclosure required in this subdivision (b)(36) shall be printed in not less than 10-point type;

(D) This subdivision (b)(36) shall not apply to an advertisement by any attorney, law firm, bank, savings institution, trust company, or registered securities broker-dealer which is directed to clients or customers of such person with whom such person has had a client or customer relationship within the prior two (2) years. This subdivision (b)(36) shall also not apply to any continuing education seminars or conferences conducted for the benefit of bankers, attorneys, accountants, or other professional financial advisors;

(37) Refusing to accept the return of clothing or accessories sold at retail directly to a purchaser, who seeks to return the same for any reason for refund or credit; provided, that:

(A) The purchaser presents the clothing or accessories within the retailer's prescribed period for return of merchandise;

(B) The purchaser presents satisfactory proof of purchase;

(C) The merchandise is, in no way, damaged and exhibits no sign of wear or cleaning;

(D) All tags and stickers affixed or attached to the merchandise at the time of sale remain affixed or attached at the time of return; and

(E) The sale of the merchandise was not marked, advertised or otherwise characterized as "final", "no return", "no refunds", or in any manner reasonably indicating that the merchandise would not be accepted for return;

(38)(A) Requiring the purchaser to present that purchaser's driver license as a prerequisite for accepting the return of clothing or accessories for refund or credit, notwithstanding compliance with the conditions set forth in subdivision (b)(37), unless such a requirement is for the purpose of preventing fraud and abuse;

(B) Notwithstanding any provision of subdivision (b)(37) or (b)(38)(A) to the contrary, return denials are permitted for the purpose of preventing fraud and abuse;

(39) Representing that a person, or such person's agent, authorized designee or delegee for hire, has conducted a foreclosure on real property, when such person knew or should have known that a foreclosure was not actually conducted on the real property;

(40)(A) Selling or offering to sell a secondhand mattress in this state or importing secondhand mattresses into this state for the purpose of resale in violation of § 68-15-203(b);

(B) Subdivision (b)(40)(A) shall apply to a mattress manufacturer, wholesaler or retailer. Subdivision (b)(40)(A) shall not apply to an institution or organization that has received a determination of exemption from the internal revenue service under 26 U.S.C. § 501(c)(3), and as described in § 67-6-348. The exemption

provided in this subdivision (b)(40)(B) shall be limited to institutions or organizations that are not organized or operated for profit, and no part of the net earnings of which inures to the benefit of any private shareholder or individual;

(41)(A) Knowingly advertising or marketing for sale a newly constructed residence as having more bedrooms than are permitted by the newly constructed residence's subsurface sewage disposal system permit, as defined in § 68-221-402, unless prior to the execution of any sales agreement the permitted number of bedrooms is disclosed in writing to the buyer. The real estate licensee representing the owner may rely upon information furnished by the owner;

(B) If a newly constructed residence is marketed for sale as having more bedrooms than are permitted by the subsurface sewage disposal system permit and no disclosure of the actual number of bedrooms permitted occurs prior to the execution of a sales agreement, then the buyer shall have the right to rescind the sales agreement and may recover treble damages as provided in § 47-18-109;

(C) A subsurface sewage disposal system permit issued in the name of the owner of a newly constructed residence shall serve as constructive notice to that owner of the newly constructed residence for the purpose of establishing knowledge as to the number of bedrooms of the newly constructed residence for the purpose of finding a violation of this subdivision (b)(41). A real estate licensee representing the owner must have actual knowledge transmitted from the

owner to the real estate licensee to be in violation of this subdivision (b)(41);

(42) Offering, through the mail or by other means, a check that contains an obligation to advertise with a person upon the endorsement of the check. The obligation is effective upon the check being signed and deposited into the consumer's bank account;

(43) The act or practice of directly or indirectly:

(A) Making representations that a person will pay or reimburse for a motor vehicle traffic citation for any person who purchases a device or mechanism, passive or active, that can detect or interfere with a radar, laser or other device used to measure the speed of motor vehicles;

(B) Advertising, promoting, selling or offering for sale any radar jamming device that includes any active or passive device, instrument, mechanism, or equipment that interferes with, disrupts, or scrambles the radar or laser that is used by law enforcement agencies and officers to measure the speed of motor vehicles; or

(C) Advertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state;

(44) Violating § 47-18-5402;

(45)(A) Installing, offering to install, or making available for installation, reinstallation or update a covered file-sharing program onto a computer without being an authorized user of that computer or without first providing clear and conspicuous notice to the authorized user of the computer that the files on that

computer will be made available to the public, obtaining consent of the authorized user to installation of the program, and requiring affirmative steps by the authorized user to activate any feature on the program that will make files on that computer available to the public; or

(B) Preventing reasonable efforts to disable or remove, or to block the installation or execution of, a covered file-sharing program on a computer;

(46)(A) The act or practice of directly or indirectly advertising, promoting, selling, or offering for sale international driver's licenses. It is a per se violation of this subdivision (b)(46) to:

(i) Misrepresent that any international driver's license sold or offered for sale confers a privilege to operate a motor vehicle on the streets and highways in this state; or

(ii) Represent that any international driver's license sold or offered for sale is of a particular standard, quality or grade;

(B) For purposes of this subdivision (b)(46), unless the context otherwise requires:

(i) "International driver's license" means a document that purports to confer a privilege to operate a motor vehicle on the streets and highways in this state and is not issued by a governmental entity. Such document may be an imitation of an international driving permit; and

(ii) "International driving permit" means the document issued by a duly authorized

automobile association to a holder of a valid driver license which grants such holder the privilege to operate a motor vehicle in countries or international bodies that are signatory parties to Article 24 of the 1949 United Nations Convention on Road Traffic, pursuant to 3 U.S.T. § 3008;

(C) Notwithstanding any other law to the contrary, and without limiting the scope of this section, a violation of this subdivision (b)(46) shall be punishable by a non-remedial civil penalty of a minimum of one thousand dollars ($1,000) to a maximum of three thousand dollars ($3,000) per violation. Civil penalties assessed under this subdivision (b)(46) are separate and apart from the remedial civil penalties authorized in § 47-18-108(b)(3);

(47) A home improvement services provider:

(A) Entering into a contract for home improvement services without providing to the residential owner in written form:

(i) That it is a criminal offense for the person entering into the contract for home improvement services with a residential owner to do any of the prohibited acts set out in § 39-14-154(b), by writing out the text of each prohibited act, and providing the penalty and available relief for such; and

(ii) The true and correct name, physical address and telephone number of the home improvement services provider; or

(B) Having complied with subdivision (b)(47)(A), failing to provide to the residential owner in written form a correct current or forwarding address if the person changes the physical address initially provided to the residential owner and any or all work to be performed under the contract has not been completed;

(48) Failing to comply with title 62, chapter 6, part 6;

(49) Engaging in a Ponzi scheme, defined as a fraudulent investment scheme in which money placed by later investors pays artificially high dividends to the original investor, thereby attracting even larger investments;

(50) Making fraudulent statements or intentional omissions in order to induce a consumer to sell securities or other things of value to fund an investment;

(51) Advertising services for the provision of a warranty for a motor vehicle, as defined in § 55-8-101, in a deceptive manner that is likely to cause the owner of the motor vehicle to believe that the advertisement originated from the original manufacturer of the motor vehicle or from the dealer that sold the motor vehicle to the owner;

(52)(A)(1) Using the trade name or trademark, or a confusingly similar trade name or trademark of any place of entertainment, or the name of any event, person, or entity scheduled to perform at a place of entertainment in the domain of a ticket marketplace URL, without written authorization from the place of

entertainment, event, person, or entity scheduled to perform at a place of entertainment to use the trade name, trademark, or name in the domain of the URL prior to the use; or

(2) Using or displaying any combination of text, images, website graphics, website display, or website addresses that are substantially similar to the website of an operator with the intent to mislead a potential purchaser, without written authorization from the operator;

(B) For purposes of subdivision (b)(52)(A):

(i) "Domain" means the portion of text in a URL that is to the left of the top-level domains such as .com, .net, or .org;

(ii) "Operator" means an individual, firm, corporation, or other entity, or an agent of such individual, firm, corporation, or other entity that:

(a) Owns, operates, or controls a place of entertainment or that promotes or produces a performance, concert, exhibit, game, athletic event, or contest; and

(b) Offers for sale a first sale ticket to the place of entertainment or performance, concert, exhibit, game, athletic event, or contest;

(iii) "Place of entertainment" means an entertainment facility in this state, such as a theater, stadium, museum, arena, amphitheater, racetrack, or other place where

performances, concerts, exhibits, games, athletic events, or contests are held;

(iv) "Ticket" means a printed, electronic, or other type of evidence of the right, option, or opportunity to occupy space at, to enter, or to attend a place of entertainment, even if not evidenced by any physical manifestation of the right, option, or opportunity; and

(v) "Ticket marketplace" means a website that provides a forum for or facilitates the buying and selling, or reselling, of a ticket;

(53) A violation of § 33-2-424;

(54) A violation of § 33-2-1402(b);

(55) A violation of § 33-2-1403(a);

(56) Issuing or delivering a home service contract to a consumer in this state that does not specify the merchandise and services to be provided, and any limitations, exceptions, or exclusions;

(57) Violating § 47-18-133;

(58) A violation of § 47-18-135;

(59) Violating § 47-18-3203;

(60) Violating § 36-1-108(a) or (b);

(61) Violating § 36-1-109; and

(62) Providing services related to the placement of a child or children for adoption, including, but not limited to, counseling or facilitating, and the services are provided using false or misleading representations of fact or deceptive representations.

(c) The following are among the acts or practices which will be considered in determining if an offer to sell goods or services is not bona fide:

(1) Refusal to reasonably show, demonstrate or sell the goods or services offered in accordance with the terms of the offer;

(2) Disparagement by acts or words of the advertised goods or services or disparagement with respect to the guarantee, credit terms, availability of service, repairs or parts, or in any other respect, in connection with the advertised goods or services;

(3) Failure to make available at all outlets listed in the advertisement a sufficient quantity of the advertised goods or services to meet reasonably expectable public demand, unless the advertisement clearly and conspicuously discloses that the availability of a particular good is limited and/or the goods or services are available only at designated outlets, or unless the advertisement discloses that a particular good is to be closed out or offered for a limited time. In the event of an inadequate inventory, issuing of "rain checks" for goods or offering comparable or better goods at the sale price may be considered a good faith effort to make the advertised goods available, unless there is a pattern of inadequate inventory or unless the inadequate inventory was intentional. If rain checks are offered, the goods must be delivered within a reasonable time;

(4) Refusal to take orders or give rain checks for the advertised goods or services, when the advertisement does not disclose their limited quantity

or availability to be delivered within a reasonable period of time;

(5) Showing or demonstrating goods or services which are defective, unusable or impractical for the purpose represented or implied in the advertisement when such defective, unusable or impractical nature is not fairly and adequately disclosed in the advertisement; and

(6) Use of a sales plan or method of compensating or penalizing salespersons designed to prevent or discourage them from selling the advertised goods or services. This does not prohibit compensating salespersons by use of a commission.

(d) The fact that a seller occasionally sells the advertised goods or services at the advertised price does not constitute a defense when the seller's overall purpose is to engage in bait and switch tactics.

(e) Nothing in § 47-18-103(1) or subdivisions (b)(21)-(23) and subsections (c) and (d) shall prevent a seller from advertising goods and services with the hope that consumers will buy goods or services in addition to those advertised.

(f) For the purposes of subsection (b), investment does not include a security defined in § 48-1-102 or any insurance or annuity contract.

Tenn. Code Ann. § 53-1-110

New drugs; sales

(a) 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.

(b) This section shall not apply to:

(1) A drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety in drugs; provided, that the drug is plainly labeled "For Investigational Use Only"; and provided, further, that all reports of investigations that are being made and that have been made to show whether or not the drug is safe for use, and whether the drug is effective in use are furnished upon request to the commissioner;

(2) A drug sold in this state at any time prior to February 15, 1941, or introduced into interstate commerce at any time prior to the enactment of the federal act; or

(3) Any drug that is licensed under the Virus-Serum-Toxin Act (21 U.S.C. § 151 *et seq*.).