JS-6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

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

Plaintiff,

v.

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

Defendants.

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

The Honorable Christina A. Snyder

AMENDED FINAL JUDGMENT

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

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

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

3. **Permanent Injunction.**

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

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

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

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

b. In addition to the injunction set forth in paragraph 3.a, Defendants and their officers, agents, servants, employees, attorneys, and all those acting in concert with any of them, shall also be permanently enjoined from directly or indirectly dispensing or

distributing any unapproved sodium thiosulfate product from a Section 503B outsourcing facility into California, Connecticut, Florida, South Carolina, or Tennessee, unless:

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

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

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

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

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

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

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

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

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

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

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

IT IS SO ORDERED, ADJUDGED, AND DECREED.

DATED: March 31, 2022

Christina A. Snyder

THE HONORABLE CHRISTINA A. SNYDER
UNITED STATES DISTRICT JUDGE