CAUSE NO. 07-14410

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DEPUTY

STATE OF TEXAS, Plaintiff	§	IN THE DISTRICT COURT OF
vs.	§	
APOTHECURE, INC., SPECTRA PHARM, INC., and GARY D. OSBORN, individually,	§	DALLAS COUNTY
	§	D-95th
Defendants.	§	____ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, THE STATE OF TEXAS, acting by and through Attorney General Greg Abbott ("State"), filing Plaintiff's Original Petition complaining of and against APOTHECURE, INC., SPECTRA PHARM, INC., and GARY DOUGLAS OSBORN, individually, ("Defendants"), and would respectfully show the court the following:

1. AUTHORITY

1.1 This action is brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §§ 431.060, 431.047, and 431.0585 of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. § 431.001 *et seq.* ("TFDCA"). Section 431.060 of the TFDCA specifically provides that the Attorney General, to whom the Commissioner of the Texas Department of State Health Services ("Department" or "TDSHS") reports a violation of the TFDCA, shall initiate and prosecute appropriate proceedings. In addition, § 431.047 of the TFDCA authorizes the Attorney General to seek

injunctive relief under certain circumstances and recover any costs and attorney fees incurred thereby. This action is also brought pursuant to § 431.0585 of the TFDCA, which authorizes the Commissioner of Health to refer persons who violate § 431.021 of the TFDCA and its associated regulations to the Attorney General so that he may seek civil penalties against such violators.

1.2 This action is further brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by § 17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. § 17.41 *et seq.* ("DTPA") (Vernon 2002, Supp. 2007) upon the grounds that Defendants have engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§17.46(a) and (b) of the DTPA.

2. PARTY DEFENDANTS

2.1 Defendant APOTHECURE, INC., is a domestic corporation doing business in Dallas, Texas at 4001 McEwen Road, Suite 100, 75244, and may be served with process at this address.

2.2 Defendant SPECTRA PHARM, INC., is a domestic corporation doing business in Dallas, Texas at 4001 McEwen Road, Suite 100, 75244, and may be served, with process at this address.

2.3 Defendant GARY OSBORN, individually, is the registered agent, President, sole director, and sole shareholder of both Defendants APOTHECURE, INC., and SPECTRA PHARM, INC. Defendant GARY OSBORN is also designated as the pharmacist-in-charge of Defendant APOTHECURE, INC., and actively directs and participates in all business activities

of APOTHECURE, INC., and SPECTRA PHARM, INC. OSBORN is in charge of conducting business at 4001 McEwen Road, Suite 100, Dallas, Texas 75244 and may be served with process at this address, or alternatively, he can be served at the following address: 40 Kennington Court, Dallas, Texas 75248.

3. VENUE

3.1 Venue of this action lies in Dallas County on the basis of TFDCA §§ 431.047(c) and 431.0585(d) by virtue of the fact that Defendants were engaged in the business of manufacturing, offering to sell, and selling adulterated and misbranded drugs, unapproved new drugs, and/or misbranded or adulterated foods in Texas.

4. PUBLIC INTEREST

4.1 Because Plaintiff STATE OF TEXAS has reason to believe that APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, have engaged in, and will continue to engage in, the unlawful practice set forth below, Plaintiff STATE OF TEXAS has reason to believe that APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, have caused and will cause immediate and irreparable injury, loss and damage to the STATE OF TEXAS, and its citizens, and will also cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

5. ACTS OF AGENTS

5.1 Whenever in this petition it is alleged that Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, did any act or thing, it is meant

that Defendants performed or participated in such act or thing or that such act was performed by agents or employees of Defendants and in each instance, the agents or employees of Defendants were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually.

6. TRADE AND COMMERCE

6.1 Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, have, at all times described below, engaged in conduct which constitutes "trade" and "commerce" as those terms are defined by § 17.45(6) of the DTPA.

7. NOTICE BEFORE SUIT

7.1 Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, were informed in general of the alleged unlawful conduct described below and as may be required by § 17.47(a) of the DTPA by certified and regular mail on November 28, 2007.

8. FACTUAL SUMMARY

8.1 Defendant GARY DOUGLAS OSBORN ("OSBORN") is a Texas-licensed pharmacist, who is engaged in various pharmaceutical business enterprises. In particular, Defendant OSBORN is the President, sole director, and sole shareholder of both Defendants APOTHECURE, INC. ("APOTHECURE") as the pharmacist in charge and SPECTRA PHARM, INC., ("SPECTRA PHARM").

A. APOTHECURE, INC.

8.2 Defendants APOTHECURE and GARY OSBORN, as President, sole-director,

and pharmacist-in-charge, conduct business in a facility located in Dallas, Texas. From that facility, APOTHECURE and OSBORN manufacture, distribute, and retail prescription and over-the-counter drugs, manufacture dietary supplements, and operate a pharmacy. To that end, APOTHECURE is licensed by the Department as a food manufacturer (dietary supplements are foods under Texas law) and as a drug manufacturer/distributor. Additionally, APOTHECURE is licensed in Texas by the Texas Board of Pharmacy as a community or "Class A" pharmacy and OSBORN is designated as the pharmacist-in-charge.

8.3 The entrance of APOTHECURE is a walk-in retail store where dietary supplements, privately labeled dietary supplements, homeopathic drugs, and over-the-counter drugs are available for sale. Product handouts and promotional brochures are available on a turnstile display rack inside the storefront. APOTHECURE and OSBORN provide similar promotional materials and sell the same products on its website (www.apothecure.com), as well as the retail website for SPECTRA PHARM (www.ruhealthy.com) and the website for one of Defendant OSBORN's other companies, the Texas Institute of Functional Medicine ("TIFM") (www.tifm.com). Within the business establishment, APOTHECURE and OSBORN manufacture various foods or dietary supplements, over-the-counter drugs, and prescription drugs, and acts as a "Class A" pharmacy. The establishment is divided into various rooms dedicated to particular tasks related to the bulk manufacture of drugs and foods, the filling of drug prescriptions, as well as the labeling and storage of such products.

(a). **APOTHECURE Manufactures Drugs.**

8.4 APOTHECURE and OSBORN purchase bulk raw active ingredients from third parties for over-the-counter and prescription drug and food manufacturing and do not conduct

identity testing on those ingredients as required by federal and state laws and regulations, particularly the Good Manufacturing Practices. The raw materials are stored in a "warehouse" which is a storage room. A separate storeroom for SPECTRA PHARM products is located within APOTHECURE's main storeroom. Dry ingredients are pulled from bulk containers in the storeroom and moved to the dry mixing area and encapsulating area, where food and both types of drugs are manufactured. All dry ingredients are measured on a balance. Prior to the deaths of three people who expired after taking an adulterated and misbranded drug described below, APOTHECURE and OSBORN kept no record of the weight measurements of the actual dry ingredients placed in the drugs. APOTHECURE and OSBORN still do not record volumetric measurements for liquid ingredients actually placed in the drugs.

8.5 Defendants APOTHECURE and OSBORN also manufacture unapproved new drugs and adulterated and misbranded prescription drugs. Similarly, APOTHECURE and OSBORN manufacture stock batches of over-the-counter drugs for general sale. Both types of drugs are manufactured in lots of varying quantities. The production of such lots is documented on a "Logged Formula Worksheet" ("Worksheet"). The Worksheets document various pieces of information relative to the batch, such as the date and time of production, chemicals to be used, quantity to be used, and lot numbers of the bulk chemical ingredients. Then, lot numbers are assigned by APOTHECURE and OSBORN to each food or drug upon completion of the manufacturing process. The particular number is derived from a code designed to include information referencing the year, month and day of manufacture, as well as a number identifying where in the chronological manufacturing sequence for the particular day the lot was created. For example lot number 20070122@26 refers to the twenty-sixth lot manufactured in 2007 on

January twenty-second.

8.6 Defendants APOTHECURE and OSBORN appear to specialize in manufacturing injectable versions of prescription drugs. To that end, APOTHECURE combines active drug ingredients with United States Pharmacopeia ("USP") Sterile Water for Irrigation, instead of USP Sterile Water for Injection.[1] Particularly, APOTHECURE and OSBORN have combined the following prescription drug products with USP Water for Irrigation: DMPS, EDTA Disodium, Polidocanol, and Colchicine. USP Water for Injection is designed solely for use in combination with drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection. USP Sterile Water for Injection is purified using distillation or double pass reverse osmosis. USP Sterile Water for Irrigation, on the other hand, is not for use in injections. Rather, it is primarily indicated for use as an irrigating fluid, and is generally less expensive than USP water for injection. Nevertheless, APOTHECURE and OSBORN manufacture injectable drugs with USP Sterile Water for Irrigation despite the fact that the label of such water bears the following warning: "**Contradindications: Not for injection.**"

8.7 APOTHECURE and OSBORN's use of the USP Sterile Water for Irrigation in their prescription drugs adulterates these drugs, and Defendants do not have any validation data

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[1]THE 8 TYPES OF WATER ARE:
1. Non-potable
2. Potable (drinkable) water
3. USP purified water
4. USP water for injection (WFI)
5. USP sterile water for injection
6. USP sterile water for inhalation
7. USP bacteriostatic water for injection
8. USP sterile water for irrigation

The USP designation means that the water is the subject of an official monograph in the current US PHARMACOPEIA with various specifications for each type.
http://www.fda.gov/ora/inspect_ref/itg/itg46.html.

for the process where Defendants filter drugs mixed with sterile water for irrigation to prove that this process makes the drugs suitable for intravenous injection. In addition, APOTHECURE and OSBORN use single bottles of USP water for irrigation labeled as "Single-dose Container" to manufacture multiple batches of sterile, injectable prescription drugs. APOTHECURE and OSBORN do this even though they do not have validation data demonstrating the propriety of using single-dose containers of USP Water for Irrigation for multiple batches.

8.8 After APOTHECURE and OSBORN combine the prescription drugs with Sterile Water for Irrigation, the drug products are taken to a filling room where an employee filters the drug products into vials. At this point, lot numbers are computer-generated in sequential order for that day. Then, the vials are taken to a label printing area, where an employee applies each label to each drug product (e.g., drug vial).

8.9 After being labeled, the drugs are taken to a quarantine room. APOTHECURE and OSBORN store the drugs there while samples from each lot are sent to a third party for laboratory testing. Generally, APOTHECURE and OSBORN only have testing done for microbial and bacterial endotoxins. Prior to the three deaths described below, APOTHECURE and OSBORN did not attempt to test the potency of its drugs. According to Defendant OSBORN and other APOTHECURE employees, the firm has since instituted an informal policy for potency testing of certain high risk, potentially lethal drugs to avoid a repeat of adverse reactions.

8.10 In addition to manufacturing food and drugs, APOTHECURE and OSBORN also compound and dispense prescription drugs for individual patient prescriptions. This is completed in a prescription filling area adjacent to the warehouse/storage room. In this area, individual patient prescriptions are verified by one of the APOTHECURE pharmacists. The

labels for these prescription drugs bear the individual patient's name.

(b). APOTHECURE's Manufacture of Drugs Beyond the Scope of the Practice of Pharmacy in Texas.

8.11 Defendant OSBORN purports to operate APOTHECURE only as a pharmacy that "compounds drugs,"[2] rather than as a prescription drug manufacturer.[3] However, the actual activities of APOTHECURE and OSBORN extend beyond the scope of the practice of pharmacy in Texas and the specific activities reserved for pharmaceutical compounding. APOTHECURE's and OSBORN 's manufacture of numerous prescription drugs extends beyond the scope of the practice of pharmacy in Texas as follows:

A. APOTHECURE and OSBORN, as the pharmacist-in-charge, introduced into commerce the prescription drug Colchicine that was adulterated and misbranded which is beyond the scope of the practice of pharmacy in Texas. Three deaths in

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[2] Pharmaceutical compounding is generally described as the combining, mixing, or altering of ingredients to create a customized medication for an individual patient in response to a licensed practitioner's prescription. *See e.g.* http://www.fda.gov/CDER/pharmcomp/survey.htm. *Cf.* TEX. OCC. CODE § 551.003(9) ("Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device: (A) as the result of a practitioner's prescription drug order based on the practitioner-patient-pharmacist relationship in the course of professional practice; (B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice; (C) in anticipation of a prescription drug order based on a routine, regularly observed prescribing pattern; or (D) for or as an incident to research, teaching, or chemical analysis and not for selling or dispensing, except as allowed under Section 562.154 or Chapter 563.)

[3] "Manufacture" means: (A) the process of combining or purifying food or packaging food for sale to a person at wholesale or retail, and includes repackaging, labeling, or relabeling of any food; (B) the process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing, or quality control of a drug or drug product, but does not include compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Section 562.154, Occupations Code; ..." TEX. HEALTH & SAFETY CODE §431.002(23)

Oregon and Washington were reported after injections of Defendants' misbranded and adulterated Colchicine.

B. APOTHECURE and OSBORN, as the pharmacist-in-charge, manufacture drugs that have not been approved for marketing by the FDA, and such manufacturing is outside the practice of pharmacy as it is illegal to compound any drugs that have not been approved by the Food and Drug Administration ("FDA") for marketing. Only variations of drugs approved for marketing by the FDA can legally be compounded by a licensed pharmacist in Texas, therefore it is beyond the scope of the practice of pharmacy in Texas to compound a new drug that has not been approved for marketing by the FDA.

C. APOTHECURE and OSBORN, as the pharmacist-in-charge, have been manufacturing and selling these and other prescription drugs to persons who are not practitioners,[4] as defined by the Texas Pharmacy Code, specifically §551.003(34). These non-practitioners are not lawfully capable of prescribing such drugs in Texas. Consequently, each sale to non-practitioners is beyond the

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[4]"Practitioner" means: (A) a person licensed or registered to prescribe, distribute, administer, or dispense a prescription drug or device in the course of professional practice in this state, including a physician, dentist, podiatrist, or veterinarian, but excluding a person licensed under this subtitle; (B) a person licensed by another state, Canada, or the United Mexican States in a health field in which, under the law of this state, a license holder in this state may legally prescribe a dangerous drug; (C) a person practicing in another state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a current federal Drug Enforcement Administration registration number and who may legally prescribe a Schedule II, III, IV, or V controlled substance, as specified under Chapter 481, Health and Safety Code, in that other state; or (D) an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders under Section 157.0511, 157.052, 157.053, 157.054, 157.0541, or 157.0542. TEX. OCC. CODE § 551.003(34).

scope of the practice of pharmacy in Texas. For example, APOTHECURE and OSBORN sold the prescription drug Colchicine to a Naturopath and Acupuncturist in Alaska, even though a Naturopath is not included in the definition of "Practitioner" found in the Texas Pharmacy Act, TEX. OCC. CODE § 551.003(34). In addition, Defendants sold prescription drugs to a non-practitioner in the United Kingdom which is beyond the scope of the practice of pharmacy in Texas.

D. APOTHECURE and OSBORN, as the pharmacist-in-charge, have been manufacturing and selling prescription drugs to persons in numerous states and countries, although APOTHECURE is not licensed in these states or countries as a pharmacy and/or as a manufacturer/distributor of prescription drugs. For example, APOTHECURE and OSBORN sold the prescription drug Colchicine in Portland, Oregon, despite the fact that APOTHECURE is not licensed by Oregon as a pharmacy or as a manufacturer/distributor and cannot lawfully distribute drugs in Oregon. Therefore, manufacturing and selling prescription drugs to persons in numerous states and countries in which APOTHECURE is not licensed as a pharmacy and/or as a manufacturer/distributor of prescription drugs are beyond the scope of the practice of pharmacy in Texas.

E. APOTHECURE and OSBORN, as the pharmacist-in-charge, manufacture drugs that have been withdrawn or removed from the market for safety reasons and are specifically prohibited from being compounded. For example, APOTHECURE manufactured Adrenal Cortex sublingual drops and Adrenal Cortex Kits although

all drug products containing Adrenal Cortex are on the Food and Drug Administration's list of compounding drugs removed from the market for safety reasons. Despite the FDA ban on compounding drugs with Adrenal Cortex and the safety concerns, APOTHECURE and OSBORN still manufacture two drugs with adrenal cortex and advertise in their catalog that "Although it is illegal to sell ACE for injection use, it is perfectly legal to filter sublingual ACE with a 0.22 micron barrel filter, which renders it sterile. For more information on this technique, call 1-800-969-6601." APOTHECURE and OSBORN are engaging in deception and trying to circumvent the law by manufacturing, advertising, offering for sale, and selling an illegal, not safe, and banned drug by selling the Adrenal Cortex kits and sublingual drops and then instructing the public how to make an injectable drug when such drugs are against the law. Therefore, APOTHECURE and OSBORN have manufactured prescription drugs that extend beyond the scope of the practice of pharmacy in Texas.

(c). Defendants' Manufacture Adulterated and/or Misbranded Drugs, Including Colchicine

8.12 For at least one year, APOTHECURE and OSBORN have been manufacturing an intravenous form of the potentially toxic drug, Colchicine. On February 7, 2007, APOTHECURE and OSBORN sold to the Center for Integrative Medicine ("CIM"), in Portland, Oregon, seventy (70) 4-milliliter vials and two (2) ten-milliliter vials of injectable Colchicine that APOTHECURE and OSBORN manufactured. APOTHECURE and OSBORN sold these vials of injectable Colchicine into Oregon and the invoice indicated that Defendants did not have a

practitioner's prescription drug order or initiative for specific patients from the purchaser based on an actual practitioner-patient-pharmacist relationship. APOTHECURE is not licensed by the state of Oregon as a pharmacy or as a manufacturer/distributor to lawfully distribute drugs in Oregon. Nevertheless, APOTHECURE and OSBORN filled CIM's order from three previously manufactured batches of Colchicine (APOTHECURE lot numbers 20070122@26, 20061214@28 and 20061227@10).

8.13 APOTHECURE and OSBORN manufactured and sold Colchicine, which was adulterated through the use of substandard manufacturing practices, in at least two of the batches from which CIM's order was filled. Particularly, batch 20070122@26 contained vials of injectable Colchicine that were far more potent that their labels indicated. These vials of injectable Colchicine were both adulterated and misbranded by APOTHECURE and OSBORN prior to introducing these adulterated and misbranded drugs into commerce.

8.14 Approximately one month after selling the injectable Colchicine to CIM, three deaths were reported as being associated with these misbranded and adulterated drugs. Particularly, it has been alleged that two Portland residents who were treated at the Center for Integrative Medicine in Portland and a Yakima, Washington woman who was treated at her local clinic died after being administered this super-potent Colchicine that was sold unlawfully by APOTHECURE and OSBORN.

8.15 In response to those deaths, the Oregon Medical Examiner detained the remaining unused vials sold to CIM, and conducted potency testing. According to the Oregon deputy state medical examiner, remaining vials from lot 20070122@26 were found to have a potency of 4 milligrams per milliliter, rather than the 0.5 milligrams per milliliter stated on labels. Further,

the deputy medical examiner determined that one injection of the mislabeled, super-potent Colchicine would be potent enough to cause death.[5]

8.16 The FDA also tested the Colchicine lots associated with these three deaths and also determined the super-potency of lot number 20070122@26. The FDA had to obtain an inspection warrant to enter Defendants' premises as Defendants claim that the FDA has no jurisdiction over a pharmacy and would not voluntarily allow the FDA to enter.

8.17 APOTHECURE and OSBORN conducted its own internal investigation of the Colchicine lots associated with the three deaths. As a result, the super-potency of lot number 20070122@26 was confirmed through third-party testing commissioned by APOTHECURE and OSBORN. Further, OSBORN has admitted that APOTHECURE's staff had determined that "human error" likely caused the "mis-weighing" of the Colchicine active ingredient, which resulted in the super-potent lot.

8.18 APOTHECURE and OSBORN also adulterate drugs when they use the USP Sterile Water for Irrigation in their drugs and do not have validation data for the process whereby Defendants filter drugs mixed with sterile water for irrigation to prove that this process makes the drugs suitable for intravenous injection and do not list the ingredient accurately on the label. In addition, APOTHECURE and OSBORN adulterate drugs when they use single bottles of USP water for irrigation labeled as "Single-dose Container" to manufacture multiple batches of sterile, injectable drugs without having validation data demonstrating the propriety of using single-dose containers of USP Water for Irrigation for multiple batches. APOTHECURE and OSBORN also

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[5] *See* http://www.portlandtribune.com/news/story.php?story_id=117762598274410600.

misbranded drugs when the actual amount of Colchicine's active ingredient is incorrectly listed on the label of the drugs.

8.19 In addition, APOTHECURE and OSBORN, as the pharmacist-in-charge, manufacture both prescription and over-the-counter drugs with numerous deficient manufacturing practices for prescription and over-the-counter drug products, as specifically identified in paragraphs 8.25 through 8.27 below.

(d). APOTHECURE and OSBORN's Manufacture of Unapproved New Drugs

8.20 APOTHECURE and OSBORN, as the pharmacist-in-charge, manufacture the following drugs that have not been approved for marketing by the FDA: DMPS and Polidocanol. Such manufacturing is outside the practice of pharmacy as it is illegal to compound any drugs that have not been approved by the FDA for marketing. Only variations of drugs approved for marketing by the FDA can legally be compounded by a licensed pharmacist in Texas, therefore making it beyond the scope of the practice of pharmacy in Texas to compound a new drug that has not been approved for marketing by the FDA.

8.21 APOTHECURE and OSBORN, as the pharmacist-in-charge, manufacture an illegal injectable Adrenal Cortex drug in violation of 21 CFR § 216.24. Particularly, APOTHECURE and OSBORN manufacture and sell an Adrenal Cortex Kit, containing Adrenal Cortex with a vial of sterile water for injection and directions for mixing them. Injectable Adrenal Cortex drugs are illegal. Therefore, the manufacture of Adrenal Cortex Kits by APOTHECURE and OSBORN, as the pharmacist-in-charge, constitutes the manufacturing of a banned and unapproved new drug and is beyond the scope of the practice of pharmacy in Texas. In addition, Defendants manufacture and advertise unapproved new drugs when they advertise

and promote products labeled as dietary supplements to cure, treat, prevent, or mitigate diseases since these products have not been approved by the FDA for these intended uses since they are labeled as dietary supplements as identified in paragraphs 8.28-8.32 below.

B. Regulatory Investigations and APOTHECURE's Response

8.22 Following the three deaths, the Texas State Board of Pharmacy (" Texas BOP") requested that APOTHECURE issue a recall of its injectable Colchicine drug products. Consequently, on April 30, 2007, APOTHECURE issued a recall for all strengths, sizes and lots of injectable Colchicine it sold within the previous year.

8.23 After that recall, the Texas BOP commenced efforts to investigate APOTHECURE and its relation to the three reported deaths. Specifically, on July 10, 2007, the Board issued an administrative subpoena seeking various records and information from APOTHECURE. Because APOTHECURE is a licensed pharmacy in Texas, it is subject to regulation by the Texas BOP, and Chapter 556 of the Texas Occupations Code requires APOTHECURE to comply with the Board's lawful administrative subpoenas. Nevertheless, when the Board's representative appeared at APOTHECURE's facility to review and copy said records, APOTHECURE refused to permit the BOP access to its records. As a result, in October 2007, the Board filed suit[6] against APOTHECURE in Travis County seeking a court order directing and compelling APOTHECURE to produce the documents, records, and information requested. That litigation is pending and BOP still has not been allowed records from an entity that it licenses.

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[6] Texas State Board of Pharmacy v. APOTHECURE, Inc., Trial Court Cause No. D-1-GN-07-003611 (District Court Travis County, Texas 200th Judicial District).

8.24 After becoming aware of the three deaths associated with the APOTHECURE's Colchicine drugs, the FDA also commenced an investigation. The FDA was also denied access by APOTHECURE and OSBORN to inspect and had to obtain a warrant to inspect Defendants' facilities. The FDA then inspected APOTHECURE and determined that it was a manufacturer of prescription drugs and subject to regulation by the FDA.

(a). May 17, 2007 and June 12, 2007 Inspections by TDSHS

8.25 On April 26, 2007, the Texas Department of State Health Services received a complaint alleging that the three people in Oregon and Washington died after receiving an intravenous Colchicine drug product manufactured by APOTHECURE and OSBORN. In response, the Department conducted an inspection of APOTHECURE. More specifically, the Department inspected the APOTHECURE facility, on May 17, 2007 and June 12, 2007, and also made investigative observations of APOTHECURE's website (www.apothecure.com) and Osborn's related website, www.ruhealthy.com. During its investigations, the Department identified numerous unlawful conditions. Particularly, the Department found numerous violations which generally relate to the following: (1) manufacturing, offering to sale, and sale of a super and sub-potent drug product (i.e., Colchicine), which both adulterates and misbrands this drug; (2) numerous deficient manufacturing practices for prescription and over-the-counter drugs which adulterates these products; (3) manufacturing unapproved new drugs; (4) dietary supplement advertising and labeling violations related to unlawful disease and/or drug claims; and (5) various other violations of the Texas Food, Drug and Cosmetic Act.

8.26 Specifically, the Department found the following violations related to the manufacturing and sale of a super and sub-potent prescription drug product:

A. Colchicine labeled as 1mg/2ml (lot# 20070122@26) was tested and found to have an actual strength of 4mg Cochicine/ml.

B. Colchicine labeled as 1mg/2ml (lot#20070122@26) and determined to have an actual strength of 4 mg Colchicine/ml was sold and shipped to Geoffrey Wiss, M.D. at the Center for Integrative Medicine, 5125 S.W. Macadam Ave., Suite 200, Portland, Oregon, on February 2, 2007 (31 vials).

C. Colchicine labeled as 1mg/2ml (lot# 20061214@28) was tested and found to have an actual strength of 0.38mg Colchicine/ml.

D. Colchicine labeled as 1mg/2ml (lot#20061214@26) and determined to have an actual strength of 0.38 mg Colchicine/ml was sold and shipped to:

i. Geoffrey Wiss, M.D. at the Center for Integrative Medicine, 5125 S.W. Macadam Ave., Suite 200, Portland, Oregon, on January 2, 2007 (35vials);
ii. Paul Stallone, NMD at the Arizona Integrative Med. Center, 8144 E. Cactus Rd., Ste. 820, Scottsdale, Arizona on January 8, 2007 (10 vials); and
iii. Geoffrey Wiss, M.D. at the Center for Integrative Medicine, 5125 S.W. Macadam Ave., Suite 200, Portland, Oregon, on February 7, 2007 (39 vials).

8.27 The Department further found the following violations related to various deficient manufacturing practices for prescription and over-the-counter drug products:

A. The firm generally failed to have laboratory records.

B. The firm lacked laboratory records which assure compliance with established specifications and standards. For example, Defendants lacked data establishing compliance with specifications and standard for the following two drug products: SDA 1600 Alcohol Gel; and SDA 1600 Mouthwash with Xylitol.

C. The firm lacked written procedures for the equipment calibration. Particularly, the firm lacked written procedures for the calibration of the scales used in drug manufacturing.

D. The firm lacked documentation of validation of their cleaning procedures. For instance, the firm lacked documentation validating the cleaning procedures used for utensils and equipment used in drug manufacturing.

E. The firm failed to package drugs in tamper resistant packaging. For example, the

firm's SDA 1600 Mouthwash with Xylitol (lot#20070604@12) was not sealed with tamper-resistant packaging.

F. The firm failed to adequately test, approve or reject prescription drug components during manufacture. For example, the firm accepts reports of analysis from suppliers, without performing at least one specific identity test on each component.

G. The firm failed to adequately document the weight and measure of prescription drug components during manufacture.

H. The firm failed to adequately document each batch of a prescription drug component (i.e., no lot number identification). Particularly, sixteen (16) bottles of SDA 1600 Alcohol Gel, 2oz., and eleven (11) bottles of SDA 1600 Alcohol Gel, 8oz., did not have lot numbers.

I. The firm failed to calculate or state an actual yield in determining satisfactory conformance to specifications for prescription drug products. For instance, the firm does not test each batch of drug products, whether injectables, capsules, creams, or any other product, to verify the product quality specifications such as potency and identity.

J. The firm failed to adequately document in-process and laboratory control results. For instance, the firm's master production and control records do not describe the specific equipment and mixing instructions, sampling and testing procedures, nor do they include the specifications of components used in manufacturing.

K. The firm lacks sterilization procedures designed to prevent microbiological contamination of drug products. For instance, the firm does not have written procedures or validation data to demonstrate the multiple use of USP sterile water for irrigation as a component in sterile, injectable drugs. Yet, the label for sterile water for irrigation read in part, "Contraindications: Not for injection. ***Single-dose container."

L. The firm failed to validate the sterilization process for prescription drugs. For instance, the firm failed to have adequate evidence showing the effectiveness of using a 0.2 micro-filter for the sterile filling of all injectable drug products, including but not limited to, Calcium-Disodium EDTA, Disodium EDTA, DMPS, Lidocaine, Polidoccanol, Procaine, and Colchicine.

M. The firm manufactured over-the-counter drug products with active ingredients that are not approved for their indicated uses. For example, the firm manufactured SDA 1600 Mouthwash with Xylitol (lot#20070604@12) and labeled it as a

"spectracidal disinfectant agent," however that product does not contain an active drug ingredient approved for the indicated use.

8.28 The Department additionally found the following violations related to dietary supplement advertising and misbranding violations related to unlawful disease and/or drug claims which also makes these products unapproved drugs:

A. **D-MannoseUSP 650mg** : The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"D-Mannose is a new product on the market for urinary tract infections."
"D-mannose . . . can cure more than 90 percent of all UTIs within 1 to 2 days."
"...because it gets rid of UTI-causing bacteria without committing 'bacteriacide,' people who use it suffer none of the unwanted side effects of antiobiotics."
"...women(even pregnant women) who are susceptible to recurrent UTIs can safety take D-Mannose as a preventive measure to head off future attacks. D-Mannose is also ideally suited for children with UTIs."
"...have demonstrated its mode of action and effectiveness against E.coli the microorganism that causes most UTIs."
"...it is just about as effective at curing UTIs as antibiotic drugs.";

B. **Arginine 500mg**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"...when combine with Lysine, ...reduce the risk of cardiovascular disease..."
"...helpful with alcoholism."
"...helpful with hepatitis"
"...may help some cases of high blood pressure";

C. **Pregnenolone**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"...precursor to other hormones, including dehydroeplandrosterone (DHEA) and progesterone.";

D. **Oregacillin**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Oregacillin products are for anti-fungal, anti-viral, anti-bacterial, anti-parasitic and anti-spasmatic uses.";

E. **HCI Plus**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"...acidify systemically (bursitis, tendonitis and environmental sensitivity), symptoms of hypochlorhydria (gas, bloating, bad breath, body odor, loss of taste

for meat, anemia, pregnancy, low mineral values as seen on a hair-mineral analysis).";

F. **Super EPA**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Supplementation with fish oils might benefit some of these conditions:
Allergies, Chronic diarrhea, Cancer, Aging, Autoimmune diseases, Heart disease, Lupus, Arthritis, Rashes, and Anti-inflammation";

G. **Absorb Aid**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"... eliminate the symptoms of indigestion, heartburn and reflux naturally, through better digestion.";

H. **Pro Biotic Live 12 Plus**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
Decreases incidents of digestive ailments
Decreases incidents of stomach ailments
Decreases incidents of bloating/heartburn
Decreases incidents of constipation/diarrhea
Decreases presence of yeast infection
Decreases incidents of certain infections
Decreases incidents of oral cavity infections;

I. **Essential Daily Defense**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Formulated to help the body excrete undesirable toxins, heavy metals and lipids, while helping to control excessive blood clotting tendencies (blood clots are believed to cause 85% of the deaths from heart attacks and strokes)...";

J. **Endozyme**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
Specifically, Endozyme Medicine contains:
-Nattokinase - to enhance the body's ability to fight blood clots and reduce blood pressure
-Bromelain - an anti-inflammatory to balance the immune system
-Papain - to degrade accumulation of age-related proteins
-Rutin - a powerful anti-inflammatory to help promote a healthier environment for joint mobility
-White Willow Bark - a herbal extract to help normalize inflammation;

K. **DHEA 25mg**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:

Health Benefits of DHEA: Fights Osteoporosis and Fights Auto-immune Diseases;

L. **Chromium Polynicotinate**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"A recent study on antidepressant pharmacotherapy for dysthymic disorder (depression) in 5 patients showed that chromium polynicotinate supplementation led to remission of dysthymic symptoms and concluded that "preliminary observations suggest that chromium may potentate antidepressant pharmacotherapy for dysthymic disorder."
"For many with diabetes, chromium enhances the ability of insulin to lower serum glucose levels.";

M. **Biotin with Horsetail**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Uses:
-Cradle cap (seborrheic dermatitis)
-Diabetes
-Biotin deficiency is a rare nutritional disorder caused by a deficiency of biotin. Biotin deficiency can have a very serious, even fatal, outcome if it is allowed to progress without treatment;

"Initial symptoms of biotin deficiency include:
-Dry skin
-Seborrheic dermatitis
-Fungal infections
-Rashes including erythematous periorofacial macular rash
-Hair loss or total alopecia;

-If left untreated, neurological symptoms can develop, including: Mild depression
-Changes in mental status
-Generalized muscular pains (myalgias)
-Hyperesthesias and paresthesias;

N. **Liquid Health Attention**: The website www.apothecure.com and www.ruhealthy.com had the following labeling:
"...for ADD/ADHD."

O. **Adrenal Cortex Support**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"We have found this particular blend to be very effective in supporting adrenal dysfunction and chronic fatigue syndrome.
"Adrenal dysfunction is one of the major underlying cause and/or result of most

chronic illnesses.
Indicated for use with allergies;

P. **Adrenal Cortex Sublingual**: The website www.apothecure.com, www.ruhealthy.com and promotional literature had the following labeling claims:
"... helps in resistance to infections and stress of all types, increases blood lymphocytes, and decreases serum gamma globulin content."
"Adrenal Cortex Extract has shown to be effective for hypoglycemia, inflammation, drug and alcohol withdrawal, stress management, trauma, allergies, and of course Addison's Disease."
"...indicated for stress, renal insufficiencies, inflammation, trauma, and toxic infections."
"Although it is illegal to sell ACE for injection use, it is perfectly legal to filter sublingual ACE with a 0.22 micron barrel filter, which renders it sterile."
Indicated for use with allergies
In addition, the product is a sublingual delivery system bypassing the digestive tract;

Q. **Youth Reborn** (topical Vitamin C): The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
Protects against or lessens the severity of sunburns.
Wound healing as it aids in stabilizing collagen;

R. **Bumble Bar**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims for the product:
"...help protect against heart disease, cancer, arthritis..."
"...protect against breast, colon and prostate cancers.";

S. **Free Radical Quenchers**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Free radicals are associated with both the initiation & promotion of cancer, all types of inflammation, arthritis, circulatory disorders, Parkinson's disease & many other health problems.";

T. **Complete Prostate Formula**: The pamphlet had the following labeling claims:
"...most common problems are prostatisis, benign prostatic hyperplasia, and prostate cancer.";

"How can you prevent any of the above conditions? Taking the unique combination of supplements can help prevent inflammation and cancer (saw palmetto extract, red clover extract, nettle, pygeum extract, lycopene, pumpkin seed extract, beta sitosterol, zinc, and copper- all ingredients found in Complete Prostate Formula).";

U. **Liquid Health, Women's Multi**: The pamphlet for this product had the following labeling claims:
"...improve circulation for the reduction of spider and varicose veins.";

V. **Collagen/Hyaluronic Acid Anti-Aging Powder Drink Mix**: The pamphlet for this product had the following labeling claims:
"...can rid the body of cellulite, eliminate hemorrhoids..."
"...connective tissue disorders, such as mitral valve prolapse, TMJ, osteoarthritis, and keratoconus.";

W. **Ascorbic Acid (Ascorbate) #8**: The pamphlet for this product had the following labeling claims:
"...such as healing of wounds and burns. It assists in the prevention of blood clotting and bruising..."
"...help reduce cholesterol levels, high blood pressure and preventing arteriosclerosis."
Indicated for use with allergies;

X. **FYI**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims: "...control and prevent inflammation, they have no side effects whatsoever and may, oftentimes, prevent the occurrence of unwanted side effects caused by prescription medications.";

Y. **5-Hydroxytryptophane**
Website indications include: Anxiety and Depression:

Z. **Magnesium Glycinate 750 mg.:**
Website indication is for high blood pressure;

AA. **Relieve Blue Pain Gel**: The product does not comply with the over-the-counter federal monograph for topical analgesics, in that the active drug ingredients (MSM, Aloe Vera and Emu Oil) are not approved for the indicated uses advertised, such as: pain relief, arthritis, reducing joint degeneration and inflammation of tissue. Some of the following claims were found on the website www.apothecure.com and www.ruhealthy.com for the product Relieve Blue Pain gel:
"...for just about any persistent or chronic pain."
"...MSM...highly useful in targeting certain types of arthritis pain and stiffness...";

BB. **Choles/TIFM**

The use of the phrase "For Blood Fat Disorders" implies that the product treats

disease condition; and

CC. **Insulin Support:**
Website indication is for diabetes.

8.29 Furthermore, the Department found additional violations of the Texas Food, Drug and Cosmetic Act, including several related to false or misleading advertising and misbranding violations:

A. **SDA 1600 Mouthwash with Xylitol and SDA 1600 Alcohol Gel** do not have a Drug Facts Panel;

B. **SDA 1600 Alcohol Gel, 8oz**: Eleven (11) bottles did not have a Drug Facts Panel;

C. **Relieve Blue Pain Gel**: The product does not comply with the over-the-counter federal monograph for topical analgesics, in that the active drug ingredients (MSM, Aloe Vera and Emu Oil) are not approved for the indicated uses advertised, such as: pain relief, arthritis, reducing joint degeneration and inflammation of tissue. Some of the following claims were found on the website www.apothecure.com and www.ruhealthy.com for the product Relieve Blue Pain gel:
"...for just about any persistent or chronic pain."
"...MSM...highly useful in targeting certain types of arthritis pain and stiffness...";

D. **Progesterone Cream 16mg/ml**: The website www.apothecure.com advertises the availability of the topical drug product- "One product we have available for over the counter is Progesterone Cream.";

E. **Dermaheal Nourishing Hair Solution**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Increase the follicle size and stop hair from falling out by reducing DHT."
"Help form new blood vessels, stimulate follicles to produce stronger, healthier hair."
"Increase synthesis of Collagen & Elastin, increase blood flow, restrains hair depigmentation."
"Increase stem cell release from bulge into matrix of hair follicle."
"Play important role in the control perifolicular vascularization during hair cycling.";

F. **A'LIVE Gel**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Tests by leading medical researchers have shown that A'LIVE 5% Hydrogen Peroxide Gel provides effective therapeutic relief from a variety of irritating skin conditions including: wounds, burns & sunburn, insect bites, aging spots, chronic allergic dermatitis, rosacea & vulgaris acnes, psoriasis lotricum, atopic dermatitis, fine wrinkles, periodontal disorders."
"Improved formula A'LIVE, with active ingredient methyl sulfonyl methane (MSM), is quickly absorbed deep into the skin where it combines with certain enzymes to produce oxygen thus restoring the skin's health, beauty, and natural vitality." (claim shows that the product is delivered transdermally);

G. **EDTA Calcium Disodium Magnesium**: The website www.apothecure.com, www.ruhealthy.com and promotional literature had the following labeling claims:
"...it removes plaque and returns the arterial system to a smooth, healthy, pre-atherosclerotic state."
A better metaphor might be "Liquid-Plumr®," because, where Roto-Rooter violently scrapes deposits off the interior surfaces of your plumbing with a rapidly rotating blade, Liquid-Plumr simply dissolves them away;

H. **Apothe Cure Nutritionals MSM Plus:**
Product label lacks Supplement Facts Panel.
Product label lacks an approved FDA disclaimer statement.
The components of the capsule are not provided in the ingredients statement
The product label lacks a proper serving size in that it uses the term "recommended dosage." The term "recommended dosage" implies a therapeutic use for the product.
The statement that appears on the label "and all other medicines" appears to be false and misleading in that the product is being sold as a dietary supplement;

I. **Adrenal Cortex Support:**
The proper name for Pantothenic acid is not being used in that the term Vitamin B-5 is provided as a dietary ingredient in the Supplement Facts panel and is not a recognized synonym. In addition, the calcium source is declared in Supplement Facts panel as originating from B-5;

J. **DHEA 25 mg.:**
The common or usual name of the product does not accurately describe product in that the term is an abbreviation;

K. **MSN Metal Detox II:**
The common or usual name of the product does not accurately describe product in that the term is an abbreviation. The word "Detox" is an unapproved drug claim.

The Supplement Facts panel does not state serving size of the product.
The Supplement Facts panel does not state the servings per container.
The product ingredients are not listed in the Supplement Facts panel in the correct format in that the ingredients without %DV's are listed with the ingredients that have established %DV's.
The warnings, uses, and directions act as intervening material between the dietary ingredients and other ingredients in the Supplement Facts panel.
The term "active ingredients" appears to be false and misleading in that the product is being sold as a dietary supplement.
The label fails to identify the ingredients that do not have a %DV established.
The components of the capsule are not provided in the ingredient statement;

L. **Trace Mineral #1 with Iron:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K;

M. **Trace Mineral #1:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K;

N. **Trace Mineral # 2 with Iron:**
The common or usual name of the product does not adequately describe the product.
The % DV of Manganese contained in product does not coincide with amount per serving provided in Supplement Facts panel;

O. **Trace Mineral # 2 Iron Free:**
The common or usual name of the product does not adequately describe the product;

P. **Electrolyte #1:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K;

Q. **Electrolyte #2:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K.
The dietary ingredients are not listed in the Supplement Facts panel in the proper order.

The weight of the compound, Potassium Phosphate, is provided in the Supplement Facts panel rather than the weight of the elemental Potassium;

R. **Electrolyte #3:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K.
The dietary ingredients are not listed in the Supplement Facts panel in the proper order.
The weight of the compounds, Sodium Carbonate, Potassium Chloride, Potassium Iodate, and Potassium Phosphate, are misleading in that the weight of the entire compound is listed in the Supplement Facts panel rather than the individual weight of the Sodium and Potassium;

S. **Apothe Cal Calcium Supplement with Boron:**
The components of the capsule are not provided in the ingredients statement.
The common or usual name does not accurately describe the product.
Calcium is not declared properly in the Supplement Facts panel;

T. **Ascorbate #8:**
The components of the capsule are not provided in the ingredients statement.
The common or usual name does not accurately describe the product.
Dietary ingredients are not declared properly in the Supplement Facts panel.
The order of predominance of the ingredients statement on bulk (12 Bottles-200 capsules each) Ascorbate #8 does not match the order of predominance provided in the Supplement Facts panel;

U. **EDTA** (calcium powder) **with Magnesium Malate** (Repeat violation from 10/13/04 & 1/25/06 DSHS Inspection of Spectrapharm):
The common or usual name of product does not adequately describe the product in that the proper nomenclature for EDTA is not provided.
The Supplement Facts panel provides an incorrect %DV for Magnesium.
The Magnesium is not declared properly in the Supplement Facts panel.
The components of the capsule is not declared in the ingredients statement;

V. **Vitamin C 100mg/tsp.:**
The product label does not provide a Supplement Facts Panel.
The common or usual name of the product does not adequately describe the product.
The components of OraSweet are not provided in the Supplement Facts panel.
Artificial cherry flavorings are not identified in the ingredient statement.
Artificial colorings are not identified in the ingredients statement.
The substance in which the product is suspended is not identified in the

ingredients statement;

W. **Magnesium Glycinate 750 mg.:**
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel.
The entire weight of Magnesium Glycinate is listed in the Supplement Facts panel rather than the actual weight of the elemental magnesium.
Website indication is for high blood pressure;

X. **Glucosamine Sulfate Complex with Chondroitin & MSM:**
The common or usual name of the product does not adequately describe the product.
The servings per container are not provided in the Supplemental Facts panel.
The proper nomenclature is not provided for MSM.
The components of the capsule are not provided in the ingredients statement;

Y. **5-Hydroxytryptophane 50mg.:**
The term "pharmaceutical grade ingredients" is false and misleading in that there are no pharmaceutical grade ingredients recognized for foods.
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement facts panel.
The hypoallergenic filler ingredients are not provided in the ingredients statement.
Website indications include: Anxiety and Depression;

Z. 5-**Hydroxytryptophane 25mg.:**
The term "pharmaceutical grade ingredients" is false and misleading in that there are no pharmaceutical grade ingredients recognized for foods.
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement facts panel.
The hypoallergenic filler ingredients are not provided in the ingredients statement.
Website indications include: Anxiety and Depression;

AA. **Malic Acid Triple Plus with AKG:**
The servings per container are not provided in the Supplement Facts panel.
The common or usual name does not adequately describe the product.
The components of the capsule are not provided in the ingredients statement;

BB. **1-Melthionine 500 mg.:**
The components of the capsule are not provided in the ingredients statement.
The common or usual name does not adequately describe the product.
The servings per container is not provided in the Supplement Facts panel;

CC. **Chromium Polynicotinate 400 mcgm:**

The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

DD. **Growth Hormone Releaser Beginner Formula**
No Supplement Facts panel is provided on product label.
The components of the capsule are not provided in the ingredients statement;

EE. **D Mannose USP 650mg.:**
The components of the capsule are not provided in the ingredients statement;

FF. **Choles/TIFM**
The common or usual name does not adequately describe the product.
The use of the phrase "For Blood Fat Disorders" implies that the product treats disease condition.
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

GG. **Immune Enhancer Formula:**
The common or usual name does not adequately describe the product.
The servings per container are not provided in the Supplement Facts panel.
The components of the capsule are not provided in the ingredients statement;

HH. **Liquid Iodine:**
The servings per container are not provided in the Supplement Facts panel.
The suspension liquid is not provided in the ingredients statement.
The established % DV for Iodine is not provided in the Supplement Facts panel;

II. **Insulin Support:**
The common or usual name does not adequately describe the product.
The dietary ingredients are not provided in the proper format in the Supplement Facts panel.
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel.
The %DV is not provided in the Supplement Facts panel for the dietary ingredients with established daily values.
Website indication is for diabetes;

JJ. **L-Glutamine 500 mg.:**
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

KK. **Biotin 15 mg Capsules with Horsetail**:
The components of the capsule are not provided in the ingredients statement.

The established %DV for Biotin is not provided in the Supplement Facts panel.
The dietary ingredients with established %DV's are not separated with a bar from the dietary ingredients that do not have established %DV;

LL. **Pregnenolone 30 mg.:**
The components of the hypoallergenic filler are not provided in the ingredients statement.
The term "pharmaceutical grade" may be false and misleading in that there are no pharmaceutical grade ingredients used for food.
The components of the capsule are not provided in the ingredients statement.
The directions for use do not coincide with the mg contained in the capsules;

MM. **Zinc Complex:**
The components of the capsule are not provided in the ingredients statement.
The weight of the zinc compounds is provided in the Supplement Facts panel rather that the weight of the elemental zinc.
The dietary ingredients with %DV's are not separated from those that do not;

NN. **Asparagine 500 mg.**:
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

OO. **Carnitine 500 mg.:**
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

PP. **I-Histidine 500 mg.**:
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

QQ. **Arginine 500 mg.**:
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

RR. **Bulk Ascorbate #8:**
No Supplement Facts panel is provided on product label;

SS. **Celtic Sea Salt:**
The product label does not contain the statement, "This salt does not supply iodine, a necessary nutrient."

C. SPECTRA PHARM, INC.

8.30 Defendant OSBORN operates SPECTRA PHARM as a retail establishment, which offers the following food and drug products: dietary supplements, SPECTRA PHARM's private label dietary supplements, homeopathic drugs, and over-the-counter drugs. SPECTRA PHARM maintains a retail store, adjacent to APOTHECURE's Dallas, Texas facility, where SPECTRA PHARM sells these products. Also, SPECTRA PHARM advertises and sells it products via its website, www.ruhealthy.com.

8.31 Coinciding with its inspection of APOTHECURE on May 17, 2007 and June 12, 2007, the Texas Department of State Health Services also inspected the SPECTRA PHARM facility. Further, the Department made investigative observations of SPECTRA PHARM's website during its investigations, and identified numerous unlawful conditions. Particularly, the Department found the following false advertising and/or misbranding violations, which generally relate to SPECTRA PHARM's unlawful and misleading labeling of dietary supplements:

A. **DHEA 25mg.**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
Health Benefits of DHEA
   a. Fights Osteoporosis
   b. Fights Auto-immune Diseases;

B. **Adrenal Cortex Support**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims for the product:
We have found this particular blend to be very effective in supporting adrenal dysfunction and chronic fatigue syndrome.
Adrenal dysfunction is one of the major underlying cause and/or result of most chronic illnesses.
Indicated for use with allergies;

C. **Adrenal Cortex Sublingual**: The website www.apothecure.com, www.ruhealthy.com and promotional literature had the following labeling claims:
"... helps in resistance to infections and stress of all types, increases blood

lymphocytes, and decreases serum gamma globulin content."
"Adrenal Cortex Extract has shown to be effective for hypoglycemia, inflammation, drug and alcohol withdrawal, stress management, trauma, allergies, and of course Addison's Disease."
"...indicated for stress, renal insufficiencies, inflammation, trauma, and toxic infections."
"Although it is illegal to sell ACE for injection use, it is perfectly legal to filter sublingual ACE with a 0.22 micron barrel filter, which renders it sterile."
Indicated for use with allergies.
In addition, the product is a sublingual delivery system bypassing the digestive tract;

D. **Complete Prostate Formula**: The pamphlet for this product had the following labeling claims:
"...most common problems are prostatisis, benign prostatic hyperplasia, and prostate cancer."
How can you prevent any of the above conditions? Taking the unique combination of supplements can help prevent inflammation and cancer (saw palmetto extract, red clover extract, nettle, pygeum extract, lycopene, pumpkin seed extract, beta sitosterol, zinc, and copper- all ingredients found in Complete Prostate Formula);

E. **Ascorbic Acid (Ascorbate) #8**: The pamphlet for this product had the following labeling claims:
"...such as healing of wounds and burns. It assists in the prevention of blood clotting and bruising..."
"...help reduce cholesterol levels, high blood pressure and preventing arteriosclerosis."
Indicated for use with allergies, colds, flu, and asthma;

F. **EDTA Calcium Disodium Magnesium**: The website www.apothecure.com, www.ruhealthy.com and promotional literature had the following labeling claims:
"...it removes plaque and returns the arterial system to a smooth, healthy, pre-atherosclerotic state."
A better metaphor might be "Liquid-Plumr®," because, where Roto-Rooter violently scrapes deposits off the interior surfaces of your plumbing with a rapidly rotating blade, Liquid-Plumr simply dissolves them away;

G. **Apothe Cure Nutritionals MSM Plus:**
Product label lacks Supplement Facts Panel
Product label lacks an approved FDA disclaimer statement
The components of the capsule are not provided in the ingredients statement
The product label lacks a proper serving size in that it uses the term

"recommended dosage." The term "recommended dosage" implies a therapeutic use for the product.
The statement that appears on the label "and all other medicines" appears to be false and misleading in that the product is being sold as a dietary supplement;

H. **Adrenal Cortex Support:**
The proper name for Pantothenic acid is not being used in that the term Vitamin B-5 is provided as a dietary ingredient in the Supplement Facts panel and is not a recognized synonym. In addition, the calcium source is declared in Supplement Facts panel as originating from B-5;

I. **DHEA 25 mg.:**
The common or usual name of the product does not accurately describe product in that the term is an abbreviation;

J. **MSN Metal Detox II:**
The common or usual name of the product does not accurately describe product in that the term is an abbreviation. The word "Detox" is an unapproved drug claim.
The Supplement Facts panel does not state serving size of the product.
The Supplement Facts panel does not state the servings per container.
The product ingredients are not listed in the Supplement Facts panel in the correct format in that the ingredients without %DV's are listed with the ingredients that have established %DV's.
The warnings, uses, and directions act as intervening material between the dietary ingredients and other ingredients in the Supplement Facts panel.
The term "active ingredients" appears to be false and misleading in that the product is being sold as a dietary supplement.
The label fails to identify the ingredients that do not have a %DV established.
The components of the capsule are not provided in the ingredient statement;

K. **Trace Mineral #1 with Iron:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K;

L. **Trace Mineral #1:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K;

M. **Trace Mineral # 2 with Iron:**
The common or usual name of the product does not adequately describe the product.

The %DV of Manganese contained in the product does not coincide with the amount per serving provided in Supplement Facts Panel;

N. **Trace Mineral # 2 Iron Free:**
The common or usual name of the product does not adequately describe the product;

O. **Electrolyte #1:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K;

P. **Electrolyte #2:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K.
The dietary ingredients are not listed in the Supplement Facts panel in the proper order.
The weight of the compound, Potassium Phosphate, is provided in the Supplement Facts panel rather than the weight of the elemental Potassium;

Q. **Electrolyte #3:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K.
The dietary ingredients are not listed in the Supplement Facts panel in the proper order.
The weight of the compounds, Sodium Carbonate, Potassium Chloride, Potassium Iodate, and Potassium Phosphate, are misleading in that the weight of the entire compound is listed in the Supplement Facts panel rather than the individual weight of the Sodium and Potassium;

R. **Apothe Cal Calcium Supplement with Boron:**
The components of the capsule are not provided in the ingredients statement.
The common or usual name does not accurately describe the product.
Calcium is not declared properly in the Supplement Facts panel;

S. **Ascorbate #8:**
The components of the capsule are not provided in the ingredients statement.
The common or usual name does not accurately describe the product.
Dietary ingredients are not declared properly in the Supplement Facts panel.
The order of predominance of the ingredients statement on bulk (12 Bottles-200 capsules each) Ascorbate #8 does not match the order of predominance provided

in the Supplement Facts panel; and

T. **EDTA** (calcium powder) **with Magnesium Malate** (Repeat violation from 10/13/04 & 1/25/06 DSHS Inspection of Spectrapharm)
The common or usual name of product does not adequately describe the product in that the proper nomenclature for EDTA is not provided.
The Supplement Facts panel provides an incorrect %DV for Magnesium.
The Magnesium is not declared properly in the Supplement Facts panel.
The components of the capsule are not declared in the ingredients statement.

D. Referral

8.32 Based upon its investigations of Defendant OSBORN's companies APOTHECURE and SPECTRA PHARM, the Department identified numerous violations of the TFDCA, which posed a threat to the public health and safety. As a result, the Department referred Defendants APOTHECURE, SPECTRA PHARM, and OSBORN to the Texas Attorney General requesting that his office seek appropriate remedies.

9. VIOLATIONS OF THE TEXAS FOOD, DRUG AND COSMETIC ACT

9.1 Based on the findings in paragraphs 8.1 through 8.32, Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, have manufactured and/or introduced into commerce adulterated drugs, misbranded drugs, and/or unapproved new drugs; introduced misbranded food products (i.e., dietary supplements) into commerce; and falsely represented that these unapproved new drugs and misbranded foods are intended to cure, mitigate, treat, or prevent human diseases.

A. <u>Unapproved New Drugs</u>

9.2 Defendant APOTHECURE is a drug manufacturer and Defendant OSBORN is the pharmacist-in-charge of APOTHECURE and owns, directs, and participates in the manufacture of drugs. Many of the products Defendants manufacture constitute drugs, as defined

in §431.002(14) of the TFDCA, because these products are intended to cure, mitigate, treat, or prevent disease in man. Several of the drugs Defendants manufacture are additionally "new drugs" because their compositions are not generally recognized among experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.[7] *See* TEX. HEALTH & SAFETY CODE §431.002(25). Moreover, these new drugs are not approved for sale by the FDA.

9.3 Paragraphs 8.1 through8.32 generally, and specifically paragraphs 8.20 through 8.21 and 8.28 identify unapproved new drugs manufactured by Defendants as drugs.

9.4 Another example of Defendants' manufacture of drugs involves its manufacture of products labeled as dietary supplements. Dietary supplements are foods as defined in §431.002(16) of the TFDCA, but Defendants APOTHECURE, SPECTRA PHARM, and OSBORN advertise and promote these products to cure, mitigate, treat, or prevent human diseases. These products are drugs as defined in §431.002(14) of the TFDCA based upon these claims. Moreover, these drugs are also new drugs as defined in §431.002(25) of the TFDCA because they are not recognized in the official United States Pharmacopoeia National Formulary and are neither approved by the FDA, nor generally recognized among experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

9.5 Defendants APOTHECURE, SPECTRA PHARM, and OSBORN manufacture and sell numerous unapproved new drugs through Defendants' websites www.ApotheCure.com

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[7]TDSHS is unaware of any evidence that establishes that these drugs are generally recognized as safe and effective for their intended uses.

and www.ruhealthy.com and in their retail store. To that end, Defendants' websites and promotional literature make the following claims for the product Adrenal Cortex Sublingual:

> "Adrenal Cortex Extract has shown to be effective for hypoglycemia, inflammation, drug and alcohol withdrawal, stress management, trauma, allergies, and of course Addison's Disease."
>
> "...indicated for stress, renal insufficiencies, inflammation, trauma, and toxic infections."

These claims that Adrenal Cortex Sublingual is intended to cure, mitigate, treat, or prevent human diseases made these products drugs. Further, these supplements are "new drugs" as they are not generally recognized as safe and effective for such intended uses, and the FDA has not approved such products as drugs. Defendants' products labeled as dietary supplements and identified in paragraphs 8.1 through 8.32 above that are promoted to cure, mitigate, treat, or prevent human diseases are also drugs and unapproved new drugs in violation of state and federal laws.

9.6 Defendants APOTHECURE, SPECTRA PHARM, and OSBORN also manufacture and/or sell unapproved new drugs, which they improperly market as over-the-counter drugs. Over-the-counter ("OTC") drugs are drugs that are available to consumers without a prescription. Federal monographs specify the active ingredients that can be contained within OTC drug products. Only OTC drug products containing ingredients that comply with standards established in an applicable monograph are considered to be "generally recognized as safe and effective" ("GRASE") and do not require specific FDA approval before marketing.

9.7 Alternatively, OTC drug products with active ingredients, dosage forms, dosage strengths, or routes of administration new to the OTC marketplace are regulated under the new

drug application ("NDA") process. Under the NDA process, legal marketing is under the authority of an approved product-specific new drug application. The FDA must approve the NDA for an OTC drug product before that product can be marketed OTC. In order to be approved, a drug manufacturer must submit data in an NDA demonstrating that the drug product is safe and effective for use by consumers without the assistance of a healthcare professional. The drug manufacturer can only market the product with the specific formulation and exact labeling approved by the FDA. To make a change, the manufacturer must submit an NDA supplement and the FDA must approve that supplement.[8]

9.8 Despite these laws regulating the sale of OTC drug products, Defendants APOTHECURE, SPECTRA PHARM, and OSBORN continue to illegally market unapproved OTC drugs. For example, APOTHECURE and SPECTRA PHARM market an OTC product called "Relieve Blue Pain Gel," which does not comply with the over-the-counter federal monograph for topical analgesics and does not have an FDA approved product-specific new drug application. Particularly, the active drug ingredients in Defendants' OTC drug Relieve Blue Pain Gel (i.e., MSM, Aloe Vera and Emu Oil) are not approved for the indicated uses advertised, such as: pain relief, arthritis, reducing joint degeneration and inflammation of tissue. Nevertheless, the following claims were found on the website www.ApotheCure.com and www.ruhealthy.com regarding the product Relieve Blue Pain gel:

> "...for just about any persistent or chronic pain."
>
> "...MSM...highly useful in targeting certain types of arthritis pain and stiffness..."

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[8] *See* http://www.fda.gov/cder/Offices/OTC/reg_mechanisms.htm.

Because Defendants make such drug claims and do not have an FDA approved NDA, they are illegally marketing an unapproved OTC drug product. The same can be said for other OTC drug products described in paragraphs 8.1 through 8.24 above.

9.9 Section 431.114(a)(1) of the TFDCA provides that a person shall not sell, deliver, offer for sale, hold for sale or give away any new drug without an FDA approved new drug application. Further, the introduction or delivery for introduction into commerce of any article that violates § 431.114 of the TFDCA is prohibited under § 431.021(e) of the TFDCA.

B. Adulterated Drugs

9.10 Defendants APOTHECURE and OSBORN manufactured adulterated drugs and then introduced those products into commerce as described in paragraphs 8.1 through 8.32 above. This adulteration occurred in the following ways:

A. The manufacture and selling of super and sub-potent drugs, including 70 vials from a batch of intravenous Colchicine (Apothecure lot number 20070122@26) that was more potent that their labels indicated (a potency of 4 milligrams per milliliter, rather than the 0.5 milligrams per milliliter stated on labels); and

B. The manufacture and selling of a Colchicine drug product labeled as having a potency of 1 milligram per 2 milliliter (Apothecure lot number 20061214@28), which was tested and found to have an actual strength of 0.38mg Colchicine per milliliter.

Section 431.111(d) of the TFDCA provides that a drug is deemed to be adulterated if its strength differs from, or its purity or quality falls below, that which it purports to be or is represented to possess. Therefore, APOTHECURE and OSBORN's super and sub-potent lots of a prescription

drug were adulterated because their strengths differed from that which they purported to possess.

9.11 Defendants also adulterated numerous drug products through the use of deficient manufacturing processes, including those identified in paragraphs 8.24 through 8.26 above. For example, during its inspection of APOTHECURE's facility, the Department's representatives determined that APOTHECURE failed to adequately test, approve, or reject prescription drug components. Further, they found that APOTHECURE failed to document the weight and measure of actual prescription drug components during manufacture. Moreover, the Department's representatives also determined that APOTHECURE manufactured injectable versions of prescription drugs with USP Sterile Water for Irrigation, instead of USP Sterile Water for Injection. USP Water for Irrigation is primarily indicated for use as an irrigating fluid, and the label for such water bears the following warning: "**Contradindications: Not for injection.**" Nevertheless, APOTHECURE manufactured injectable drugs with USP Sterile Water for Irrigation. Further, APOTHECURE lacked any validation data demonstrating that the use of USP Sterile Water for Irrigation is an appropriate component in sterile, injectable drug products. These manufacturing practices fail to comply with the federal regulations that prescribe the current good manufacturing practices for pharmaceuticals. *See* 21C.F.R.§§ 211.84, 211.113(b), 211.188(b)(4).[9] Section 431.111(a)(2)(B) of the TFDCA provides that a drug is

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[9]Section 211.84 of the good manufacturing practices provides: "[e]ach lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit." 21 C.F.R. § 211.84(a)

Section 211.113(b) of the good manufacturing practices provides: "[a]ppropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of any sterilization process." 21 C.F.R. § 211.113(b)

deemed adulterated if the methods used in its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practice. *See* TEX HEALTH & SAFETY CODE §431.111(a)(2)(B). Thus, Defendants are adulterating drug products through their failure to adhere to current good manufacturing practices. Defendants other deficient manufacturing practices are described in paragraphs 8.1 through 8.32 above and further elaborate the extent of Defendants' adulteration of drug products.

9.12 The TFDCA prohibits the adulteration of drugs pursuant to § 431.021(b) of the TFDCA. Further, the TFDCA prohibits the introduction into commerce (or delivery for introduction into commerce, or causing the introduction or delivery for introduction into commerce), within the State of Texas, of any adulterated drug. *Id.* at § 431.021(a). Nevertheless, Defendants' sold adulterated drug products in Texas, and thereby introduced them into commerce. Particularly, Defendants sold drugs that are adulterated because they are more or less potent than Defendants represent them to be and/or they are manufactured in a manner that does not comply with current good manufacturing practices. Since Defendants manufactured drugs that are adulterated under Texas law and introduced them into commerce, Defendants violated §§ 431.021(a), (b), and (h) of the TFDCA.

C. <u>Misbranded Drugs</u>

9.13 Defendants APOTHECURE, SPECTRA PHARM, and OSBORN manufacture

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Section 211.188 of the good manufacturing practices provides: "Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include: (b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including: (4) Weights and measures of components used in the course of processing." 21 C.F.R. § 211.188(b)(4)

misbranded drug products and introduce those products into commerce. This misbranding occurred in numerous ways as identified in paragraphs 8.1 through 8.32 above. APOTHECURE and OSBORN manufactured and misbranded the prescription drug Colchicine when the label did not accurately reflect the ingredients in the product, pursuant to § 431.112 of the TFDCA.

9.14 SPECTRA PHARM and OSBORN's labeling and packaging of OTC drugs without accurate information on the label misbrands these drugs. The TFDCA provides that a drug shall be deemed to be misbranded if information required to appear on the label or labeling is not prominently placed thereon. *See* TEX HEALTH & SAFETY CODE § 431.112(c). For example, all OTC drugs are required to provide a drug facts panel on their labeling pursuant to 21 CFR § 201.66; 25 TAC §§ 229.242, 229.251(a) and (g). Defendants manufacture and/or market and sell the following two OTC drugs: SDA 1600 Alcohol Gel and SDA 1600 Mouthwash with Xylitol. Nevertheless, the labeling for these drugs omits the requisite fact panels. These specific drugs are mislabeled, in addition to the other OTC drugs as indicated in paragraphs 8.1 through 8.32 above.

9.15 Defendants' drugs are also misbranded, under the terms of the TFDCA, because their labeling fails to provide adequate directions regarding the uses for which these drugs are intended and are being promoted in Texas. The TFDCA provides that a drug is deemed to be misbranded if its labeling fails to provide adequate directions for use, unless the drug has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services. *See* TEX. HEALTH & SAFETY CODE § 431.112(e)(1).

9.16 Per federal regulation, "adequate directions for use" means "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 CFR

§ 201.5. The drugs promoted and sold by Defendants fail to provide adequate directions for their intended use, because adequate directions cannot be written providing for the use of an unapproved drug by a layperson. Therefore, all unapproved drugs found by TDSHS in paragraphs 8.1 through 8.32 are misbranded under the terms of § 431.112(e)(1) of the TFDCA.

9.17 The TFDCA prohibits the manufacturing of misbranded drugs and the introduction into commerce (or delivery for introduction into commerce, or causing the introduction or delivery for introduction into commerce), within the State of Texas, of any misbranded drug, including Defendants' unapproved new drugs and drug products with labels and/or labeling that do not conform with state and federal standards. TEX. HEALTH & SAFETY CODE §§ 431.021(a) and (h). Since Defendants' drugs are misbranded under Texas law, Defendants are in violation of §§ 431.021(a) and/or (h) of the TFDCA as indicated in paragraphs 8.1 through 8.32 above.

D. Misbranded Foods

9.18 Defendants manufacture, advertise, offer for sale, and sell dietary supplements, which the TFDCA defines as "food" in § 431.002(16) of the TFDCA. The TFDCA further provides that food shall be deemed to be misbranded if: (1) the food's labeling is false or misleading in any particular; (2) fails to prominently display information and statements required by regulations in such a manner to render it likely to be read and understood by the ordinary individual under customary conditions; or (3) the food labels do not bear the common or usual name of the foods and/or ingredients. *See* TEX. HEALTH & SAFETY CODE § 431.082(a), (f), (g), and (j).

9.19 Therefore, Defendants' foods, including the products it markets as dietary

supplements, are misbranded under the terms of the TFDCA based upon the disease claims made for these food products and by virtue of labeling or advertising that is misleading or otherwise inadequate. For example, Defendants' websites make the following disease/drug labeling claim for their "nutritional supplement," Chromium Polynicotinate: "For many with diabetes, chromium enhances the ability of insulin to lower serum glucose levels." Additionally, labeling for several of Defendants' dietary supplements, including "Electrolyte #1," do not provide consumers with the common name of the food or their ingredient that adequately describe the product. Another example of misbranding is the product label for Celtic Sea Salt which does not contain the requisite statement, "[t]his salt does not supply iodine, a necessary nutrient."

9.20 Thus, Defendants' foods, as indicated in paragraphs 8.1 through 8.32 above, are deemed misbranded because their labeling: (1) is false or misleading; (2) fails to bear the common or ususal names of the foods and their underlying ingredients; and/or (3) fails to prominently display information and statements required by regulations in such a manner to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

9.21 The TFDCA prohibits the misbranding of foods in commerce pursuant to § 431.021(b) of the TFDCA and the introduction into commerce (or the delivery for introduction into commerce or causing the introduction or delivery for introduction into commerce) within the State of Texas of any misbranded food, such as Defendants' dietary supplements with labels and/or labeling that make drug/disease claims and/or otherwise do not conform with state and federal standards. *Id.* at § 431.021(a). The TFDCA prohibits the manufacture of misbranded food pursuant to §431.021(h) of the TFDCA. Since Defendants' foods are misbranded under

Texas law, Defendants are violating §§ 431.021(a) and/or (b) and (h) of the TFDCA as indicated in paragraphs 8.1 through 8.32 above.

E. False Advertisement

9.22 Based on the conduct alleged above, including paragraphs 8.1 through 8.32 and 9.1 through 9.22 above, Defendants APOTHECURE, SPECTRA PHARM, and OSBORN have falsely advertised their drugs and foods, and thereby violated § 431.021(f) of the TFDCA. Particularly, Defendants have engaged in false advertisement through their promotion of unapproved new drugs, adulterated and misbranded drugs, and misbranded food.

9.23 Defendants' Internet websites, labeling, and promotional materials constitute advertising within the definition set out in § 431.002(1) of the TFDCA[10] because they contain representations disseminated for the purpose of inducing consumers to purchase Defendant's drugs or foods.

9.24 Defendants' promotion of unapproved new drugs is false within the meaning of § 431.182 of the TFDCA because it is misleading in numerous particulars as set out above. For instance, Defendants' advertisements for unapproved new drugs are false because the FDA has not approved these drugs, and they are therefore illegal to market. Additionally, any such advertisement by Defendants for unapproved new drugs is false because it is directed toward the public and is not consistent with labeling claims permitted by the FDA in § 431.183 of the TFDCA.

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[10] "Advertising" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics. TEX. HEALTH & SAFETY CODE § 431.002(1)

9.25 Defendants' advertising of foods (i.e., dietary supplements) is also false within the meaning of § 431.182 of the TFDCA because it is misleading in numerous particulars, as set out above. For instance, Defendants advertisements of several dietary supplements are false because they make disease claims that cannot be made for foods, and it is illegal to market these foods with such claims.

9.26 The TFDCA prohibits the dissemination of any false advertisements. TEX HEALTH & SAFETY CODE § 431.021(f). Defendants have engaged in false advertisement through their promotion of unapproved new drugs, adulterated and misbranded drugs, and misbranded food. Therefore, Defendants have violated § 431.021(f) of the TFDCA.

F. Fair Packaging and Labeling

9.27 Several food products and dietary supplements held, stored, transported, packed and/or re-packed by the Defendants SPECTRA PHARM and OSBORN are consumer commodities that fail to conform to the TFDCA's Fair Packaging and Labeling requirements set out in § 431.181 of the TFDCA because, as alleged above, they have labels on product packages that do not bear the common or usual name of the consumer commodity.

10. PROHIBITED ACTS UNDER THE TEXAS FOOD, DRUG AND COSMETIC ACT

10.1 Based on the conduct alleged above in paragraphs 8.1 through 8.32 and 9.1 through 9.27 above, Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, have committed or caused to be committed the following acts prohibited and declared to be unlawful by the TFDCA:

A. Introducing or delivering for introduction into commerce adulterated drugs in violation of § 431.021(a) of the TFDCA;

B. Introducing or delivering for introduction into commerce misbranded drugs in violation of § 431.021(a) of the TFDCA;

C. Introducing or delivering for introduction into commerce misbranded foods in violation of § 431.021(a) of the TFDCA;

D. Misbranding drugs in commerce in violation § 431.021(b) of the TFDCA;

E. Misbranding foods in commerce in violation § 431.021(b) of the TFDCA;

F. Disseminating false advertisements in violation § 431.021(f) of the TFDCA;

G. Failing to package drug products in tamper resistant packaging pursuant to 25 T.A.C. § 229.251(c) and 21 C.F.R. § 211.132 and manufacturing adulterated drugs, in violation of § 431.021(h) of the TFDCA;

H. Manufacturing within this state drugs that are adulterated in violation of § 431.021(h) of the TFDCA;

I. Manufacturing within this state drugs that are misbranded in violation of § 431.021(h) of the TFDCA;

J. Manufacturing within this state foods that are misbranded in violation of § 431.021(h) of the TFDCA;

K. Introducing an unapproved new drug into commerce in violation of § 431.021(e) of the TFDCA;

L. Selling, distributing or transferring a prescription drug to a person who is not authorized under state law to receive the prescription drug in violation of § 431.021(ee) of the TFDCA; and

M. Refusing to permit access to or copying of any record as authorized by §§ 431.042 through 431.044 of the TFDCA, including records associated with the manufacture or prescription drugs in violation of § 431.021(g) of the TFDCA.

11. VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT

11.1 Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, as alleged above in paragraphs 8.1 through 8.32 and 9.1 through 9.27 above, have in the course of trade and commerce engaged in false, misleading and deceptive

acts and practices declared unlawful in § 17.46(a) of the DTPA. Additionally, Defendants have violated § 17.46(b) of the DTPA as follows:

A. Causing confusion or misunderstanding as to the approval of the drugs manufactured, advertised, or sold by Defendants, in violation of § 17.46(b)(2) of the DTPA;

B. Causing confusion or misunderstanding as to the approval of the foods manufactured, advertised, or sold by Defendants, in violation of § 17.46(b)(2) of the DTPA;

C. Representing that Defendants' drugs have benefits which they do not have, in violation of § 17.46(b)(5) of the DTPA;

D. Representing that Defendants' foods have benefits which they do not have, in violation of § 17.46(b)(5) of the DTPA;

E. Representing that Defendant APOTHECURE has the status of a compounding pharmacy, when it is acting beyond the scope of the practice of pharmacy, in violation of § 17.46(b)(5) of the DTPA;

F. Representing that Defendant APOTHECURE has the approval of various state agencies and boards, which it does not, in violation of § 17.46(b)(5) of the DTPA;

G. Representing that Defendants' drugs are of a particular standard, quality, or grade, if they are of another, in violation of § 17.46(b)(7) of the DTPA;

H. Representing that Defendants' foods are of a particular standard, quality, or grade, if they are of another, in violation of § 17.46(b)(7) of the DTPA;

I. Failing to disclose that Defendants' dietary supplements advertised and labeled to cure, prevent, treat, or mitigate diseases have not been approved by the FDA as drugs, when the failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of § 17.46(b)(24) of the DTPA;

J. Failing to disclose that Defendants' foods and drugs are misbranded and therefore may not be introduced into commerce, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of § 17.46(b)(24) of the DTPA; and

K. Failing to disclose that Defendants' drugs are adulterated and therefore may not be introduced into commerce, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of §17.46(b)(24) of the DTPA.

12. INJURY TO CONSUMERS

12.1 By means of the foregoing unlawful acts and practices, Defendants have acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

13. TEMPORARY AND PERMANENT INJUNCTION

13.1 The State alleges that by reason of the foregoing, Defendants should not continue to operate as food and drug manufacturing establishments, advertise, or sell their products in violation of the laws of Texas. The interests of the State of Texas require a temporary and permanent injunction to prohibit Defendants from continuing to unlawfully operate food and drug manufacturing establishments and to advertise and sell its products, unless and until their food and drug manufacturing establishments are determined upon inspection by TDSHS to be free of violations of the TFDCA. The interests of the State of Texas also require a temporary and permanent injunction to prohibit Defendants from advertising and selling their products, unless Defendants are in compliance with the DTPA and the TFDCA.

13.2 Unless injunctive relief is granted, Defendants will continue to violate the laws of the State of Texas to irreparable injury of the State of Texas and to the general public.

14. PRAYER

14.1 WHEREFORE, Plaintiff prays that Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, be cited according to law to

appear and answer herein; that after due notice and upon a hearing a TEMPORARY INJUNCTION be issued; and that after due notice and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, their successors, assigns, officers, agents, servants, employees, and any other person in active concert or participation with Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, from engaging in the following acts or practices:

A. Manufacturing an adulterated or misbranded drug in Texas;

B. Manufacturing any drug in Texas without a new drug application having been submitted to and approved by the FDA for each drug manufactured;

C. Selling, delivering, advertising, offering for sale, holding for sale, or giving away any drug in Texas unless the drug has been approved by the FDA;

D. Introducing into commerce a misbranded drug by manufacturing, advertising, offering to sell, and selling a drug that has not been approved by the FDA;

E. Falsely advertising or falsely representing that a drug or dietary supplement is effective for treating diseases of the body, when the FDA has not approved these drugs;

F. Producing, preparing, packing, repacking, or holding drugs under unsanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered diseased, unwholesome, or injurious to health;

G. Introducing into commerce an adulterated drug that has been produced, prepared, packed, repacked, or held under unsanitary conditions;

H. Representing that Defendants' drugs have benefits which they do not have;

I. Causing confusion or misunderstanding as to the approval of drugs manufactured and/or sold by Defendants;

J. Causing confusion or misunderstanding as to the approval of dietary supplements manufactured and sold by Defendants;

K. Representing that Defendants' dietary supplements have benefits which they do not have;

L. Representing that Defendants' dietary supplements have any benefits or characteristics unless Defendants have in their possession at the time such representation is made scientific substantiation for such representation and the representation does not make the product a drug;

M. Representing that Defendants' dietary supplements are drugs and have benefits which they do not have;

N. Representing that Defendants' drugs and dietary supplements are of a particular standard, quality, or grade, if they are of another;

O. Representing that Defendants' dietary supplements are drugs that are of a particular standard, quality, or grade, if they are of another;

P. Failing to disclose that Defendants' dietary supplements are not approved by the FDA to cure, treat, mitigate, or prevent disease;

Q. Failing to disclose that the FDA has not determined that Defendants' drugs and dietary supplements are safe and effective to cure, treat, mitigate, or prevent disease and that such claims are illegal to make for dietary supplements;

R. Introducing into commerce or causing the introduction into commerce of a new drug not approved by the FDA;

S. Advertising or causing the advertising of new drugs the FDA has not approved as safe and effective;

T. Introducing into commerce or causing the introduction into commerce a misbranded drug;

U. Misbranding or causing the misbranding of a drug in commerce;

V. Falsely advertising or causing the false advertising of drugs in Texas;

W. Manufacturing, within this state, food that is misbranded;

X. Distributing in commerce or causing the distribution into commerce of a consumer commodity that has a label that does not conform to state law;

Y. Introducing into commerce or causing the introduction into commerce a food that is misbranded;

Z. Misbranding or causing the misbranding of a food in commerce;

AA. Falsely advertising or causing the false advertising of foods in Texas;

BB. Introducing into commerce or causing the introduction into commerce an adulterated drug;

CC. Adulterating or causing the adulteration of a drug in commerce;

DD. Manufacturing, within this state, drugs that are adulterated by failing to adhere to good manufacturing practices;

EE. Distributing in commerce a consumer commodity that has a label which does not conform to the provisions of the TFDCA and of rules adopted under the authority thereunder;

FF. Failing to produce distribution records requested by the Texas Department of State Health Services;

GG. Failing to develop and implement a plan for monitoring and regulating Defendants' websites and all advertising and promotional materials for foods, including dietary supplements, to insure that claims to treat, cure, mitigate, or prevent diseases and serious illnesses are not included;

HH. Representing that APOTHECURE is a compounding pharmacy when it is acting beyond the scope of the practice of pharmacy;

II. Selling, distributing or transferring a prescription drug to a person who is not authorized under Texas law to receive the prescription drug;

JJ. Failing to package drug products in tamper-resistant packaging;

KK. Refusing to permit access to or copying of any record as authorized by TFDCA §§ 431.042 through 431.044, including records associated with the manufacture of prescription drugs;

LL. Failing to maintain laboratory records which assure compliance with established drug specifications and standards;

MM. Failing to maintain written procedures for the calibration of food and drug

manufacturing equipment;

NN. Failing to maintain documentation of validation of cleaning procedures for facilities, utensils, equipment used in food and drug manufacturing;

OO. Failing to adequately test, approve or reject prescription drug components during drug manufacturing;

PP. Failing to adequately document the weight and measure of prescription drug components during manufacture;

QQ. Failing to adequately document each batch of a prescription drug component (i.e., no lot number identification);

RR. Failing to test each batch of drug product, whether injectables, capsules, creams, or any other product, to verify the product quality specifications such as potency and identity;

SS. Failing to adequately document in-process and laboratory control results, including a description of the specific equipment, mixing instructions, sampling and testing procedures, and specifications of components used in drug manufacturing;

TT. Failing to maintain sterilization procedures designed to prevent microbiological contamination of drug products; and

UU. Failing to validate the sterilization process for prescription drugs manufactured by any Defendants.

14.2 Plaintiff further prays that this court upon final hearing order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to pay civil penalties in favor of the STATE OF TEXAS in the amount of $25,000.00 per day per violation of § 431.021 of the TFDCA pursuant to § 431.0585 of the TFDCA.

14.3 Plaintiff further prays that this court, upon final hearing, order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to destroy all products that were manufactured, adulterated, or misbranded in violation of § 431.021

of the TFDCA pursuant to of § 431.051 of the TFDCA .

14.4 Plaintiff further prays that, upon final hearing, this Court will order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to pay civil penalties in favor of the STATE OF TEXAS in the amount of $20,000.00 per violation of the DTPA pursuant to of § 17.47(c)(1) of the DTPA.

14.5 Plaintiff further prays that upon final hearing that his Court order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to restore all money or other property taken from persons by means of unlawful acts or practices, or, in the alternative, award judgment for damages to compensate for such losses pursuant to § 17.47(d) of the DTPA.

14.6 Plaintiff further prays that upon final hearing that this Court order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to pay to the STATE OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE § 402.006(c) (Vernon 2005, Supp. 2007).

14.7 Plaintiff further prays that upon final hearing that this court order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to pay to the Office of the Attorney General and to the Texas Commissioner of Health their reasonable expenses incurred in obtaining injunctive relief under § 431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees, witness fees, and deposition expenses pursuant to § 431.047(d) of the TFDCA.

14.8 Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may show itself entitled.

Respectfully submitted,

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