

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
	§	
Plaintiff	§	
	§	
VS.	§	
	§	
INTERNATIONAL ASSOCIATION FOR	§	
COLON HYDROTHERAPY, CLASS 3	§	
STUDY GROUP, and AUGUSTINE R.	§	DALLAS COUNTY, T E X A S
HOENNINGER, III, individually,	§	
	§	
Defendants.	§	____ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, the STATE OF TEXAS, plaintiff, acting by and through Attorney General GREG ABBOTT, filing Plaintiff’s Original Petition complaining of and against Defendants INTERNATIONAL ASSOCIATION FOR COLON HYDROTHERAPY (“IACT”), CLASS 3 STUDY GROUP (“C3SG”), and AUGUSTINE R. HOENNINGER, III, individually, (“Defendants”), based on their false advertising and misrepresentations regarding the use of prescription colon irrigation systems, including rectal nozzles, and the legality of their investigational study and would respectfully show the court the following:

JURISDICTION

1. This suit is brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the STATE OF TEXAS and in the public interest under the authority granted to him by §431.047 (b) of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH AND SAFETY CODE ANN. (“TFDCA”) and any regulations promulgated pursuant to this law, upon the grounds that the Commissioner of Health of the State of Texas and his authorized agents find that Defendants have violated and have threatened to violate provisions of §431.021 of the TFDCA.

2. This suit is also brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the State of Texas under the authority granted to him by §17.47 of the Texas Deceptive Trade Practices Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.*, (“DTPA”) upon the grounds that Defendants have engaged in false, misleading and deceptive acts and practices in the conduct of trade or commerce as defined and declared unlawful by §17.46 (a) and (b) of the DTPA.

PARTY DEFENDANTS

3. Defendant AUGUSTINE R. HOENNINGER, III, is an individual who directs Defendants IACT and C3SG, at 11103 San Pedro, Suite 117, San Antonio, Texas 78216. Defendant AUGUSTINE R. HOENNINGER, III, may be served with process by serving him at his business address.

4. Defendant IACT may be served with process through serving its registered agent, Defendant A. R. HOENNINGER, its Executive Director, at 11103 San Pedro, Suite 117, San Antonio, Texas 78216.

5. Defendant C3SG may be served with process through serving its registered agent, Defendant A. R. HOENNINGER, its Executive Director, at 11103 San Pedro, Suite 117, San Antonio, Texas 78216.

VENUE

6. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA and §431.047 (c) and §431.0585(d) of the TFDCA by virtue of the fact that Defendants engaged in the business of advertising and promoting colon hydrotherapy without practitioner involvement using prescription colon irrigation systems, including rectal nozzles¹; in the training

¹In this petition, the phrase “prescription colon irrigation system” includes all parts of the system required to provide colon cleansing, including rectal nozzles, as the nozzles are accessories of the system and cannot be used separately from the system.

of individuals to administer these prescription colon irrigation systems; promoting the use of prescription irrigation systems for unapproved uses; and in promoting and conducting an investigational study not approved by the Federal Food and Drug Administration (“FDA”) to individuals and businesses in Dallas County, Texas, specifically to Eternal Health, Inc., and Cynthia Pitre and to Jennifer Jackson d/b/a Body Cleanse Spa.

PUBLIC INTEREST

7. By reason of the institution and operation of the unlawful practices set forth herein, Defendants have 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 enterprise which conducts its 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.

TRADE AND COMMERCE

8. Defendants are engaged in trade and commerce, as that term is defined by §17.45(6) of the DTPA, in that they were engaged in the business of advertising and promoting individuals and businesses to use prescription colon irrigation systems without a practitioner; to use the prescription devices for uses not approved by FDA; to purchase their training services on how to use these prescription devices, and to participate in their investigation study not approved by FDA, throughout the United States, other countries, and specifically in Texas and Dallas County.

NOTICE BEFORE SUIT

9. Pursuant to §17.47(a) of the Deceptive Trade Practices Act, contact has been made with Defendants to inform them of the unlawful conduct alleged herein, by letter mailed by certified mail, return receipt requested.

ACTS OF AGENTS

10. Whenever in this petition it is alleged that Defendants 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 the officers, agents or employees of said Defendants, and in each instance, the officers, agents or employees of said Defendants that were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of the Defendants.

OVERVIEW OF DEFENDANTS' OPERATION

11. Defendants advertised and solicited individuals and businesses to participate in a bogus investigational study not approved by FDA and falsely represent and advertise in publications and in training services that prescription colon irrigation systems can be used without practitioner involvement and for uses not approved by FDA at 11103 San Pedro, Suite 117, San Antonio, Texas 78216.

12. Defendants advertise, train, and promote the use of colon irrigation systems that FDA has only cleared for a Class II intended use, as defined in 21 CFR 876.5210, for colon cleansing when medically indicated, such as before radiological or endoscopic examinations. Based upon this intended use, FDA has limited the use of all colon irrigation systems cleared for marketing to prescription use only. Therefore, all colon irrigation systems cleared for marketing by FDA are required to bear the statement on their labels that "Federal Law restricts this device to sale by or on the order of a _____", the blank to be filled in with the word 'physician, dentist, veterinarian, or with the description designation of any other practitioner licensed by the law of the State in which he practices to use and order the use of the device.'²

²Under Texas law, the only practitioner licensed to use prescription colon irrigation systems on humans are those licensed by the Texas Board of Medical Examiners. Therefore, in this petition, when the term "practitioner" is used, it refers only to those persons licensed by the Texas Board of Medical Examiners.

13. Defendants advertising, promoting, and training involving any use of prescription colon irrigation systems without practitioner involvement misbrands and/or adulterates or causes misbranding and/or adulteration of these devices in violation of the TFDCA. Defendants advertising and representations for use of colon irrigation systems for uses not approved by FDA also misbrands and/or adulterates or causes misbranding and/or adulteration of these devices in violation of the TFDCA.

14. Defendants advertising and representations regarding use of colon irrigation systems without practitioner involvement or for uses not approved by FDA constitutes false advertising in violation of both the TFDCA and the DTPA.

15. Defendants advertising, promoting, and conducting of an investigational study to change the intended use of colon irrigation systems to include other uses, including general well-being, from only clearance for colon cleansing when medically indicated under the supervision and order of a practitioner, such as before radiological or endoscopic examinations also violates the TFDCA by misbranding and/or adulterating or causes misbranding and/or adulteration of colon irrigation systems.

16. Defendants falsely advertised, represented, and promoted their association publications, training, and investigational study participation to use prescription colon irrigation systems in violation of state law to consumers in the United States, Texas, and in Dallas County, Texas, specifically to Eternal Health, Inc., and Cynthia Pitre and to Jennifer Jackson d/b/a Body Cleanse Spa.

FDA Sends Defendants Warning Letter for Violating Federal Law

17. Defendants were sent a Warning Letter from the FDA on March 21, 2003, notifying them that they were violating federal law by conducting an investigation involving a significant risk device without an Investigational Device Exemption approved by FDA in

violation of 21 CFR812.20 (a); by conducting an investigation without an Institutional Review Board in violation of 21 CFR812.42; and without the informed consent of any subjects because no such form had been developed as required by 21 CFR 812.100 and Part 501.

18. Defendants were also found by FDA to violate federal law by failing to obtain signed agreements from the participating colon hydrotherapists in violation of 21 CFR 812.43(c); failing to have written monitoring procedures as part of the investigational plan in violation of 21 CFR 812.25(e); and failing to maintain device accountability records in violation of 21 CFR 812.140(b)(2).

19. Based on FDA's Warning Letter, Defendants also violated state law by failing to comply with any requirement required by 520(g) of the Federal Act by furnishing any notification or information regarding any investigational device exemption in which Defendant is involved, in violation of § 431.021(t) (1)(B) of the TFDCA.

20. Based on FDA's Warning Letter, Defendants also violated state law by failing to provide a notice required by Section 510 (k) of the Federal Act prior to introducing into commerce a colon irrigation device for a new or unapproved use, unless exempt by a 520(g) investigational device exemption, in violation of § 431.021(t)(1)(A) of the TFDCA.

21. During TDH's inspection of Eternal Health, Inc., and Cynthia Pitre's facility in Dallas on November, 2002, Defendant HOENNINGER, Executive Director of Defendant IACT, misrepresented to Cynthia Pitre by telephone that her involvement in a study to reclassify colon irrigation systems for general well being qualified her to possess and use the prescription colon irrigation systems as part of an Investigational Device Exemption without a practitioner's order or authorization.

Defendants' Advertising and Representations Violate State Law

22. Defendants also advertise and promote colon hydrotherapy by displaying and

providing brochures to IACT members to use in their offices. These brochures fail to disclose that the “FDA-registered equipment” that the brochure promotes the use of for colon cleansing are considered by FDA to be prescription colon irrigation systems and that such devices can only be purchase or possessed; used by or on the order of; and its use supervised by a practitioner.

23. Defendants’ brochure also advertises and promotes colon hydrotherapy with a section titled, Historical View, that makes a general well-being claim by stating “It was an acceptable practice in Parisian society to enjoy as many as three or four enemas a day, the belief being that an internal washing or "lavement" was essential to well-being.” Defendants’ advertising of prescription colon irrigation systems for uses, not approved by FDA, constitute false advertising and misbranding or causes the misbranding and/or adulteration of prescription colon irrigation systems used for such use.

24. Defendants’ brochure also advertises and promotes colon hydrotherapy with a section titled, How Many Colon Hydrotherapy Sessions Does One Need? that states or implies a general well-being claim by stating “Just as some people exercise on a daily or weekly basis to tone and tighten their outer body, some people follow an ongoing cleansing, toning, and rebuilding regime for the inner body. Colon hydrotherapy could be used as part of any regular maintenance program.” Defendants’ advertising of prescription colon irrigation systems for these uses, not approved by FDA, constitutes false advertising and misbranding or causes the misbranding and/or adulteration of prescription colon irrigation systems used for such uses.

25. Defendants also advertise and promote colon cleansing using prescription colon irrigation systems by providing educational presentations utilizing a slide presentation that claims colon hydrotherapy may be used for many uses unapproved by FDA. For example, Defendants’ slide presentation promotes the use of prescription colon irrigation systems to improve muscle tone, to minimize absorption of toxic waste, to reduce the stagnation in the colon, to cleanse and

balance the colon, and for overall healthcare or general well-being. Defendants' advertising and promotion of prescription colon irrigation systems for these uses, not approved by FDA, constitute false advertising and misbranding or causes the misbranding and/or adulteration of prescription colon irrigation systems used for such uses.

26. Defendants' slide presentation also advertises and promotes colon hydrotherapy using prescription colon irrigation systems with a slide entitled "Colon Hydrotherapy Indications" that promotes the use of these devices for constipation, diarrhea, intestinal toxemia, autointoxication (defined in presentation as a form of blood poisoning), bowel re-training, and following pregnancy. Defendants' advertising and promotion of prescription colon irrigation systems for these uses, not approved by FDA, constitute false advertising and misbranding or causes the misbranding and/or adulteration of prescription colon irrigation systems used for such uses.

27. Defendants' slide presentation also misleads consumers by failing to disclose that the "FDA-registered equipment" that the presentation promotes the use of are considered by FDA to be prescription colon irrigation systems and that such devices can only be purchased or possessed; used by or on the order of; and its use supervised by a practitioner.

28. Defendants' slide presentation also failed to disclose that colon irrigation systems have only been approved by the FDA for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations and not for the uses for which Defendants advertise the procedures. Defendants' false advertising misbrands or causes the misbranding and/or adulteration of colon irrigation systems by advertising the use of these devices for unapproved uses.

29. Defendants' slide presentation and their quarterly newsletters advertise and represents that patients should insert the rectal nozzle themselves and fail to disclose that such

devices are cleared only to be used by a practitioner or under the supervision of a practitioner. These advertisements and representations constitute false advertising and misbranding or cause the misbranding and/or adulteration of prescription colon irrigation systems because these devices are not approved for self-use because FDA determined that adequate directions for use by a layman cannot be written and that these devices can only be used by a practitioner or under the supervision of a practitioner.

30. Defendants also mislead their members in their newsletters by misrepresenting that “...there are no laws in Texas about colon hydrotherapy.” Defendants fail to disclose that the Texas Food, Drug and Cosmetic Act regulates the advertising and use of colon irrigation devices used to provide colon hydrotherapy pursuant to FDA’s clearance of these devices as prescription devices requiring practitioner involvement to purchase, possess, use or order the use of, and to supervise the use of such devices.

31. Defendants promote the use of prescription colon irrigation systems for uses not approved by FDA and without the involvement of a practitioner in its training classes and in its lesson plans. Defendants fail to disclose that colon irrigation devices are prescription devices and can only be purchased, possessed, used or the use order by, and the use supervised by a practitioner. Defendants’ failure to disclose this information constitutes false advertising and misbranding or causes the misbranding and/or adulteration of prescription colon irrigation devices used without practitioner involvement and for unapproved uses.

OVERVIEW OF REGULATION OF PRESCRIPTION MEDICAL DEVICES

32. The Texas Food, Drug, and Cosmetic Act (“TFDCA”) lists acts and the causing of acts that are unlawful and prohibited, including, but not limited to, manufacturing or introducing into commerce misbranded or adulterated medical devices; misbranding or adulterating medical devices in commerce; and the dissemination of any false advertisement. TDH determines if the

advertising or use of a medical device violates any prohibited acts depending on the classification and regulation of each medical device by the Federal Food and Drug Administration (“FDA”).

FDA Regulates and Classifies Medical Devices According to Intended Use

33. FDA regulates and classifies medical devices for use in humans according to their intended use, relying upon the manufacturer or distributor’s labeling of the device to determine its intended use. FDA is responsible for classifying and approving medical devices after they determine whether they are safe and effective for their stated intended uses.

34. FDA has classified colon irrigation systems intended for “colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations” as Class II medical devices when used for this purpose in 21 C.F.R. §876.5220 (b)(1). Colon irrigation systems are described as usually consisting of a container for fluid; the tubing; the nozzle; a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled; a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes; and electrical power to heat the water.

35. FDA classified colon irrigation systems as class III medical devices when the intended use is for “other uses, including colon cleansing routinely for general well being” as shown in 21 C.F.R. §876.5220 (b)(2). No such class III devices have been cleared for marketing by FDA.

36. Class III medical devices must have an premarket approval (“PMA”) in effect before being placed in commercial distribution to show that the device is safe and effective for the new intended use pursuant to 21 C.F.R. §876.5220 (c). No such PMA is in effect for any colon irrigation devices cleared by FDA.

37. FDA requires that, unless specifically exempted, any medical device must have “adequate directions for use” as defined in 21 C.F.R. § 801.5 to mean directions under which the

layperson can use a device safely and for the purposes for which it is intended. Unless subject to an exemption, a medical device must have “adequate directions for use” or it cannot be sold to or used by a lay person. No colon irrigation systems cleared by FDA for marketing have such an exemption.

FDA Considers All Colon Irrigation Systems To Be Prescription Medical Devices

38. FDA defines a prescription device in 21 C.F.R. § 801.109 to be a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which “adequate directions for use” cannot be prepared.

39. FDA regulations (21 C.F.R. § 801.109) allow a medical device to qualify for an exemption from “adequate directions for use” only if it is in the possession of a practitioner licensed by state law to use or order the use of such device; sold only to or on the prescription or other order of such practitioner for use in professional practice; and the label has to bear the statement “Caution: Federal law restricts this device to sale by or on the order of a _____, to be filled in with the descriptive designation of any practitioner licensed by state law in which he practices to use or order the use of the device.

40. The FDA considers the colon irrigation systems advertised and whose use is promoted by Defendants to be prescription medical devices, as defined in 21 C.F.R. § 801.109. As such, FDA has determined that these devices cannot bear adequate directions for safe use by a layperson, and therefore must comply with the exemption requirements in paragraph 39. FDA’s Warning Letter, dated October 23, 2003, to Jimmy John Girouard and Colon Therapeutics, Inc., reaffirms this prescription medical device status of all cleared colon irrigation systems.

41. In addition, prescription medical devices are restricted devices because they are subject to certain controls related to sale, distribution, or use as specified in §520(e)(1) of the

Federal Food, Drug and Cosmetic Act. Restricted devices pursuant to 25 T.A.C. §229.433 (27) are devices that are subject to certain controls related to sale, distribution, or use as specified in §520(e)(1) of the Federal Food, Drug and Cosmetic Act. Because colon irrigation systems are prescription medical devices, under Texas law all such devices are also restricted devices since they are subject to certain controls related to the sale, distribution, or use, as defined in 25 T.A.C. §229.433 (27).

Prescription Colon Irrigation Systems Are “Dangerous Drugs” Under Texas Law

42. Prescription colon irrigation systems are “dangerous drugs” pursuant to §483.001 (2) of the Texas Dangerous Drug Act because these devices bear or are required to bear a legend to comply with federal law regarding their sale as prescription medical devices pursuant to 21 C.F.R. § 801.109.

43. Under Texas law, only those practitioners listed in § 483.001(12) of the Texas Dangerous Drugs Act, also defined in 25 T.A.C. §229.433 (22), are authorized to purchase, possess, use or order the use of prescription or restricted medical devices, including prescription colon irrigation systems, including rectal nozzles. The only practitioners licensed in Texas who can purchase, possess, use or order the use of colon irrigation systems on humans in the course of their professional practice are those practitioners licensed by the Texas Board of Medical Examiners.

DEFENDANTS’ ADVERTISING AND PROMOTION MISBRANDS DEVICES

44. As set out in paragraphs 1 through 43 and incorporated herein, Section 431.112(f)(1) of the TFDCA provides that a device is misbranded unless its labeling bears adequate directions for use or unless the device has been exempted from those requirements by regulations. Since instructions for safe use by a layperson cannot be written for prescription colon irrigation systems, these devices are only exempt from this requirement, pursuant to 21 C.F.R. § 801.109, and are required to have a licensed practitioner to purchase and possess, to order the

procedure, and to supervise the use of colon irrigation systems.

45. Defendants' advertisements and representations promoting the use of prescription colon irrigation systems fail to disclose that a licensed practitioner must purchase or authorize the purchase and possession by individuals or clinics and, therefore, misbrand or cause the misbranding of such devices if purchased or possessed without practitioner involvement, pursuant to § 431.112 (f) of the TFDCA.

46. Defendants' advertisements and representations promoting the use of prescription colon irrigation systems without being used by a practitioner or without an order of a practitioner for each use misbrands or causes the misbranding of these device pursuant to § 431.112 (f) of the TFDCA.

47. Defendants' advertisements and representations promoting the use of prescription colon irrigation systems without being used by a practitioner or without supervision by a practitioner misbrands or causes the misbranding of these device pursuant to § 431.112 (f) of the TFDCA.

48. Defendants' advertisements and representations promoting the use of prescription colon irrigation systems for uses not approved by FDA misbrands or causes the misbranding of these devices pursuant to § 431.112 (f) of the TFDCA.

49. Defendants' advertisements and representations for self-insertion misbrand or cause the misbranding of prescription colon irrigation systems because these devices are not approved for self-use because FDA determined that adequate directions for use by a layman cannot be written and that these devices can only be used by a practitioner or under the supervision of a practitioner, pursuant to § 431.112 (f) of the TFDCA.

50. In addition, the prescription colon irrigation systems promoted by Defendants for use in colon hydrotherapy are also restricted devices, as defined in by 25 T.A.C. §229.433 (27), since they are subject to certain controls related to the sale, distribution, or use. Therefore,

Defendants' advertisements and representations promoting the use of prescription colon irrigation systems without purchase, possession, use by or on the order of, and supervision by a practitioner misbrands or causes the misbranding of these device colon irrigation systems pursuant to § 431.112 (r) of the TFDCA.

51. Under the terms of § 431.021 (a) and (b) of the TFDCA, the introduction into commerce of misbranded devices or the misbranding of any device in commerce in Texas is unlawful and prohibited. Defendants' advertisements and representations of prescription and restricted medical devices as described above misbrands or causes the misbranding of these devices in Texas.

DEFENDANT'S DEVICES ARE ADULTERATED

52. As set out in paragraphs 1 through 51 and incorporated herein, colon irrigation systems used for other uses, including for general well being purposes, (than those stated in 21 C.F.R. §876.5220 (b)(1)), have not been approved previously by FDA. For these uses, colon irrigation devices are by regulation (21 C.F.R. §876.5220 (b)(2)) and by statute classified as Class III medical devices and may not be marketed without an approved application for Premarket Approval ("PMA") under section 515 of the Federal Food, Drug, and Cosmetic Act. FDA has not approved any application for PMA for colon irrigation systems for any purposes.

53. The prescription colon irrigation systems advertised and promoted by Defendants are Class III medical devices when used for purposes other than those stated in 21 C.F.R. §876.5220 (b)(1), including colon cleansing routinely for general well being; and require premarket approval, or must fall into an exemption from such approval, before they can be used in the marketplace.

54. A device is adulterated if it is a Class III medical device, whether by statute or regulation, and is in the marketplace without receiving approval from FDA.

55. Defendants' advertisements and representations of prescription colon irrigation

devices for uses not approved by FDA moves these devices into Class III and adulterates or causes the adulteration of such devices used for unapproved uses under state law, according to §431.111(f)(1)(A) of the TFDCA. Section 431.111 states that a device shall be deemed to be adulterated :

(f)(1) if it is a class III device:

(A)(i) that is required by a regulation adopted under Section 515(b) of the federal Act to have an approval under that section of an application for premarket approval and that is not exempt from Section 515 as provided by Section 520(g) of the federal Act; and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the United States Food and Drug Administration by the 90th day after the date of adoption of the regulation; or

(II) for which that application was filed and approval was denied or withdrawn, for which that notice was filed and was declared incomplete, or for which approval of the device under the protocol was withdrawn.

56. Under the terms of § 431.021 (a)and (b) of the TFDCA, the introduction into commerce or the causing of introduction into commerce of an adulterated device and the adulteration or the causing of adulteration of any device in commerce in Texas is unlawful and prohibited. Defendants violate § 431.021(a) and (b) of the TFDCA with each unapproved use that their advertisements or representations promote since FDA codifies any use, including for general well being, other than the approved use as a Class III use since these devices have not been approved through pre-market approval as required by FDA to show their safety and effectiveness for Class III uses.

DEFENDANT’S ADVERTISEMENTS ARE FALSE, MISLEADING OR DECEPTIVE

57. As set out in paragraphs 1 through 56 and incorporated herein by reference, Defendants advertise and represent that prescription colon irrigation systems have uses other than those for which FDA has allowed the devices to be sold or used, including for general well being. Defendants’ representations for the use of prescription colon irrigation systems for unapproved uses constitute false advertising in violation of § 431.021(f) of the TFDCA.

58. Defendants also have violated § 431.021(f) of the TFDCA because Defendants' advertisements and representations of the use of prescription colon irrigation systems without practitioner involvement constitute false advertisements under the TFDCA because they solicited persons to purchase prescription medical devices and training services which are unlawful and violate § 431.021(b) of the TFDCA.

59. Defendants' advertisements and representations fail to disclose that the "FDA-registered equipment" that they promote the use of are considered by FDA to be prescription colon irrigation systems and that such devices can only be purchased or possessed; used by or on the order of; and its use supervised by a practitioner and constitute false advertising in violation of § 431.021(f) of the TFDCA.

60. Defendants' advertisements and representations also failed to disclose that colon irrigation systems have only been approved by the FDA for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations and not for the uses for which Defendants advertise the procedures and constitute false advertising in violation of § 431.021(f) of the TFDCA.

61. Defendants' advertisements and representations that patients should insert the rectal nozzle themselves fail to disclose that such devices are cleared only to be used by a practitioner or under the supervision of a practitioner because these devices are not approved for self-use and constitute false advertising in violation of § 431.021(f) of the TFDCA .

62. Defendants' advertisements and representations also mislead their members by misrepresenting that "...there are no laws in Texas about colon hydrotherapy." Defendants' failure to disclose that the Texas Food, Drug and Cosmetic Act regulates the advertising and use of colon irrigation devices used to provide colon hydrotherapy pursuant to FDA's clearance of these devices as prescription devices requiring practitioner involvement to purchase, possess, use or order the use of, and to supervise the use of such devices constitutes false advertising in violation

of § 431.021(f) of the TFDCA.

63. Defendants' advertisements and representations of their investigational study using prescription colon irrigation systems without an investigational device exemption approved by the FDA and their failure to disclose all of FDA's requirements constitute false advertising in violation of § 431.021(f) of the TFDCA.

64. Defendants promote the use of prescription colon irrigation systems for uses not approved by FDA and without the involvement of a practitioner in its training classes and in its lesson plans. Defendants fail to disclose that colon irrigation devices are prescription devices and can only be purchased, possessed, used or the use order by, and the use supervised by a practitioner. Defendants' failure to disclose this information constitutes false advertising and misbranding or causes the misbranding and/or adulteration of prescription colon irrigation devices used without practitioner involvement and for unapproved uses constitute false advertisements in violation of § 431.021(f) of the TFDCA.

65. Such advertising and representations listed above constitute advertising within the definition set out in §431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendants' training services, publications, and to be a member.

66. Any such advertising and representations by Defendants as listed above are declared to be false by the terms of §431.182(a) of the TFDCA.

PROHIBITED ACTS

67. Defendants, as set out in paragraphs 1 through 66 and incorporated herein by reference, have committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.021 of the TFDCA:

- a. Misbranding prescription colon irrigation systems by causing someone other than a practitioner licensed by state law to purchase such devices, in violation of §431.021(a) and/or (b);

- b. Misbranding prescription colon irrigation systems by causing someone other than a practitioner licensed by state law to use such devices, in violation of §431.021(a) and/or (b);
- c. Falsely advertising or representing that prescription colon irrigation systems do not need to be purchased, possessed, used, or supervised by a practitioner licensed by state law to use such devices in violation of §431.021(f);
- d. Misbranding prescription colon irrigation systems by advertising and representing that such devices can be used for uses not approved by FDA, in violation of §431.021(a) and/or (b);
- e. Adulterating prescription colon irrigation systems by advertising such devices for uses not approved by FDA, in violation of §431.021(a) and/or (b);
- f. Adulterating prescription colon irrigation systems by causing such devices to be used for uses not approved by FDA, in violation of §431.021(a) and/or (b);
- g. Falsely advertising that prescription colon irrigation nozzles, as approved by the FDA, can be self-inserted when FDA has cleared these nozzles only for use by a practitioner or under the supervision of a practitioner, in violation of §431.021(f);
- h. Falsely advertising that prescription colon irrigation systems are effective for general well-being when FDA has not approved these devices for such use in violation of §431.021(f);
- i. Falsely advertising and representing an investigational study using prescription colon irrigation systems without an investigational device exemption approved by the FDA, in violation of §431.021(f);
- j. Introducing or delivery or causing the introduction or delivery into commerce of a misbranded or adulterated prescription colon irrigation systems, in violation of §431.021(a);
- k. Misbranding or causing the misbranding of a prescription colon irrigation system in commerce, in violation of §431.021(b);
- l. Adulteration or causing the adulteration of a prescription colon irrigation system in commerce, in violation of §431.021(b);
- m. Receiving or causing the receiving in commerce of a prescription colon irrigation system that is adulterated or misbranded, in violation of §431.021(c);
- n. Disseminating false advertising or causing the dissemination of false advertising, in violation of §431.021(f);
- o. Failing to provide a notice required by Section 510 (k) of the Federal Act prior to introducing into commerce a colon irrigation system, including rectal nozzles, for a

new or unapproved use, unless exempt by a 520(g) investigational device exemption, in violation of § 431.021(t)(1)(A);

- p. Failing to comply with any requirement required by 520(g) of the Federal Act by furnishing any notification or information regarding any investigational device exemption in which Defendant is involved, in violation of § 431.021(t) (1)(B); and
- q. Failing to comply with federal medical device reporting requirement to report a serious injury and/or death, as required by 21 CFR § 803 and Section 519 of the federal Act, in violation of § 431.021(t) (1)(B).

VIOLATIONS OF THE DTPA

68. Defendants, as set out in paragraphs 1 through 67 and incorporated herein by reference, in the course and conduct of trade and commerce, have directly and indirectly engaged in false, misleading, deceptive and unconscionable acts and practices declared unlawful by §17.46

(a) and (b) of the Texas Deceptive Trade Practices Act, including but not limited to:

- a. Causing confusion as to the approval of a good by advertising and promoting the purchase, possession, and use of prescription colon irrigation systems without the authorization or order of a licensed practitioner;
- b. Failing to disclose that prescription colon irrigation systems are only to be sold under the order or authorization of a practitioner licensed to use and order the use of such device;
- c. Failing to disclose in any advertising, representations, training or publications that prescription colon irrigation systems are only to be used under the supervision of a licensed practitioner;
- d. Failing to disclose in any advertising, training or publications that colon cleansing using prescription colon irrigation system can only be performed upon the order of a licensed practitioner;
- e. Falsely representing to a consumer that colon cleansing using prescription colon irrigation systems can legally be performed without the supervision or order of a licensed practitioner;
- f. Falsely advertising that colon cleansing using prescription colon irrigation systems are appropriate for self-administration or self-insertion when they are not; and
- g. Failing to disclose that prescription colon irrigation systems are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

69. Moreover, the Consumer Protection Division has reason to believe that the above actions specifically violate §17.46 (a) and the following provisions of §17.46 of the DTPA:

- (b)(2) causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- (b)(5) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have;
- (b)(7) representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
- (b)(24) failing to disclose information concerning goods or services which was known at the time of the transaction 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.

INJURY TO CONSUMERS

70. By means of the foregoing unlawful acts and practices which were producing causes of injury to the persons affected, 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.

CONTINUING VIOLATIONS

71. By reason of the institution and continued operation of the acts and practices described in paragraphs 1 through 70 above, Defendants have violated and will continue to violate the laws as hereinabove alleged. Defendants, unless restrained by this Honorable Court, will continue violating the laws of the State of Texas and injury, loss and damage will result to the State of Texas and to the general public. Defendants have violated and continue to violate these sections of the TFDCA and the DTPA.

PRAYER

72. WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendants be cited according to law to appear and answer herein; that after due notice and hearing a

TEMPORARY INJUNCTION be issued and upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendants and by their agents, servants, employees, and representatives from making the representations, doing the acts, and engaging in the practices set out in the preceding paragraphs as well as from making the following representations and doing the following acts and engaging in the following practices in the pursuit and conduct of trade or commerce within the State of Texas as follows:

- a. Misbranding prescription colon irrigation systems by causing someone other than a practitioner licensed by state law to use such devices to purchase such devices;
- b. Misbranding prescription colon irrigation systems by causing someone other than a practitioner licensed by state law to use such devices to use such devices;
- c. Falsely advertising or representing that prescription colon irrigation systems do not need to be purchased, possessed, used, or supervised by a practitioner licensed by state law to use such devices;
- d. Misbranding prescription colon irrigation systems by advertising and representing that such devices can be used for uses not approved by FDA;
- e. Adulterating prescription colon irrigation systems by advertising such devices for uses not approved by FDA;
- f. Adulterating prescription colon irrigation systems by causing such devices to be used for uses not approved by FDA;
- g. Falsely advertising that prescription colon irrigation nozzles, as approved by the FDA, can be self-inserted when FDA has cleared these nozzles only for use by a practitioner or under the supervision of a practitioner;
- h. Falsely advertising that prescription colon irrigation systems are effective for general well-being when FDA has not approved these devices for such use;
- i. Falsely advertising and representing an investigational study using prescription colon irrigation systems without an investigational device exemption approved by the FDA;
- j. Introducing or delivery or causing the introduction or delivery into commerce of a misbranded or adulterated prescription colon irrigation systems;
- k. Misbranding or causing the misbranding of a prescription colon irrigation system in commerce;

- l. Adulteration or causing the adulteration of a prescription colon irrigation system in commerce;
- m. Receiving or causing the receiving in commerce of a prescription colon irrigation system that is adulterated or misbranded;
- n. Disseminating false advertising or causing the dissemination of false advertising;
- o. Failing to provide a notice required by Section 510 (k) of the Federal Act prior to introducing into commerce a colon irrigation system, including rectal nozzles, for a new or unapproved use, unless exempt by a 520(g) investigational device exemption;
- p. Failing to comply with any requirement required by 520(g) of the Federal Act by furnishing any notification or information regarding any investigational device exemption in which Defendant is involved;
- q. Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- r. Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have;
- s. Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
- t. Failing to disclose information concerning goods or services which was known at the time of the transaction 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.; and
- u. Failing to provide written notice to any agent, servant, employee or representative of the existence and terms of any injunction entered in this case, and of their duty to comply with the terms set forth herein.

73. .Plaintiff further prays that upon final hearing this Court order Defendants to pay civil penalties to the State of Texas up to \$25,000 per violation per day for each violation of §431.021 of the TFDCA, as provided in §431.0585(b) of the TFDCA.

74. Plaintiff further prays that upon final hearing that this court order Defendants to pay to the State of Texas 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 pursuant to § 431.047(d) of the TFDCA.

75. Plaintiff further prays that upon final hearing this Court order Defendants to restore all money or other property taken from identifiable persons by Defendant's unlawful acts or practices, or, in the alternative, award judgment for damages to compensate identifiable persons for such losses as provided in §17.47(d) of the DTPA.

76. Plaintiff further prays, that upon final hearing, this Court order Defendants to pay civil penalties of not more than \$20,000.00 per violation, as provided in §17.47(c)(1) of the DTPA.

77. Plaintiff further prays that upon final hearing this Court order Defendants to pay an additional amount in civil penalties, not to exceed a total of \$250,000.00, to the State of Texas, for any act or practice that was calculated to acquire or deprive money or other property from a consumer who was 65 years of age or older when the act or practice occurred as provided in §17.47(c)(2) of the DTPA.

78. Plaintiff further prays that upon final hearing that this Court order Defendants to pay to the STATE OF TEXAS attorney fees and to pay the costs of court pursuant to the TEX. GOVT. CODE §402.006(c).

79. Plaintiff further prays that the court set this matter for trial and upon final hearing issue a permanent injunction against Defendants.

80. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may be justly entitled.

Plaintiff State of Texas

GREG ABBOTT
Attorney General of Texas

BARRY MCBEE
First Assistant Attorney General

ED D. BURBACH
Deputy Attorney General for Litigation

PAUL D. CARMONA
Assistant Attorney General
Chief, Consumer Protection Division

JOYCE WEIN ILIYA
Assistant Attorney General
Consumer Protection Division
State Bar No. 00784319
1600 Pacific Avenue, Suite 1700
Dallas, Texas 75201-3513
(214) 969-7639, ext. 111
Facsimile: (214) 969-7615
Attorneys for the State