

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	
	§	
TILLER MIND BODY, INC., d/b/a MIND	§	
BODY NATUROPATHIC INSTITUTE,	§	DALLAS COUNTY, T E X A S
JERI TILLER, 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 TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually (“Defendants”), based on their manufacturing, advertising, training, and selling of colon irrigation systems and colon cleansing in violation of state law 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 JERI TILLER is an individual who is President of Defendants TILLER MIND BODY, INC., and MIND BODY NATUROPATHIC INSTITUTE at 10911 W. Avenue, San Antonio, Texas 78213, Baxter County. Defendant JERI TILLER may be served with process by serving her at this business address.

4. Defendant TILLER MIND BODY owns and operates Defendant MIND BODY NATUROPATHIC INSTITUTE and may be served with process through serving its registered agent, Norbert Gonzales, Jr., 7800 IH-10 West #505, San Antonio, Texas 78230, or Defendant JERI TILLER, President of both entities, at 10911 W. Avenue, San Antonio, Texas 78213, Baxter County.

VENUE

5. 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, promoting, training, and selling Defendants’ prescription colon irrigation systems, including rectal tubes or nozzles¹, in Dallas County, Texas, specifically to

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

Deanna Asencio at Dallas Colon Care Center, Don Blaylock at D.R.B. Therapies, Jean Morosko at Morosko's Center, and George Lafgren, N.D. In addition, Defendants advertised and promoted their training services, their brochures, and their prescription colon irrigation systems in Dallas County.

PUBLIC INTEREST

6. 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

7. 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, marketing, training, manufacturing, and selling prescription colon irrigation systems and colon cleansing in Texas, the United States, and other countries.

NOTICE BEFORE SUIT

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

ACTS OF AGENTS

9. 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

10. Defendants advertise, sell, and manufacture prescription colon irrigation systems and provide training, publications, and colon cleansing at 10911 W. Avenue, San Antonio, Texas 78213, Baxter County. Defendants identify their colon irrigation system as "LIBBE Lower Bowel Evacuation" and their rectal nozzles for use with this system as "LIBBE Rectal Tube".

Defendants' Colon Irrigation System Is Cleared For Marketing Only As Prescription Device

11. FDA informed Defendants that the LIBBE Lower Bowel Evacuation and LIBBE Rectal Tubes were cleared for marketing as prescription medical devices in response to Defendants' submissions K941279 and K962259. (See attached Exhibit A and B, FDA Clearance Letters.) Therefore, Defendants' colon irrigation system and rectal tubes 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 Both the LIBBE Lower Bowel Evacuation and the LIBBE Rectal Tubes are labeled with this required federal legend.

12. All premarket clearance letters that FDA sent to Defendants cleared Defendants colon irrigation system and rectal tubes only for the same intended use, as defined in 21 CFR

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.

876.5210, for “colon cleansing when medically indicated under the supervision of a practitioner, such as before radiological or endoscopic examinations and as Class II.

13. In addition on April 17, 1995, FDA sent a letter to Defendants informing them that “Because your device can be used by prescription only, please include the following statement in the labeling and on the actual colonic hydrotherapy device: “Caution: Federal law restricts this device to use by or on the order of a physician.””

Defendants Ignore FDA Restrictive Clearance of Prescription Colon Irrigation Devices

14. Despite such restrictive clearance for Defendants’ colon irrigation system by FDA, Defendants advertise and distribute in commerce thousands of prescription colon irrigation systems throughout Texas, much of the United States, and foreign countries. Defendants advertised, offered to sale, and sold their prescription colon irrigation systems without an order or authorization to purchase or possess these devices from a practitioner, as required by state and federal law, and, therefore, misbranded them.

15. Defendants specifically advertised, sold, and delivered prescription colon irrigation systems to consumers in Texas, most states in the United States, and other countries. Defendants advertised, sold, and delivered prescription colon irrigation systems to Dallas County, Texas to Deanna Asencio at Dallas Colon Care Center, Don Blaylock at D.R.B. Therapies, Jean Morosko at Morosko’s Center, and George Lafgren, N.D. without an order or authorization to purchase or possess these prescription devices from a practitioner.

16. Defendants admit in a statement written voluntarily and signed by Defendant JERI TILLER on February 4, 2003, that “We supply the LIBBE Rectal Tubes to customers who purchase the LIBBE Lower Bowel Evacuation device and sales have not been restricted to licensed practitioners or clinics with a licensed practitioner serving in the official capacity as a

medical director because I did not consider the LIBBE device a prescription device.” This statement immediately follows Defendant JERI TILLER’s statement that FDA told her in a letter dated April 17, 1995 that Defendants’ device could only be used by prescription.

17. Defendants have manufactured and sold approximately 317 LIBBE Lower Bowel Evacuation systems since February, 1998 and thousands of rectal tubes yearly without restricting sales to or on the authorization of a practitioner and have misbranded each device and tube sold in such a manner.

18. Defendants admit in a statement written voluntarily and signed by Defendant JERI TILLER on February 4, 2003, that they administered colonic irrigations since March, 1997 using Defendants’ colon irrigation systems and have not required the “client” to bring a prescription or physician’s order prior to administering the “colon irrigation treatment”. Defendant JERI TILLER states that there are no prescriptions or physician’s orders in the client records for any colon irrigations and that in 2001, Defendants administered approximately 1,205 colonic treatments; in 2002, approximately 1,375 colonic treatments were administered; and from January 1, 2003 to January 29, 2003, 72 colonic treatments were administered.

19. Defendants advertised and marketed their prescription colon irrigation systems for other purposes than the approved intended use of colon cleansing when medically indicated as shown below. Defendants’ advertising and marketing of these prescription devices for other uses, including for general well being, that have not been approved by the FDA adulterated these devices.

20. Defendants continued to sell prescription colon irrigation systems without practitioner involvement even after Texas Department of Health (“TDH”), on January 27-February 4, 2003, confirmed with Defendants, who acknowledged that FDA considered the colon

irrigation systems that Defendants manufactured, offered for sale, sold, and advertised prescription medical devices and that they were restricted to purchase upon the order of a practitioner licensed in Texas to use or order the use of such device. Defendants continued to sell prescription rectal tubes to Texas and other consumers without requiring orders from practitioners licensed in the state of the purchaser to use or order the use of such prescription devices.

21. During a July 1, 2003 inspection to review distribution records, TDH cited Defendants objectionable conditions for selling approximately 5,800 prescription LIBBE rectal tubes/nozzles from February 4, 2003 to June 26, 2003, with no documentation to indicate that a practitioner has purchased or authorized the purchase of these prescription devices. TDH again cited Defendant for selling 600 rectal tubes/nozzle to a Texas consumer in July, 2003 and instead of requiring the purchaser to provide a practitioner's order or authorization to purchase Defendants' rectal tubes, Defendants provided "Medical Oversight, Awareness, and or Approval..." from a Joseph R. Zacharko, Tx. Lic. PA03251 for the consumer's purchase for a Houston clinic. Purchases of prescription rectal tubes with an order or authorization of a long-distance medical director in San Antonio for a clinic in Houston constitutes a "sham" relationship and does not provide proper authorization for such sales by Defendants.

22. Defendants advertise on the internet site found at www.colon-hydrotherapy.com and www.colonic.net and contains links and articles that make claims that colon hydrotherapy will aid in silicone breast implant exposure, allergies, acne, arthritis, ADD, hypertension, asthma, seizures, and many other diseases and illnesses. In addition, Defendants' advertise and sell a booklet entitled "Are You A Toxic Waste Site" written by Defendants that reports that colon hydrotherapy clears up acne, allergies, as well as asthma. Defendants' brochures, internet sites,

and any other advertising that are false or misleading misbrand their prescription colon irrigation systems under state and federal law by advertising them for uses other than the FDA approved uses. This false advertising also constitutes false advertising and false representations in violation of state law.

23. Defendants failed to disclose on the internet site, in advertisements or brochures, in their operations manual, or in their training of colon hydrotherapists that prescription colon irrigation systems may be possessed or purchased to use on humans only by order of a practitioner and that their use must be by or under the supervision of a practitioner with an order or prescription for each procedure.

24. Defendants failed to disclose on the internet site, in advertisements, in brochures, or in their training that their colonic irrigation system has been approved by the FDA only 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 misbranded their colon irrigation systems by advertising the use of these devices for unapproved uses.

Inspections of January 27-February 4, 2003:

25. On January 27-February 4, 2003, an investigator from TDH conducted a routine inspection of Defendants' office at 10911 W. Avenue, San Antonio, Texas 78213, that resulted in TDH cited Defendants for 12 objectionable conditions or practices for TILLER MIND BODY, INC., and four objectionable conditions for MIND BODY NATUROPATHIC INSTITUTE, including but not limited to the following:

- a. Defendants distributed prescription devices, including the LIBBE Lower Bowel Evacuation system and rectal tubes/nozzles, to persons other than a licensed

practitioner and without an order or prescription of licensed practitioner for use in the course of his professional practice;

- b. Defendants' internet websites links to booklets or articles that contain statements promoting colon cleansing for uses not approved by FDA, such as silicone breast implant exposure, allergies, acne, arthritis, ADD, hypertension, asthma, seizures, and many other diseases and illnesses, as well as Defendants' advertise and sell a booklet entitled "Are You A Toxic Waste Site" written by Defendants that reports that colon hydrotherapy clears up acne, allergies, as well as asthma and also makes claims for uses not approved by FDA;
- c. Defendants refer to the oxygen injection feature in its operation manual and no evidence exists that the addition of breathing air or oxygen has been approved by FDA;
- d. Procedures were not established to address when verification of design changes is sufficient in lieu of validation prior to their implementation and design changes have been implemented to the LIBBE Lower Bowel Evacuation device without any rationale for why verification was appropriate;
- e. The Device Master Record did not include or refer to the location of packaging procedures and specifications, production and process specifications, all quality assurance procedures and specifications;
- f. Procedures for implementing corrective and preventive actions were not established;
- g. Defendants administered colonic irrigations since March, 1997, using their colon irrigation systems and did not required the client to bring a prescription or

physician's order prior to administering the colon irrigation treatment and for uses, such as parasites, weight loss, hernia, energy, better well being, etc., not approved by FDA; and

- h. Defendants had not developed and maintained written Medical Device Reporting procedures to include documentation, record keeping requirements, and a standardized review process;

Inspections of July 1, 2003, August 22, 2003, and September 16-17, 2003:

26. During a July 1, 2003 inspection to review distribution records, TDH cited Defendants objectionable conditions for selling approximately 5,800 prescription LIBBE rectal tubes/nozzles from February 4, 2003 to June 26, 2003, with no documentation to indicate that a practitioner has purchased or authorized the purchase of these prescription devices.

27. On August 22, 2003, TDH inspected Defendants to investigate a complaint involving alleged injury associated with a colon hydrotherapy clinic in Houston, Texas. TDH cited Defendants for failing to provide evidence to indicate that they documented an oral complaint about a colon perforation on or about March 3, 2003 and for failing to investigate a reportable medical device reporting event after being reported to them. Defendants were also cited for failing to file an MDR to FDA within 30 days of receiving information that reasonably suggests that a marketed device may have caused or contributed to a serious injury.

28. TDH also questioned the provision of medical supervision and a sufficient patient-practitioner or physician assistant-patient relationship for a physician assistant in San Antonio working for Defendants to authorize the use of prescription colon irrigation systems and the purchase and possession of Defendants' rectal tubes for a clinic in Houston. Defendants developed this procedure after TDH reminded her that the sale and use of Defendants' prescription colon irrigation systems required a practitioner's order or authorization and a

practitioner's order for the use of these devices for colon cleansing.

29. During the inspection on September 16-17, 2003, TDH cited Defendants for failing to submit a medical device report ("MDR") on an alleged injury that was reported to Defendants on 5/19/03 within 30 days of becoming aware of the injury. TDH also follow-up to determine if they had records of orders or authorization for each sale from a practitioner for the previous years. TDH determined that orders or authorization from a practitioner were still not being required from at least one Texas purchaser and from all out of state purchasers and that Defendants had sold at least 600 prescription colon irrigation rectal tubes in Texas, without orders or authorization from a practitioner.

OVERVIEW OF REGULATION OF PRESCRIPTION MEDICAL DEVICES

30. 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 offering for sale, sale, 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

31. 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.

32. 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, including rectal nozzles 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.

33. FDA approved the LIBBE Lower Bowel Evacuation system and the LIBBE rectal tube/nozzle, manufactured by Defendants, as “substantially equivalent” to other pre-existing colon irrigation systems used for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations based on premarket notification submissions to the FDA pursuant to § 510(k) of the FFDCA, 21 U.S.C. § 360(k). Therefore, these devices are Class II medical devices by regulation for this purpose and can only be used for the approved intended use.

34. FDA has also classified colon irrigation systems for other uses than the intended use authorized in 21 C.F.R. §876.5220 (b)(1). However, when the intended use is for “other uses, including colon cleansing routinely for general well being” as listed in 21 C.F.R. §876.5220 (b)(2), then these colon irrigation systems are classified as Class III medical devices.

35. Designation as Class III medical devices requires that any colonic irrigation system to be used for purposes, other than those approved in 21 C.F.R. §876.5220 (b)(1), shall have an approved 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).

36. 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.

FDA Considers All Colon Irrigation Systems To Be Prescription Medical Devices

37. 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.

38. Under FDA regulations (21 C.F.R. § 801.109), a medical device is exempt from having “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.

39. The FDA considers the colon irrigation systems manufactured, offered for sale, sold, and advertised by Defendants to be prescription medical devices, as defined in 21 C.F.R. § 801.109. As such, FDA has determined that Defendants’ devices cannot bear adequate directions for safe use by a layperson, and therefore must comply with the exemption requirements in paragraph 38. FDA’s letter, dated April 17, 1995, to Defendants reaffirms this prescription medical device status and Defendant JERI TILLER’s written statement of February 4, 2003 confirmed her knowledge of this prescription designation of the LIBBE Lower Bowel Evacuation and the LIBBE rectal tubes/nozzles.

40. 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 are similarly defined in 25 T.A.C. §229.433 (27). Because Defendants' colon irrigation systems are prescription medical devices, under Texas law their devices are also restricted devices pursuant to 25 T.A.C. §229.433 (27) and 25 T.A.C. §229.433 (23).

Defendants' Prescription Colon Irrigation Systems Are Dangerous Drugs Under Texas Law

41. 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.

42. 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 which includes prescription colon irrigation systems. 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' DEVICES ARE MISBRANDED

43. As set out in paragraphs 1 through 42 and incorporated herein, Section 431.112(f)(1) of the TFDCFA 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 regulation. Since the prescription colon irrigation systems manufactured by Defendants cannot bear instructions for safe use by a layperson and are not exempt from this requirement, Defendants may legally only sell their devices to a licensed practitioner.

44. Defendants failed to restrict sale of their prescription colon irrigation systems to practitioners as defined by §483.001(12) of The Dangerous Drug Act.

45. Defendants' selling of prescription colon irrigation systems without evidence that the purchase was by or authorized by a practitioner misbrands these device pursuant to § 431.112 (f) of the TFDC.A.

46. In addition, Defendants' prescription colon irrigation systems 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' sale of restricted devices without authorization by a practitioner also misbrands these device pursuant to § 431.112 (r) of the TFDC.A.

47. Under the terms of § 431.021 (a) and (b) of the TFDC.A, the introduction into commerce of misbranded devices or the misbranding of any device in commerce in Texas is unlawful and prohibited. Defendants' sale of prescription and restricted medical devices without authorization by a practitioner misbrands these devices in Texas.

48. Defendants' labeling for their prescription colon irrigation systems, not the nozzle, do not make reference to the device being a prescription device and do not contain the statement "Caution: Federal law restricts this device to sale by or on the order of a _____" licensed by the state to use and order the use of such device, and, therefore, these devices are misbranded.

DEFENDANTS' DEVICES ARE ADULTERATED

49. As set out in paragraphs 1 through 48 and incorporated herein, Defendants' prescription colon irrigation systems are Class III medical devices when advertised, sold, or used for purposes other than those stated in 21 C.F.R. §876.5220 (b)(1), including colon cleansing routinely for general well being; to detoxify the colon; to treat constipation; diarrhea. acute fecal impaction, atonic colon, flatulence or bloating, mild hemorrhoids, intestinal toxemia, nutrient

supplementation; for bowel stimulation and bowel training in para/quadruplegics. Defendants' prescription colon irrigation system have not received premarket approval for such uses and are not exempted from such approval.

50. Defendants' prescription colon irrigation systems are Class III medical devices when used for other uses as listed above, but Defendants have introduced them into commerce even though they did not receive such approval. 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.

51. Defendants' prescription colon irrigation systems are adulterated 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.

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

DEFENDANTS' ADVERTISEMENTS ARE FALSE, MISLEADING OR DECEPTIVE

53. As set out in paragraphs 1 through 52 and incorporated herein by reference, Defendants represented that their 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 advertisements in violation of § 431.021(f) of the TFDCA.

54. Defendants also have violated § 431.021(f) of the TFDCA because Defendants' representations of the illegal use of all their prescription colon irrigation systems in their internet site, advertisements, manuals, sales presentations, and training constitute false advertising 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.

55. Defendants advertise and promote prescription colon irrigation systems for self-medication or for use without practitioner supervision through their internet site, advertising, training, and manuals. Defendants do not disclose in their advertising and selling of these devices that these acts are unlawful and prohibited by the TFDCA.

56. 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.

57. Such 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' prescription colon irrigation devices and training services for unapproved uses of prescription colon irrigation systems and without involvement of a practitioner licensed in Texas to use or order the use of such devices.

58. Any such advertisement by Defendants of a prescription medical device directed toward the public that does not disclose that a practitioner licensed by the state to use such a device must order or authorize its possession or purchase; must order the use of or use the prescription colon irrigation systems; and advertisements for unapproved uses are declared to be false by §431.182(a) of the TFDCA.

PROHIBITED ACTS

59. Defendants, as set out in paragraphs 1 through 58 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 selling to 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 using and 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 using and 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 tubes/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 tubes/ 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);
- 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);
- r. Falsely advertising that prescription colon irrigation systems as approved by the FDA can be self-administered when FDA has not approved these devices for such uses, in violation of §431.021(f); and
- s. Manufacturing prescription colon irrigation systems in Texas and failing to disclose to each purchaser through labeling or a label that the device is a prescription device in violation of §431.021(a) and/or (b).

VIOLATIONS OF THE DTPA

60. Defendants, as set out in paragraphs 1 through 59 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 selling prescription colon irrigation systems without the authorization or order of a practitioner licensed in Texas;
- 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 practitioner licensed to use and order the use of such device;
- d. Failing to disclose in any advertising, representations, training, or publications that colon cleansing using prescription colon irrigation systems can only be performed upon the order of a licensed practitioner in Texas;
- 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 practitioner licensed to use or order the use of such device;
- f. Falsely advertising that colon cleansing using prescription colon irrigation systems are appropriate for self-administration when they are not; and
- g. Failing to disclose that Defendants' prescription colon irrigation systems are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations only.

61. 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

62. 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

63. By reason of the institution and continued operation of the acts and practices described in paragraphs 1 through 62 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

64. 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 selling to someone other than a practitioner licensed by state law 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;

- 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. 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;
- r. Falsely advertising that prescription colon irrigation systems as approved by the FDA can be self-administered when FDA has not approved these devices for such uses;
- s. Manufacturing prescription colon irrigation systems in Texas and failing to disclose to each purchaser through labeling or a label that the device is a prescription device;
- t. Causing confusion as to the approval of a good by selling prescription colon irrigation systems without the authorization or order of a practitioner licensed in Texas;
- u. 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;
- v. 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 practitioner licensed to use and order the use of such device;
- w. Failing to disclose in any advertising, representations, training, or publications that colon cleansing using prescription colon irrigation systems can only be performed upon the order of a licensed practitioner;
- x. Falsely representing to a consumer that colon cleansing using prescription colon irrigation systems can legally be performed without the supervision or order of a practitioner licensed to use or order the use of such device;
- y. Falsely advertising that colon cleansing using prescription colon irrigation systems are appropriate for self-administration when they are not; and
- z. Failing to disclose that Defendants' prescription colon irrigation systems are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations only.

65. .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.

66. 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.

67. Plaintiff further prays that upon final hearing this Court order Defendants to restore all money or other property taken from identifiable persons by Defendants; 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.

68. 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.

69. 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.

70. 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).

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

72. 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

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