

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

FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION

Plaintiff, the STATE OF TEXAS, acting by and through Attorney General Greg Abbott (“State of Texas”), and Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, (“Defendants”) having consented to the entry of this Final Judgment and Permanent Injunction, and before any testimony is taken in this case and without Defendants admitting to any violations of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. §431.001 *et seq.* (“TFDCA”) or the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.21 *et seq.* (“DTPA”); or any other law, have jointly moved that the Court enter this Judgment.

Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, consent and agree to the entry of this Judgment and that the terms of said agreement are fair, just and equitable. Defendants further agree that the State of Texas’ execution of this Judgment does not constitute an approval by the State of Texas of their business practices.

Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, stipulate that the LIBBE Lower Bowel Evacuation colon irrigation systems and the LIBBE Rectal Tubes, any accessories to this system, or any 21 C.F.R. § 876.5220 colon irrigation systems, are prescription medical devices as cleared for marketing by the Federal Food and Drug Administration and are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, also stipulate that the term “colon irrigation system” used in this Final Judgment and Agreed Permanent Injunction includes prescription rectal nozzles and/or tubes, or any accessories/parts to the system as identified in 21 C.F.R. §876.5220, even if not explicitly stated in each term.

Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, also stipulate that Defendants’ indebtedness to the State of Texas for civil penalties, identified in paragraph 16 below, for violations of the TDPTA and TFDCA, having been found by this court to constitute a civil fine or penalty to and for a governmental unit and not compensation for actual pecuniary loss, would be a debt that would be nondischargeable in a subsequently filed bankruptcy proceeding under either Chapter 7 or Chapter 11 and that, in the event a voluntary or involuntary chapter 7 or chapter 11 bankruptcy proceeding is commenced against debtor, the debtor stipulates that she shall not contest either directly or indirectly future attempts, if any, by the State of Texas to have such debt declared nondischargeable in accordance with 11 U.S.C. § 523(a)(7).

The Court, after reading the pleadings and stipulations of the parties and it appearing to the Court that all parties agree to and have approved its entry of this Judgment, makes the following orders under the provisions of the TFDCA and the DTPA. The Court is of the opinion that, in view of these findings, said agreement should be and is hereby in all things approved, and accordingly that this Judgment should be entered.

IT IS THEREFORE ORDERED, ADJUDGED and DECREED THAT:

1. This Court has jurisdiction, through the TFDCA and the DTPA, over the subject matter and over all parties to this action.
2. Plaintiff's Original Petition states a claim for relief against TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually.
3. Venue of this matter is proper in Dallas County by virtue of the fact that Defendants are engaged in the business of advertising and marketing prescription colon irrigation systems and training services in Dallas County, Texas.
4. By entering into this Judgment, Defendants admit no wrongdoing and this Judgment does not constitute any evidence or admission of any kind regarding any issues set forth herein, nor does it acknowledge that Defendants have engaged in any unlawful activity, nor shall it be construed as evidence that Defendants have engaged in any methods, acts, practices, uses or solicitations declared to be unlawful under the TFDCA and the DTPA. Defendants do not admit the truth of any alleged facts, any of the characterizations of Defendants' alleged conduct, or any of the conclusions in Plaintiff's Original Petition, or any amended pleadings pertaining to this matter.
5. The following definitions shall be used in construing this Judgment:

- A. “Adequate directions for use” means directions under which the layman can use a medical device safely and for the purposes for which it is intended as defined in 21 C.F.R. §801.5.
- B. “Adulterate” means any violation of § 431.111 of the Texas Health and Safety Code.
- C. “Advertising” means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics.
- D. “Colon irrigation systems”, as used in this injunction, shall mean the LIBBE Lower Bowel Evacuation colon irrigation systems, the LIBBE Rectal Tubes, any accessories to this system, or any colon irrigation systems, rectal nozzles and/or tubes, or accessories/parts to the system as identified in 21 C.F.R. §876.5220.
- E. “Country” means a country other than the United States.
- F. “Dangerous drug” means a device or drug that is unsafe for self-medication that bears or is required to bear a federal legend, as defined by Chapter 483, Texas Dangerous Drug Act, of the Texas Health and Safety Code.
- G. “False advertisement” of a food, drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any particular as defined in §431.182(a) of the TFDCA.
- H. “FDA” means the Federal Food and Drug Administration.
- I. “Federal Act” means the Federal Food, Drug and Cosmetic Act.
- J. “Labeling” means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
- K. “Medical device reporting requirements” means reporting requirements in Section 519 of the Federal Act.
- L. “Misbrand” a device means any violation of §431.112 of the Texas Health and Safety Code, including but not limited to, labeling of a device if it is false or misleading in any particular; labeling of a device without adequate directions for use unless otherwise exempted; advertising of a restricted device if the advertising is false or misleading in any particular; or if a restricted device is sold, distributed, or used by Defendants in violation of federal regulations.
- M. “Practitioner” within the State of Texas means a person as defined in §483.001 (12),

Texas Dangerous Drug Act, TEX. HEALTH AND SAFETY CODE ANN or as defined in other states' or countries' laws or regulations authorizing a practitioner_licensed by that state or country to use or order the use of such device.

- N. "Prescription device(s)" means device(s) 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 direction for use" cannot be prepared; and therefore are required to be 1) in the possession of a practitioner, licensed by law to use or order the use of such device and 2) is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice. The label of the device bears the statement: "Caution: Federal law restricts this device to sale by or on the order of a _____" with the blank filled in with the word "physician" or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device, as required by 21 CFR § 801.109.
- O. "Purchaser" means a practitioner or a person on the prescription or other order of such practitioner for use in the course of the practitioner's professional practice in compliance with 21 CFR § 801.109 (a)(2).
- P. "State" means one of the fifty states in the United States.
- Q. "User" means a practitioner or person supervised by a practitioner who provides colon irrigation services or uses prescription colon irrigation systems in the course of the practitioner's professional practice in compliance with 21 CFR § 801.109.

6. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, and their officers, agents, servants, employees, subsidiaries, assigns, and any other person acting in concert or participation with or on behalf of TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, and all such persons or entities shall not in the future:

- A. Sell prescription colon irrigation systems to a purchaser except on the order of a practitioner licensed by the laws of the state or country of the purchaser to use or order

the use of such devices;

- B. Use prescription colon irrigation systems except on the order of a practitioner licensed to use or order the use of such devices under the law of the state or country of the user and under the supervision of a practitioner licensed by the laws of the state or country of the user to direct the use of such devices;
- C. Advertise or represent that prescription colon irrigation systems do not need to be purchased or possessed without the order of a practitioner licensed by the laws of the state or country of the purchaser or used without the supervision of a practitioner licensed by the laws of the state or country of the user to direct the use of such devices;
- D. Misbrand prescription colon irrigation systems by advertising, representing, and using such devices for uses not approved by FDA;
- E. Adulterate prescription colon irrigation systems by advertising such devices for uses not approved by FDA;
- F. Adulterate prescription colon irrigation systems by using and causing such devices to be used for uses not approved by FDA;
- G. Advertise that prescription colon irrigation systems can be self-administered;
- H. Advertise that prescription colon irrigation systems are effective for general well-being unless the FDA has approved these devices for such use;
- I. Advertise and promote that an investigational study exists using prescription colon irrigation systems without an investigational device exemption approved by the FDA;

- J. Introduce or deliver into commerce misbranded or adulterated prescription colon irrigation systems;
- K. Misbrand prescription colon irrigation systems in commerce;
- L. Adulterate prescription colon irrigation systems in commerce;
- M. Disseminate false advertising of a prescription colon irrigation system;
- N. Fail to provide a notice required by Section 510 (k) or obtain approval required by Section 515 of the Federal Act prior to introducing into commerce a colon irrigation system for a new or unapproved use, unless exempt by a 520(g) investigational device exemption;
- O. Fail to comply with any requirement required by 520(g) of the Federal Act regarding any investigational device exemption in which Defendants are involved;
- P. Fail to comply with federal medical device reporting requirements to report a serious injury and/or death, as required by 21 CFR § 803 and Section 519 of the Federal Act;
- Q. Manufacture prescription colon irrigation systems in Texas without complying with the labeling requirements of 21 CFR 801.109, including placing a label on the device as required by federal law;
- R. Cause confusion as to the approval of a good by selling prescription colon irrigation systems without the authorization or order of practitioner licensed by the laws of the state or country of the purchaser to use or order the use of such devices;
- S. Fail to disclose that prescription colon irrigation systems are to be sold only to or on the prescription or other order of a practitioner licensed by the laws of the state or country

of the purchaser to use or order the use of such devices;

- T. Fail to disclose in any advertisement, training or user manual, or publication that prescription colon irrigation systems are only to be used by or on the order of a practitioner licensed by the laws of the state or country of the user to use or order the use of such devices;
- U. Fail to disclose in any representation regarding the purchase or use of colon irrigation systems that prescription colon irrigation systems are only to be used by or on the order of a practitioner licensed by the laws of the state or country of the user to use or order the use of such devices;
- V. Fail to disclose in any advertisement, training or user manual, or publication that prescription colon irrigation can only be used by or under the supervision of a practitioner licensed by the laws of the state or country of the user to direct the use of such devices;
- W. Fail to disclose in any representation regarding the purchase or use of colon irrigation systems that prescription colon irrigation systems can only be used by or under the supervision of a practitioner licensed by the laws of the state or country of the user to direct the use of such devices;
- X. Represent to a consumer that colon cleansing using prescription colon irrigation systems can legally be performed without the order of a practitioner licensed by the laws of the state or country of the user to use or order the use of such devices and under the supervision of a practitioner licensed by the laws of the state or country of the user to

direct the use of such devices;

- Y. Fail to disclose in training services related to the use of prescription colon irrigation systems that such devices must be used by or under the supervision of a practitioner licensed by the laws of the state or country of the user to direct the use of such devices;
- Z. Fail to disclose in training services related to the use of prescription colon irrigation systems that the use of such devices for each patient must be ordered in writing by a practitioner licensed by the laws of the state or country of the user to use or order the use of such devices;
- AA. Fail to disclose in training services related to the use of prescription colon irrigation systems that such devices can only be sold to or on a written order from a practitioner licensed by the laws of the state or country of the purchaser to use or order the use of such devices;
- BB. Perform colon irrigation services using prescription colon irrigation systems, without a written order in the patient's file from a practitioner licensed by the laws of the state or country of the user to use or order the use of such devices; and
- CC. Fail to disclose that Defendants' prescription colon irrigation systems are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations, as identified in 21 C.F.R. §876.5220.

7. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, shall, prior to manufacturing, marketing, or selling any prescription colon irrigation systems

develop, adopt, and implement labeling and marketing materials that clearly and conspicuously disclose that purchasing, holding, possessing and/or using of prescription colon irrigation systems requires a practitioner licensed by the laws of the state of the purchaser and/or user to use or order the use of such devices.

8. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, shall clearly and conspicuously disclose in any marketing, advertising, consulting, or training information or materials, whether in writing or orally, that the purchasing, holding, possessing, or using prescription colon irrigation systems requires an order by a practitioner licensed by the laws of the state or country of the purchaser to use or order the use of such devices and the supervision of a practitioner licensed by the laws of the state or country of the user to direct the use of such devices.

9. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, must disclose in any advertising, marketing, or representations regarding the purchase or use of colon irrigation systems, whether oral or in writing, relating to prescription colon irrigation systems that such devices are prescription medical devices and approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations, as identified in 21 C.F.R. §876.5220.

10. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually,

shall develop, adopt, and implement protocols to insure that a written order from a practitioner licensed by the laws of the state of the purchaser or user to use or order the use of such devices is in Defendants' files prior to the sale or use of the system and kept in compliance with state and federal laws.

11. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, shall notify, in writing within 30 days of the entry of this Final Judgment, all of the previous persons or businesses who purchased its colon irrigation systems, the LIBBE Rectal Tubes, or any accessories/parts to the system, as identified in 21 C.F.R. §876.5220, from Defendants that these colon irrigation systems are prescription devices and approved only for colon cleansing by the FDA, when medically indicated, such as before radiologic or endoscopic examinations.

12. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, shall provide a copy of "Exhibit A" to this judgment to all persons or businesses who use Defendants' prescription colon irrigation devices to train colon hydrotherapists or who market or distribute Defendants' prescription colon irrigation devices and Defendants shall cease doing business with any person or business who violates the terms of "Exhibit A" to this judgment through their training, advertisements, marketing, or representations of Defendants' devices.

13. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually,

shall develop, adopt, and implement protocols, in conjunction with a licensed practitioner in Texas who is the medical director for Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, for the purposes of supervision of and delegation of health care tasks in compliance with Chapter 151 of the TEXAS OCCUPATIONS CODE ANN, regulating the practice of medicine in Texas, concerning the using of prescription colon irrigation systems, including rectal nozzles or tubes.

14. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, shall not advertise, print, sell, or distribute in any manner the brochure “Are You A Toxic Waste Site” or any other brochure that makes any reference to any use or benefit of colon hydrotherapy other than its approved use for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations, as identified in 21 C.F.R. §876.5220, and Defendants shall remove the brochure and all advertisements and links to this brochure from Defendants’ website.

15. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, shall not describe, advertise, promote, or market the use of medical oxygen in conjunction with their prescription colon irrigation systems unless FDA approves, in writing, the use of oxygen injection with Defendants’ devices. This prohibition includes, but is not limited to, any advertising, promotional, or marketing information and any representations whether in writing or oral.

16. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, shall pay and deliver Thirty-Three Thousand Five Hundred Dollars (\$33,500.00) to the Office of the Attorney General as civil penalties pursuant to § 431.0585 of the TFDCA and to DTPA §17.47(c)(1) A. THIS ORDER shall further constitute a judicial determination that these civil penalties shall constitute a civil fine or penalty to and for a governmental unit, as defined under 11 U.S.C. § 101(27), and are not compensation for actual pecuniary loss.

17. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, shall pay and deliver Ten Thousand Dollars (\$10,000.00) to the Office of the Attorney General as attorneys fees and investigative costs under § 431.047 of the TFDCA and the TEX. GOVT. CODE § 402.006(c).

18. **IT IS FURTHER ORDERED THAT** Defendants TILLER MIND BODY, INC., d/b/a MIND BODY NATUROPATHIC INSTITUTE, and JERI TILLER, individually, shall pay Six Thousand Five Hundred Dollars (\$6,500.00) to the Texas Department of State Health Services, formerly the Texas Department of Health, to cover their investigative costs pursuant to § 431.047 of the TFDCA.

19. **IT IS FURTHER ORDERED** that Defendants shall pay all costs of the Court.

20. The clerk of the Court is authorized to issue such writs of execution or other

process necessary to collect and enforce this Judgment.

21. The Court retains jurisdiction to enforce this Judgment.

22. It is agreed and understood that this Judgment shall in no way affect the rights of individual citizens.

23. It is agreed and understood that this Final Judgment and Agreed Permanent Injunction is intended to comply with the applicable Federal statutes and regulations and Texas statutes and regulations regarding the use of prescription colon irrigation systems. In the event that the applicable federal or state statutes or regulations are modified to change the classification from Class II or Class III, as identified in 21 C.F.R. §876.5220, or to change the prescriptive status of colon irrigation systems, this Final Judgment and Agreed Permanent Injunction will be construed to incorporate the applicable modifications regulating the classification and use of these devices.

24. All relief not granted herein is hereby denied.

Signed this _____ day of _____, 2004.

DISTRICT JUDGE

THE UNDERSIGNED, WHO HAVE THE AUTHORITY TO CONSENT AND SIGN ON BEHALF OF THE PARTIES IN THIS ACTION, HEREBY CONSENT TO THE FORM AND CONTENTS OF THE FOREGOING FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION AND TO ITS ENTRY:

Signed this _____ day of _____, 2004.

**DEFENDANTS TILLER MIND BODY, INC., d/b/a MIND BODY
NATUROPATHIC INSTITUTE, and JERI TILLER, individually,**

By: _____
Jeri Tiller, President

By: _____
Jeri Tiller, individually

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