

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	
	§	
LISA F. RAMOIN d/b/a ALTERNATIVE	§	
HEALTH THERAPY, COLON HYDRO-	§	
THERAPY AND MASSAGE THERAPY,	§	
and COLONIC IRRIGATION AND	§	HARRIS COUNTY, TEXAS
MASSAGE CENTER	§	
Defendants.	§	____ JUDICIAL DISTRICT

FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION

Plaintiff, the STATE OF TEXAS, acting by and through Attorney General Greg Abbott (“State”), and Defendant, LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY, COLON HYDROTHERAPY AND MASSAGE THERAPY, and COLONIC IRRIGATION AND MASSAGE CENTER (“LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY”), having consented to the entry of this Final Judgment and Permanent Injunction, and before any testimony is taken in this case and without Defendant 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.

LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY consents and agrees to the entry of this Judgment and that the terms of said agreement are fair, just and equitable. Defendant further agrees that Plaintiff’s execution of this Judgment does not constitute an

approval by the Plaintiff of her business practices.

LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY stipulates that the **Tiller LIBBE colon hydrotherapy devices and rectal nozzles or tubes, owned and used by her**, are colon irrigation systems and prescription medical devices as cleared for marketing by the Federal Food and Drug Administration, pursuant to 21 C.F.R. § 876.5220, and are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY also stipulates that the term “colon irrigation system” used in this Final Judgment and Agreed Permanent Injunction includes all accessories and parts, such as rectal nozzles or tubes, even if not explicitly stated in each term.

LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY stipulates that the State of Texas’ agreement to and the Court’s approval of this Final Judgment are expressly premised upon Defendant’s compliance with Defendant’s stipulations 1) to dissolve the colon irrigation business owned and operated by LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY; 2) to cease marketing and advertising of all colon irrigation services; 3) to destroy Defendant’s two prescription colon irrigation systems; and 4) if she engages in the colon irrigation business again, she will only do so working directly under the supervision of a practitioner, as defined below, in his office; and that these stipulations are specifically relied upon by the State of Texas in negotiating and agreeing to the terms of this Final Judgment.

Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY stipulates to the amount of civil penalties, attorneys fees, and investigative costs listed **in paragraphs 7, 8, and 9 below, if Defendant fails to comply with paragraph 11 below.**

Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY stipulates that Defendant's indebtedness to the State of Texas for civil penalties, identified in **paragraph 7 below**, for violations of the DTPA 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 LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY.
3. Venue of this matter is proper in Harris County by virtue of the fact that Defendant is engaged in the business of advertising and marketing prescription colon irrigation systems in Texas and the Texas Food, Drug and Cosmetic Act allows for any action alleging

violations of this act in the county where the violations occurred.

4. By entering into this Judgment, Defendant admits 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 Defendant has engaged in any unlawful activity, nor shall it be construed as evidence that Defendant has engaged in any methods, acts, practices, uses or solicitations declared to be unlawful under the TFDCa and the DTPA. Defendant does not admit the truth of any alleged facts, any of the characterizations of Defendant's 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. "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.
- B. "Adulterate" a device means to use a device in violation of § 431.111 of the Texas Health and Safety Code, including but not limited to, using a colon irrigation system for a use not approved by FDA or using a colon irrigation system for general well being.
- C. "Colon irrigation systems", as used in this injunction, shall mean any colon irrigation system, rectal nozzles or tubes, or any part of the system as defined in 21 CFR § 876.5220.
- D. "Dangerous drug" means a device or drug that is unsafe for self-medication that bears or is required to bear a federal legend such as: Caution: federal law prohibits dispensing without prescription as defined by Section 483, Dangerous Drug Act, of the Health and Safety Code.
- E. "False advertising" of a food, drug, device, or cosmetic means advertising that is false, deceptive, or misleading in any particular.
- F. "FDA" means the Federal Food and Drug Administration.
- G. "Federal Act" means the Federal Food, Drug and Cosmetic Act.

- H. “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.
- I. “Medical device reporting requirements” means reporting requirements in Section 519 of the Federal Act.
- J. “Misbrand” a device means any violation of §431.112 of the Texas Health and Safety Code, including but not limited to, labeling for a device if it is false or misleading in any particular; labeling of a device without adequate directions for use; 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 in violation of federal regulations.
- K. “Physician” means a person licensed to practice medicine in this state as defined in § 151.002 (a)(12) of the TEXAS OCCUPATIONS CODE ANN.
- L. “Practitioner” means a person as defined in §483.001 (12), Texas Dangerous Drug Act, TEX. HEALTH AND SAFETY CODE ANN.
- M. “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 directions for use cannot be prepared; and therefore are required to bear a federal legend that states: “Caution: Federal law restricts this device to sale by or on the order of a _____” with the blank filled in with the designation of a 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.

6. **IT IS FURTHER ORDERED THAT** if Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY or any of her officers, agents, servants, employees, subsidiaries, assigns and any other person acting in concert or participation with or on behalf of LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY enters into any business relating to colon irrigation that all such persons or entities shall not:

- a. **Purchase and possess prescription colon irrigation systems, including rectal nozzles or tubes, without a practitioner licensed under Texas law to purchase and possess such devices;**

- b. Use prescription colon irrigation systems, including rectal nozzles or tubes, without the supervision of a practitioner licensed by Texas law to use such devices;
- c. Use prescription colon irrigation systems, including rectal nozzles or tubes, without a written order for each use from a practitioner licensed under Texas law to order the use of such prescription devices;
- d. Use prescription colon irrigation systems, including rectal nozzles for treating diseases of the body or for uses for which FDA has not approved these devices;
- e. Falsely advertise or falsely represent that prescription colon irrigation systems, including rectal nozzles or tubes, can be self-administered;
- f. Falsely advertise or falsely represent that prescription colon irrigation systems, including rectal nozzles or tubes, are effective for general well being if FDA has not approved these devices for such use;
- g. Fail to disclose that Defendant's prescription colon irrigation systems are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations;
- h. Fail to comply with federal medical device reporting requirements, as required by 21 CFR § 803 and Section 519 of the federal Act;
- i. Fail to disclose that the prescription colon irrigation systems used for colon irrigation are only to be used under the written order and supervision of a practitioner licensed in Texas; and
- j. Cause confusion as to the approval of a good by allowing consumers to use prescription colon irrigation systems, including rectal nozzles, for self-use.

7. **IT IS FURTHER ORDERED THAT** Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY shall pay Twelve Thousand Dollars (\$12,000.00) to the Office of the Attorney General as civil penalties pursuant to §431.0585 of the TFDCA and to DTPA §17.47(c)(1)-(2). 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, subject to paragraphs 9-12 below.

8. **IT IS FURTHER ORDERED THAT** Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY shall pay One Thousand Dollars (\$1,000.00) 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) and One Thousand Dollars (\$1,000.00) to cover the investigative costs pursuant to §431.047 of the TFDCA for the Texas Department of State Health Services (formerly the Texas Department of Health), subject to paragraphs 9 and 10 below.

9. **IT IS FURTHER ORDERED THAT** ninety-one (91) days following receipt by the State of Texas from Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY of the total sum of Two Thousand Dollars (\$2,000.00) to the Office of the Attorney General, with One Thousand Dollars (\$1,000.00) designated as attorneys fees and investigative costs under §431.047 of the TFDCA and the TEX. GOVT. CODE §402.006(c); and One Thousand Dollars (\$1,000.00) to Texas Department of State Health Services to cover the investigative costs pursuant to §431.047 of the TFDCA, the State of Texas shall consider the monetary portion of the Final Judgment, as ordered in paragraphs 7 and 8 above, satisfied in full unless the State has evidence that this Final Judgment should be reopened as outlined in paragraph 12 below. The State of Texas then may reopen this Final Judgment for the sole purpose of allowing the State of Texas to modify the monetary liability of the Defendant.

10. **IT IS FURTHER ORDERED THAT** Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY, within 30 days of this Order being signed by the

Court, shall at her own expense destroy, under supervision by the Texas Department of State Health Services, all colon irrigation systems, including any accessories, such as rectal nozzles or tubes.

11. **IT IS FURTHER ORDERED THAT** Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY's agreement to and the Court's approval of this Final Judgment are expressly premised upon the above stipulations, as relied upon by the State of Texas in negotiating and agreeing to the terms of this Final Judgment.

12. **IT IS FURTHER ORDERED** that if the State of Texas has evidence that the Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY fails to comply with Defendant's stipulations listed above, the State of Texas may reopen this Final Judgment for the sole purpose of allowing the State of Texas to modify the monetary liability of the Defendant. If the Court finds that Defendant failed to comply with the above stipulations relating to dissolving the colon irrigation business owned and operated by LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY; ceasing the marketing and advertising of all colon irrigation services; destroying Defendant's prescription colon irrigation systems; and, if engaging in the colon irrigation business again, only doing so working directly under the supervision of a practitioner, as defined above, in the practitioner's office, the Court shall reinstate the suspended judgment against Defendant LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY, in favor of the State of Texas, in the amounts listed in paragraphs 7 and 8 above. All other terms of this Final Judgment shall remain in full force and effect unless otherwise ordered by the Court. For the purposes of reopening or enforcing this Final Judgment, Defendant LISA F. RAMOIN

d/b/a ALTERNATIVE HEALTH THERAPY waives any right to contest any of the allegations set forth in **Plaintiff's Original Petition filed in this matter.**

13. **IT IS FURTHER ORDERED** that Defendant shall pay all costs of the Court.

14. The clerk of the Court is authorized to issue such writs of execution or other process necessary to collect and enforce this Judgment.

15. The Court retains jurisdiction to enforce this Judgment.

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

17. 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.

DEFENDANT LISA F. RAMOIN d/b/a ALTERNATIVE HEALTH THERAPY

By: _____
LISA F. RAMOIN

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