

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	
	§	
SOLEDAD HERRERA d/b/a/	§	EL PASO COUNTY, T E X A S
BODY MATTERS	§	
Defendant.	§	____ JUDICIAL DISTRICT

FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION

Plaintiff, the STATE OF TEXAS, acting by and through Attorney General Greg Abbott (“State”), and SOLEDAD HERRERA d/b/a BODY MATTERS (“Defendant”), 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.

SOLEDAD HERRERA d/b/a BODY MATTERS 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.

SOLEDAD HERRERA d/b/a BODY MATTERS stipulates that the Jimmy John III prescription colon irrigation system from Colon Therapeutics, Inc., and its rectal nozzles that she possessed and purchased 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.

SOLEDAD HERRERA d/b/a BODY MATTERS 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.

SOLEDAD HERRERA d/b/a BODY MATTERS stipulates that the State of Texas’ agreement to and the Court’s approval of this Final Judgment are expressly premised upon either the sale to a practitioner licensed in Texas of Defendant’s prescription colon irrigation system in conjunction with the State Department of Health Services and her ceasing of marketing and advertising of all colon irrigation services; and that these stipulations are specifically relied upon by the State of Texas in negotiating and agreeing to the terms of this Final Judgment.

SOLEDAD HERRERA d/b/a BODY MATTERS stipulates to the amount of civil penalties, attorneys fees, and investigative costs listed **in paragraphs 9, 10, and 11 below, if Defendant fails to comply with paragraph 13 below.**

SOLEDAD HERRERA d/b/a BODY MATTERS stipulates that Defendant’s indebtedness to the State of Texas for civil penalties, identified in **paragraph 9 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 SOLEDAD HERRERA d/b/a BODY MATTERS.
3. Venue of this matter is proper in Travis County by virtue of the fact that Defendant is or was engaged in the business of operating a health-related clinic using prescription medical devices in El Paso County, Texas and the Texas Food, Drug and Cosmetic Act provides for venue in either the county where the violations occurred or in Travis County.
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** Defendant SOLEDAD HERRERA d/b/a BODY MATTERS and her officers, agents, servants, employees, subsidiaries, assigns and any other person acting in concert or participation with or on behalf of SOLEDAD HERRERA d/b/a BODY MATTERS and all such persons or entities shall not in the future:

- 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, including general well being 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 advertising or falsely representing that prescription colon irrigation systems, including rectal nozzles or tubes, are effective for treating diseases of the body for which FDA has not approved these devices;
- g. 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;

- h. Fail to disclose that Defendant's prescription colon irrigation system is approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations;
- i. Fail to comply with federal medical device reporting requirements, as required by 21 CFR § 803 and Section 519 of the federal Act;
- j. 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;
- k. Advertise that prescription colon irrigation systems can be self-administered when FDA has cleared these systems only for use by a practitioner or under the supervision of a practitioner;
- l. Misbrand or adulterate prescription colon irrigation systems, including rectal nozzles or tubes in commerce;
- m. Cause confusion as to the approval of a good by allowing consumers to use prescription colon irrigation systems, including rectal nozzles, for self-use;
- n. Use or advertise oxygen bars to filter toxins from the blood and relieve stress and headaches because these devices are unapproved medical devices; and
- o. Fail 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.

7. **IT IS FURTHER ORDERED THAT** if Defendant SOLEDAD HERRERA d/b/a BODY MATTERS purchases, holds, possesses, or uses prescription colon irrigation systems, Defendant shall develop, adopt, and implement protocols, in conjunction with a licensed practitioner who is the medical director for SOLEDAD HERRERA d/b/a BODY MATTERS 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 purchasing, holding, possessing, and using of prescription colon irrigation systems, including rectal nozzles or tubes.

8. **IT IS FURTHER ORDERED THAT** Defendant SOLEDAD HERRERA d/b/a BODY MATTERS shall not promote or allow the use of any colon irrigation system, that is a prescription device and defined as a dangerous drug under Texas law, except on the order of and under the direction and supervision of a licensed practitioner acting in compliance with Chapter 151 of the TEXAS OCCUPATIONS CODE ANN regulating the practice of medicine in Texas.

9. **IT IS FURTHER ORDERED THAT** SOLEDAD HERRERA d/b/a BODY MATTERS shall pay and deliver Five Thousand DOLLARS (\$5,000.00) to the Office of the Attorney General as civil penalties pursuant to § 431.0585 of the TFDCA and to DTPA §17.47(c)(1) 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, subject to paragraphs 12-13 below.

10. **IT IS FURTHER ORDERED THAT** SOLEDAD HERRERA d/b/a BODY MATTERS, shall pay and deliver to the Office of the Attorney General One Thousand Dollars (\$1,000.00) as attorneys fees and investigative costs under § 431.047 of the TFDCA and the TEX. GOVT. CODE § 402.006(c).

11. **IT IS FURTHER ORDERED THAT** SOLEDAD HERRERA d/b/a BODY MATTERS shall pay and deliver One Thousand Hundred Dollars (\$1,000.00) to the Texas Department of State Health Services to cover their investigative costs pursuant to § 431.047 of the TFDCA.

12. **IT IS FURTHER ORDERED** that SOLEDAD HERRERA d/b/a BODY MATTERS' 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.

13. **IT IS FURTHER ORDERED** that ninety-one (91) days following receipt by the State of Texas from SOLEDAD HERRERA d/b/a BODY MATTERS of the total sum of Two Thousand Dollars (\$2,000.00), as ordered in paragraph 9, 10, and 11 above with One Thousand Dollars (\$1,000.00) designated as attorney fees and One Thousand Dollars (\$1,000.00) designated as costs to Texas Department of State Health Services , the State of Texas shall consider the monetary portion of the Final Judgment, including the civil penalty specified in paragraph 9 above, satisfied in full unless the State has evidence that this Final Judgment should be reopened as outlined in paragraph 14 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.

14. **IT IS FURTHER ORDERED** that if the State of Texas has evidence that the SOLEDAD HERRERA d/b/a BODY MATTERS 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 ceasing the marketing and advertising of all colon irrigation, the Court shall reinstate the suspended judgment against Defendant SOLEDAD HERRERA d/b/a BODY MATTERS, in favor of the State of Texas, in the amounts listed in paragraphs 9, 10, and 11 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, SOLEDAD HERRERA d/b/a BODY MATTERS waives any right to contest any of the allegations set forth in **Plaintiff's Original Petition filed in this matter.**

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

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

17. The Court retains jurisdiction to enforce this Judgment.

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

19. All relief not granted herein is hereby denied.

Signed this _____ day of _____, 2005.

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 _____, 2005.

DEFENDANT SOLEDAD HERRERA d/b/a BODY MATTERS

By: _____

SOLEDAD HERRERA

Owner

Body Matters

4300 31st N

Arlington, VA 22207

Date: _____

Plaintiff State of Texas

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