

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
	§	
Plaintiff	§	
	§	
VS.	§	
	§	
LIFESTREAM PURIFICATION	§	
SYSTEMS, LLC.	§	DALLAS COUNTY, T E X A S
	§	
Defendant.	§	____ JUDICIAL DISTRICT

FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION

Plaintiff, the STATE OF TEXAS, acting by and through Attorney General Greg Abbott (“ATTORNEY GENERAL”), and Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., 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.

Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., consent and agree 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 their business practices.

Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., stipulates that the Angel of Water Colon Hydrotherapy System and its accessories/parts, such as disposable tubing and rectal nozzles, 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.

Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., also stipulates that the term “colon irrigation system” used in this Final Judgment and Agreed Permanent Injunction includes accessories, such as disposable tubing and 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.

Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., 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 to pay the amounts required in paragraphs 12, 13, and 14 below and to comply with the terms of this injunction regarding the manufacturing, marketing, and advertising of colon irrigation systems, including any accessories, parts, nozzles, and tubes; 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 LIFESTREAM PURIFICATION SYSTEMS, LLC., stipulates to the amount of civil penalties, attorneys fees, and investigative costs listed in paragraphs 12, 13, and 14 below, if Defendants fail to comply with paragraph 17 below.

LIFESTREAM PURIFICATION SYSTEMS, LLC., also stipulates that Defendant’s

indebtedness to the State of Texas for civil penalties, identified in paragraph 12 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 LIFESTREAM PURIFICATION SYSTEMS, LLC.
3. Venue of this matter is proper in Travis County by virtue of the fact that Defendant is engaged in the business of advertising and marketing prescription colon irrigation systems in Travis County, Texas.
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. "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 if FDA has not approved such a use.
 - B. "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.
 - C. "Colon irrigation systems", as used in this injunction, shall mean the Angel of Water Colon Hydrotherapy System and any accessories/parts, such as rectal nozzles or tubes or disposable tubing, or any colon irrigation systems or accessories/parts to the system as identified in 21 C.F.R. §876.5220.
 - D. "Dangerous drug" means a device or drug that is unsafe for self-medication and is required to bear a legend that complies with federal law, as described by Section 483, Dangerous Drug Act, of the Health and Safety Code.
 - E. "False advertisement" of a food, drug, device, or cosmetic shall be deemed to be false if it is false 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 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 in violation of federal regulations.
- K. “Practitioner” 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.
- L. “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.
- M. “Purchaser” means a practitioner or a person authorized by a practitioner to purchase a prescription colon irrigation system.
- N. “User” means a practitioner or person authorized and supervised by a practitioner who provides colon irrigation services or uses prescription colon irrigation systems.

6. **IT IS FURTHER ORDERED THAT** Defendant LIFESTREAM

PURIFICATION SYSTEMS, LLC., and its officers, agents, servants, employees, subsidiaries, assigns and any other person acting in concert or participation with or on behalf of LIFESTREAM PURIFICATION SYSTEMS, LLC., and all such persons or entities shall not in the future:

- A. Misbrand prescription colon irrigation systems by selling such devices to a person 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. Advertise or represent that prescription colon irrigation systems do not need to be purchased, possessed, used, or supervised by a practitioner licensed to use or order the use of such devices under the law of the state or country of the purchaser and/or user;
 - C. Misbrand prescription colon irrigation systems by advertising and representing that such devices can be used for uses not approved by FDA;
 - D. Adulterate prescription colon irrigation systems by advertising such devices for uses not approved by FDA;
 - E. Introduce or deliver or cause the introduction or delivery into commerce of misbranded prescription colon irrigation systems by failing to properly label, including the required federal prescription legend, any accessory, such as nozzles and tubing;
 - F. Cause the receiving in commerce of a prescription colon irrigation system that is adulterated or misbranded;
 - G. Disseminate false advertising or cause the dissemination of false advertising of a prescription colon irrigation system;
 - H. Advertise that prescription colon irrigation systems can be self-administered when FDA has not approved these devices for such uses;
 - I. Cause confusion as to the approval of a good by selling accessories to prescription colon irrigation systems without a label as required by state and federal law;
 - J. Fail to disclose in any advertisement, representation, user manual, or

publication that prescription colon irrigation systems can only be performed upon 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 practitioner;

- K. 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;
- L. Fail to develop and implement written Medical Device Reporting procedures to report serious injuries and deaths alleged to involve Defendant's colon irrigation systems;
- M. Fail to keep adequate device history records with reference to or sample of labels and labeling for the Angel of Water Colon Hydrotherapy System, with dates and signatures indicating approval of inspections performed and methods/equipment used, and documentation of rework and reevaluation activities performed on nonconforming material report;
- N. Fail to maintain an adequate Device Master Record;
- O. Fail to perform quality audits at sufficient intervals; and
- P. Fail to obtain a license as a medical device manufacturer from the Texas Department of Health.

7. **IT IS FURTHER ORDERED THAT** Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., shall develop, adopt, and implement labeling and marketing materials that clearly and conspicuously disclose that purchasing, holding, possessing, or using of prescription colon irrigation systems requires a practitioner licensed to use or order the use of

such devices under the law of the state or country of the purchaser and/or user prior to manufacturing, marketing, selling, and delivering any such properly labeled devices.

8. **IT IS FURTHER ORDERED THAT** Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., shall clearly and conspicuously disclose in any marketing, advertising, consulting, or training information or materials that the purchasing, holding, possessing, and using prescription colon irrigation systems require a practitioner licensed to use or order the use of such devices under the law of the state or country of the purchaser and/or user.

9. **IT IS FURTHER ORDERED THAT** Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., must disclose in any advertising, marketing, or representations, whether oral or in writing, that its prescription colon irrigation systems are cleared for marketing by FDA only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

10. **IT IS FURTHER ORDERED THAT** Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., shall develop, adopt, and implement protocols, prior to selling any prescription colon irrigation systems for insuring that a written order from a practitioner licensed to use or order the use of such devices under the law of the state or country of the purchaser is secured and kept in compliance with state and federal laws.

11. **IT IS FURTHER ORDERED THAT** Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., shall notify, in writing within 30 days of the entry of this Final Judgment, all of the previous purchasers of the Angel of Water Colon Hydrotherapy System from Defendant that these colon irrigation devices are prescription devices as cleared by the FDA and approved only for colon cleansing, when medically indicated, such as before

radiologic or endoscopic examinations.

12. **IT IS FURTHER ORDERED THAT** Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., shall pay and deliver Twenty-five Thousand (((\$25,000.00)) 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 15, 16, and 17 below.

13. **IT IS FURTHER ORDERED THAT** Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., shall pay and deliver Two Thousand Dollars (\$2,000.00) 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) subject to paragraphs 15, 16, and 17 below.

14. **IT IS FURTHER ORDERED THAT** Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., shall pay Three Thousand Dollars (\$3,000.00) 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 subject to paragraphs 15, 16, and 17 below.

15. **IT IS FURTHER ORDERED** that ninety-one (91) days following receipt by the State of Texas from Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., of the total sum of Six Thousand Dollars (\$6,000.00) to the Office of the Attorney General, with One Thousand Dollars (\$1,000.00) payable as civil penalties pursuant to § 431.0585 of the TFDCA and to DTPA §17.47(c)(1)-(2); with Two Thousand Dollars (\$2,000.00) designated as attorneys

fees and investigative costs under § 431.047 of the TFDCA and the TEX. GOVT. CODE §402.006 (c); and Three Thousand Dollars (\$3,000.00) to the 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 12, 13, and 14 above, satisfied in full unless the State has evidence that this Final Judgment should be reopened as outlined in paragraph 17 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 Defendant.

16. **IT IS FURTHER ORDERED** that Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC.,’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.

17. **IT IS FURTHER ORDERED** that if the State of Texas has evidence that the Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., 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 Defendant. If the Court finds that Defendant failed to comply with the above stipulations relating to compliance with the terms of this injunction regarding the manufacturing, marketing, and advertising of colon irrigation systems, including any accessories, parts, nozzles, and tubes, the Court shall reinstate the suspended judgment against Defendant LIFESTREAM PURIFICATION SYSTEMS, LLC., in favor of the State of Texas, in the amounts listed in paragraphs 12, 13, and 14 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

LIFESTREAM PURIFICATION SYSTEMS, LLC., waives any right to contest any of the allegations set forth in Plaintiff's Original Petition filed in this matter.

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

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

20. The Court retains jurisdiction to enforce this Judgment.

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

22. 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 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.

23. 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:

Date: _____

DEFENDANT LIFESTREAM PURIFICATION SYSTEMS, LLC.,

By: _____
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