

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	
	§	
GENTLE COLONICS, INC., and	§	DALLAS COUNTY, T E X A S
DENSON INGRAM, individually,	§	
Defendants.	§	____ JUDICIAL DISTRICT

FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION

Plaintiff, the STATE OF TEXAS, acting by and through Attorney General Greg Abbott (“ATTORNEY GENERAL”), and Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, 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 GENTLE COLONICS, INC., and DENSON INGRAM, 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 Plaintiff’s execution of this Judgment does not constitute an approval by the Plaintiff of their business practices.

Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, stipulate that the Gentle Colonics Irrigation System and the GC Irrigator 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.

Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, also stipulate 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.

Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, stipulate that the State of Texas’ agreement to and the Court’s approval of this Final Judgment are expressly premised upon Defendants’ compliance with Defendants’ stipulations 1) to dissolve GENTLE COLONICS, INC.; 2) to cease the manufacturing, marketing, and advertising of all colon irrigation systems, including any accessories, parts, nozzles, and tubes; 3) not to sell, give, use, or transfer any of Defendants’ 510(k) clearances for the Gentle Colonics Irrigation System and the GC Irrigator rectal nozzles to any individual or entity; and 4) not to engage in the colon irrigation business individually, in any partnership, or in cooperation with any other person or business; and that these stipulations are specifically relied upon by the State of Texas in negotiating and agreeing to the terms of this Final Judgment.

Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, stipulate that Defendants will not make any claims or representations or be involved in any way with the designing, manufacturing, marketing, using, or advertising of any Class I or Class II medical devices used to cleanse the colon.

Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually,

stipulate to the amount of civil penalties, attorneys fees, and investigative costs listed in paragraphs 7, 8, and 9 below, if Defendants fail to comply with paragraph 11 below.

Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, each stipulate that Defendants' 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 either debtor, the debtors stipulate that they 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 GENTLE COLONICS, INC., and DENSON INGRAM, individually.

3. Venue of this matter is proper in Dallas County by virtue of the fact that Defendants were engaged in the business of advertising and marketing colon irrigation systems 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. "Adulterate" a device means any violation of § 431.111 of the Texas Health and Safety Code.
- 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 Gentle Colonics Irrigation System, the GC Irrigator rectal nozzles, any accessories to this system, or any colon irrigation systems, rectal nozzles or tubes, and any 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 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.
- 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 as defined in §431.182(a) of the TFDCa.

- 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 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 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.
- 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 cleansing services or uses prescription colon irrigation systems.

6. **IT IS FURTHER ORDERED THAT** if Defendants GENTLE COLONICS, INC., or DENSON INGRAM, individually, or any of their officers, agents, servants, employees, subsidiaries, assigns, successors and any other person acting in concert or participation with or on behalf of GENTLE COLONICS, INC., or DENSON INGRAM, individually, enter into any

business related to colon irrigation that all such persons or entities shall not:

- A. Misbrand prescription colon irrigation systems by selling such devices to a person other than a practitioner licensed to use or order the use of such devices under the law of the state of the purchaser;
- 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 of the practitioner;
- 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 or adulterated prescription colon irrigation systems by failing to label these devices;
- F. Misbrand or cause the misbranding of any colon irrigation system or accessory, including rectal nozzles, in commerce by failing to label these devices;
- G. Cause the receiving in commerce of a prescription colon irrigation system that is adulterated or misbranded;
- H. Disseminate false advertising or cause the dissemination of false advertising of a prescription colon irrigation system;
- I. Advertise that prescription colon irrigation systems can be self-administered at home when FDA has not approved these devices for such uses; and

- J. Manufacture prescription colon irrigation systems in Texas without placing a label on the devices, including any accessory, such as rectal nozzles as required by federal law;
- K. Cause confusion as to the approval of a good by selling prescription colon irrigation systems without a label as required by state and federal law;
- L. 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 of the purchaser;
- M. 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;
- N. Fail to develop and implement written Medical Device Reporting procedures to report injuries and deaths alleged to involve Defendants' colon irrigation systems;
- O. Fail to develop and implement procedures for handling complaints; corrective and preventive actions; device history records; acceptance activities; design control; process controls; quality system and audit; and
- P. Fail to obtain a license as a medical device manufacturer from the Texas Department of Health.

MONETARY RELIEF

7. **IT IS FURTHER ORDERED THAT** Defendants GENTLE COLONICS, INC., or DENSON INGRAM, individually, shall pay Thirty-one Thousand Dollars (\$31,000.00) 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** Defendants GENTLE COLONICS, INC., or DENSON INGRAM, individually, shall pay One Thousand Five Hundred Dollars (\$1,500.00) 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 Two Thousand Five Hundred Dollars (\$2,500.00) to cover the investigative costs pursuant to § 431.047 of the TFDCa for 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 Defendants GENTLE COLONICS, INC., or DENSON INGRAM, individually, of the total sum of Five Thousand Dollars (\$5,000.00) 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 One Thousand Five Hundred Dollars (\$1,500.00) designated as attorneys fees and investigative costs under § 431.047 of the TFDCa and the TEX. GOVT. CODE §402.006 (c); and Two Thousand Five Hundred Dollars (\$2,500.00) to the Texas Department of Health 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 Defendants.

10. **IT IS FURTHER ORDERED THAT** Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, within 30 days of this Order being signed by the Court, shall at their own expense destroy, under supervision by the Texas Department of Health, all colon irrigation systems, including any accessories, such as rectal nozzles, currently under detention.

11. **IT IS FURTHER ORDERED** that Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, 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 Defendants GENTLE COLONICS, INC., or DENSON INGRAM, individually, fails to comply with Defendants' 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 Defendants. If the Court finds that Defendants failed to comply with the above stipulations relating to dissolving GENTLE COLONICS, INC.; ceasing the manufacturing, marketing, and advertising of all colon irrigation systems, including any accessories, parts, nozzles, and tubes; not selling, giving, using, or transferring any of Defendants' 510(k) clearances for the Gentle Colonics Irrigation System or the GC Irrigator rectal nozzles to any individual or entity; or not engaging in the colon irrigation business, the Court shall reinstate the suspended judgment against Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, 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, Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, waive 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** Defendants GENTLE COLONICS, INC., and DENSON INGRAM, individually, shall notify, in writing within 30 days of the entry of this Final Judgment, all of the previous purchasers of the Gentle Colonic irrigation systems, including nozzles, from Defendants that the State of Texas has determined 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 and that Defendants are no longer manufacturing colon irrigation systems or nozzles.

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

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

16. The Court retains jurisdiction to enforce this Judgment.

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

18. 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 GENTLE COLONICS, INC., and DENSON INGRAM, individually

By: _____
DENSON INGRAM, President
GENTLE COLONICS, INC.

By: _____
DENSON INGRAM, individually

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