

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	
	§	
COLON THERAPEUTICS, INC., and	§	DALLAS COUNTY, T E X A S
JIMMY JOHN GIROUARD, 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 COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, 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 COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, 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 COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, stipulate that the Jimmy John III colon irrigation devices, Jimmy John III rectal

nozzles, any accessories to this system, and any colon irrigation devices 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 COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually each stipulate that Defendants' 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 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).

Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, also stipulate that the term "colon irrigation system" used in this Final Judgment and Agreed Permanent Injunction includes prescription rectal nozzles, tubes, or any accessories to the system, even if not explicitly stated in each term.

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 COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, 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. "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. "Colon irrigation system", as used in this injunction, shall mean the Jimmy John III colon irrigation system, the Jimmy John III rectal nozzles, any accessories to this system, or any colon irrigation systems, rectal nozzles or tubes, or accessories to these systems.

- C. “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.
- D. “False advertisement” of a food, drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any particular.
- E. “FDA” means the Federal Food and Drug Administration.
- F. “Federal Act” means the Federal Food, Drug and Cosmetic Act.
- G. “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.
- H. “Medical device reporting requirements” means reporting requirements in Section 519 of the Federal Act.
- I. “Practitioner” means a person as defined in §483.001 (12), Texas Dangerous Drug Act, TEX. HEALTH AND SAFETY CODE ANN.
- J. “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.
- K. “Purchaser” means a practitioner or a person authorized by a practitioner to purchase a prescription colon irrigation system.
- L. “User” means a practitioner or person authorized and supervised by a practitioner who provides colon cleansing services using prescription colon irrigation systems.

6. **IT IS FURTHER ORDERED THAT** Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, and their officers, agents, servants, employees, subsidiaries, assigns and any other person acting in concert or participation with or

on behalf of COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, and all such persons or entities shall not in the future:

- 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. Misbrand prescription colon irrigation systems by causing 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 to purchase such devices;
- C. 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 purchaser;
- D. Misbrand prescription colon irrigation systems by advertising and representing that such devices are effective 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 causing such devices to be used for uses not approved by FDA;
- G. 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;
- H. Advertise that prescription colon irrigation systems are effective for general well-being when FDA has not 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 or cause the introduction or delivery into commerce of misbranded or adulterated prescription colon irrigation systems;
- K. Misbrand or cause the misbranding of a prescription colon irrigation system in commerce;
- L. Adulterate or cause the adulteration of a prescription colon irrigation system in commerce;
- M. Cause the receiving in commerce of a prescription colon irrigation system that is adulterated or misbranded;
- N. Disseminate false advertising or cause the dissemination of false advertising of a prescription colon irrigation system;
- O. 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;
- P. Fail to comply with any requirement required by 520(g) of the Federal Act by furnishing any notification or information regarding any investigational device exemption in which Defendant is involved;
- Q. 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;

- R. Manufacture prescription colon irrigation systems in Texas without complying with the labeling requirements of 21 C.F.R. 801.109, including placing a label on the device as required by federal law;
- S. Cause confusion as to the approval of a good by selling prescription colon irrigation systems without the authorization or order of practitioner licensed to use or order the use of such devices under the law of the state of the purchaser;
- T. Fail to disclose that prescription colon irrigation systems are only to be sold under the order or authorization of a practitioner licensed to use or order the use of such devices under the law of the state of the purchaser;
- U. Fail to disclose in any advertisement, representation, training or user manual, or publication that prescription colon irrigation systems are only to be used by a practitioner licensed to use or order the use of such devices under the law of the state of the user;
- V. Fail to disclose in any advertisement, representation, training or 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 user;
- W. Represent to a consumer that colon cleansing using prescription colon irrigation systems can legally be performed without the supervision and order of a practitioner licensed to use or order the use of such devices under the law of the state of the user;

- X. Fail to disclose in training services related to the use of prescription colon irrigation systems that a practitioner licensed to use or order the use of such devices under the law of the state of the user must order or supervise the use of such devices;
- Y. Fail to disclose in training services related to the use of prescription colon irrigation systems that a practitioner licensed to use or order the use of such devices under the law of the state of the user must order in writing each use of such devices for each patient;
- Z. 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 the order of a practitioner licensed to use or order the use of such devices under the law of the state of the user; and
- AA. 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.

7. **IT IS FURTHER ORDERED THAT** if Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, manufacture, market, or sell prescription colon irrigation systems, Defendants shall, prior to manufacturing, marketing, or selling any such devices 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 of

the purchaser and user.

8. **IT IS FURTHER ORDERED THAT** if Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, market, advertise, consult, or provide training services regarding prescription colon irrigation systems, Defendants shall clearly and conspicuously disclose, whether in writing or orally, 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 of the purchaser and user.

9. **IT IS FURTHER ORDERED THAT** if Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, engage in any advertising, marketing, or representations, whether oral or in writing, relating to prescription colon irrigation systems, Defendants must disclose that such devices are prescription medical devices and approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

10. **IT IS FURTHER ORDERED THAT** Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, shall, prior to selling any prescription colon irrigation systems, including nozzles, develop, adopt, and implement protocols 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 of the purchaser is secured prior to sale of the system and kept in compliance with state and federal laws.

11. **IT IS FURTHER ORDERED THAT** Defendants COLON

THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, shall notify, in writing within 30 days of the entry of this Final Judgment, all of the previous persons who purchased its colon irrigation systems, nozzles, tubes, or accessories from Defendants that these colon irrigation devices are prescription devices and approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

12. **IT IS FURTHER ORDERED THAT** Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, shall pay and deliver Fifty Thousand Dollars (\$50,000.00) 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 and are not compensation for actual pecuniary loss.

13. **IT IS FURTHER ORDERED THAT** Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, shall pay and deliver Eight Thousand Dollars (\$8,000.00) 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).

14. **IT IS FURTHER ORDERED THAT** Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, shall pay Five Thousand Dollars (\$5,000.00) to the Texas Department of Health to cover their investigative costs pursuant to § 431.047 of the TFDCa .

15. **IT IS FURTHER ORDERED** that Defendants 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 _____, 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 COLON THERAPEUTICS, INC. and JIMMY JOHN GIROUARD, individually,

By: _____
Jimmy John Girouard, President

By: _____
Jimmy John Girouard, individually

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