



2010CI21368 -D045

NO. 2010 - CI - 21368

STATE OF TEXAS,
Plaintiff,

IN THE DISTRICT COURT

vs.

ELITE MED, L.L.C.,
BRIAN BAILEY, INDIVIDUALLY;
AND S & B MARKETING, INC.

45th

JUDICIAL DISTRICT

Defendants.

BEXAR COUNTY, TEXAS

EX PARTE TEMPORARY RESTRAINING ORDER

Plaintiff, STATE OF TEXAS, has filed its Original Petition in this cause seeking a Temporary Injunction and Permanent Injunction against Defendants ELITE MED, L.L.C., BRIAN BAILEY, INDIVIDUALLY and S & B MARKETING, INC. In the same Petition, Plaintiff has presented its request for an Ex Parte Temporary Restraining Order. The Court FINDS that Defendants appear to be violating §§ 17.46(a) and (b) of the Texas Deceptive Trade Practices-Consumer Protection Act, TEX. BUS. & COMM. CODE §§ 17.41 *et seq.* ("DTPA") and the Texas Food, Drug and Cosmetic Act ("TFDCA"). It appears from facts set forth in Plaintiff's Original Petition, and the exhibits and sworn affidavits attached thereto, that unless Defendants are immediately restrained from the acts and practices prohibited below, Defendants will continue to commit such acts and practices before notice can be given and a hearing can be held on Plaintiff's request for a Temporary Injunction. Furthermore, Defendants will continue to use deceptive tactics and misrepresentations in the course of trade and commerce. Such injury would be irreparable, because continued violations of the DTPA, may well cause more Texas consumers to lose money through deceptive transactions.

INFORMED BY THE COURT

1. **IT IS THEREFORE ORDERED** that Defendants ELITE MED, L.L.C., BRIAN BAILEY, INDIVIDUALLY and S & B MARKETING, INC. and their officers, agents, servants, employees, attorneys, and any other persons or entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any trust, corporation, subsidiary, division, or other devise, shall be restrained from engaging in the following acts or practices, to wit:

- A) transferring, concealing, destroying, or removing from the jurisdiction of this Court any books, records, documents, invoices or other written or computer generated materials relating to the business of Defendants currently or hereafter in their possession, custody, or control except in response to further orders or subpoenas in this cause;
- B) Operating as a distributor of devices in the State of Texas without being licensed with the Texas Department of State Health Services;
- C) Purchasing devices from an unlicensed source or source that is not regularly and lawfully engaged in the distribution of devices in the United States or Texas;
- D) Introducing and delivering into commerce a misbranded device that has false or misleading labeling or advertising;
- E) Receiving into commerce a device that was misbranded and the delivering of that misbranded device for pay or otherwise;
- F) Failing to develop, maintain and implement written procedures to comply with medical device reporting (MDR) requirements in 21 CFR Part 803 and Section 519 of the federal Act;

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- G) Refusing inspection at any time by officials of the Texas Department of State Health Services or failing to produce all distribution records for devices;
- H) Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods by distributing unapproved and/or misbranded devices to doctors or medical practices;
- I) Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods by distributing devices that are not labeled in English and that fail to have the required labeling in English to doctors or medical practices;
- J) Representing that goods have sponsorship, approval characteristics, ingredients, uses, benefits, or quantities which they do not have by distributing devices that are not legal to distribute in the United States to doctors or medical practices;
- K) Representing that goods or services are of a particular standard, quality, or grade if they are of another standard, quality, or grade by distributing devices to doctors or medical practices that are manufactured for import only;
- L) Representing that a person or entity has a sponsorship, approval, status, affiliation, or connection to which the person or entity does not have by representing that the person or entity is licensed by the State of Texas and/or the Texas Department of State Health Services; and
- M) Failing to provide written notice to any agent, servant, employee or representative of the Defendants 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, ADJUDGED AND DECREED** that, as used in this

Order, the following terms are defined as follows:

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- A) "Consumer" means an individual, person, sole proprietorship, partnership, corporation, firm, or entity of any kind, however organized, including this state, or a subdivision or agency of this state who seeks or acquires, by purchase or lease, any goods or services;
- B) "Defendant(s)" means ELITE MED, L.L.C., BRIAN BAILEY, INDIVIDUALLY and S & B MARKETING, INC., their successors, assigns, officers, agents, subcontractors, servants, employees, corporations, and any other persons in active concert or participation with them;
- C) "Device," as defined in §431.002 (13) of the Texas Food, Drug, and Cosmetic Act, means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is recognized in the official United States Pharmacopoeia National Formulary or any supplement to it; is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or is intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependant on metabolization for the achievement of any of its principal intended purposes.
- D) "Device distributor," as defined in 431.271(1) of the Texas Food, Drug, and Cosmetic Act, means a person who furthers the marketing of a finished domestic or imported device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

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- E) "Device manufacturer," as defined in 431.271(4) of the Texas Food, Drug, and Cosmetic Act, means a person who manufactures, fabricates, assembles, or processes a finished device. The term includes a person who repackages or relabels a finished device.
- F) "FDA" means the Federal Food and Drug Administration;
- G) "Label," as defined in §431.002 (21) of the Texas Food, Drug, and Cosmetic Act, means a display of written, printed, or graphic matter upon the immediate container of any article
- H) "Labeling," as defined in §431.002 (22) of the Texas Food, Drug, and Cosmetic Act, means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.
- I) "Misbrand" a drug means any action or inaction which causes a drug to meet one or more of the criteria listed in §431.112 of the Texas Food, Drug, and Cosmetic Act, including but not limited to, labeling of a drug which lacks adequate directions for use, false or misleading in any particular, and the lack of prominent placement of any word, statement, or other information required by or under the authority of the Texas Food, Drug and Cosmetic Act to be placed on the label of the drug; and
- J) "Wholesale drug distributor," as defined in 431.401(12) of the Texas Food, Drug, and Cosmetic Act, means a person engaged in the wholesale distribution of prescription drugs, including a manufacturer, repackager, own-label distributor, broker, manufacturer warehouse, distributor warehouse, other warehouse, manufacturer's exclusive distributor, retail pharmacy that conducts wholesale distribution, and pharmacy warehouse that conducts wholesale distribution.

8. **IT IS FURTHER ORDERED** that Plaintiff STATE OF TEXAS shall be granted leave to conduct expedited discovery, take telephonic, video, written, and other depositions with Requests for Production of any party, person or witness prior to any scheduled Temporary Injunction hearing and prior to Defendants' answer date upon reasonable shortened notice to Defendants or their attorneys, if known, and that Plaintiff shall be granted leave to file any corresponding Business Records Affidavits with reasonable, shortened notice.

9. **IT IS FURTHER ORDERED** that Defendants in this cause be and hereby are commanded forthwith to comply with this Order from the date of entry until and to the fourteenth (14) day after entry, or until further order of this Court.

10. The Clerk of the above-entitled Court shall forthwith issue an Ex Parte Temporary Restraining Order in conformity with the law and the terms of this Order. This Order shall be effective without the execution and filing of a bond, as Plaintiff STATE OF TEXAS is exempt from such bond pursuant to TEX. BUS. & COM. CODE § 17.47(b).

11. Hearing on Plaintiff STATE OF TEXAS' Application for Temporary Injunction is hereby

set for the 13 day of Jan., 2011, at 9:00 o'clock a. m. in Presiding Ct.
SIGNED this 30 day of Dec., 2010 at 2:02 o'clock p. m. Room 218, Bann G. Ct.

[Signature]
JUDGE PRESIDING

Submitted by: Karyn A. Meinke
Name: _____

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