

CAUSE NO. _____

IN THE MATTER OF

§ IN THE DISTRICT COURT OF

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§ DALLAS COUNTY, T E X A S

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MAUREE N. HOGGAN

§

d/b/a FETAL FOTOS DALLAS

§

§

§ _____ JUDICIAL DISTRICT

ASSURANCE OF VOLUNTARY COMPLIANCE

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW the STATE OF TEXAS, acting by and through Attorney General Greg Abbott (“State”) and comes MAUREE N. HOGGAN d/b/a FETAL FOTOS, (“Respondent”) and respectfully submit the following Assurance of Voluntary Compliance (“AVC”) in accordance with the Deceptive Trade Practices-Consumer Protection Act, TEX. BUS. & COM. CODE ANN. § 17.58, (“DTPA”).

1. Respondent MAUREE N. HOGGAN d/b/a FETAL FOTOS has an office located at 3241 Preston Rd., Ste. 6, Frisco, Texas 75034, as a franchise of FETAL FOTOS, INC., a Utah corporation located at 4835 South Highland Drive, #2107, Salt Lake City, Utah 84117.

2. The Texas Department of Health (“TDH”), now re-organized as the Texas Department of State Health Services, conducted an inspection on March 23-24, 2004, and found that Respondent was conducting fetal ultrasound imaging procedures using a prescription ultrasound device without the supervision of a practitioner licensed by Texas law to use such

devices and without a prescription or other order from a practitioner for each ultrasound performed in violation of state and federal medical device laws and regulations. Respondent advertised that the services provided include gender determination, the number of fetuses, fetal heart movement which involve the practice of medicine. In addition, TDH found that Respondent promoted ultrasound imaging procedures for keepsake purposes or emotional and maternal bonding which are uses not approved by the Federal Food and Drug Administration (“FDA”). Respondent’s website, provided by FETAL FOTOS, INC., promotes the use of diagnostic ultrasound systems for “4D, 3D and 2D fetal imaging and unmatched accuracy in gender determination” and offers three different packages with keepsake videos and still pictures. TDH also determined that Respondent did not have written Medical Device Reporting (“MDR”) procedures for review as required by federal and state regulations.

3. The State alleges and Respondent denies that Respondent has violated the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.001, *et seq.* and the Deceptive Trade Practices-Consumer Protection Act, TEX. BUS. & COM. CODE ANN. § 17.41, *et seq.*

4. The State and Respondent have agreed to settle fully these differences and have agreed to do so by entering into the AVC; therefore Respondent admits to the applicability of the DTPA for jurisdictional purposes of entering into the AVC.

5. As used in this AVC, the following terms shall have the following meaning:

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 diagnostic ultrasound system for a use not approved by FDA or using a diagnostic ultrasound system for keepsake purposes or emotional and maternal well-being.
- C. “Diagnostic ultrasound systems”, as used in this section, shall mean any diagnostic ultrasound system, ultrasonic pulsed doppler imaging system, or ultrasound transducer, as defined in 21 CFR § 892.1550, 21 CFR § 892.1560, and 21 CFR § 892.1570.
- 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 21 CFR § 803.
- 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.

PROHIBITED PRACTICES

6. In response to these allegations and without Respondent admitting the truth of these allegations and specifically denying same, Respondent agrees and voluntarily assures the State that from the date of the signing of this AVC, which shall be filed with the appropriate Court, that Respondent and each and all of their directors, officers, agents, affiliates, employees, successors and assigns, and all persons or entities in active concert or participation with Respondent and who have received actual notice of this AVC, by personal service or otherwise, shall not make the following representations, do the following acts, or engage in the following practices in the pursuit and conduct of trade or commerce within the State of Texas, as set forth below:

- A. Purchase and possess prescription diagnostic ultrasound systems without a practitioner licensed under Texas law to purchase and possess such devices;
- B. Use prescription diagnostic ultrasound systems without the supervision of a practitioner licensed by Texas law to use such devices;

- C. Use prescription diagnostic ultrasound systems 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 diagnostic ultrasound systems for keepsake purposes or emotional and maternal bonding for which FDA has not approved these devices;
- E. Falsely advertise or falsely represent that prescription diagnostic ultrasound systems can be used for keepsake purposes or emotional and maternal bonding if FDA has not approved these devices for such uses;
- F. Falsely represent that gender determination, number of fetuses, and fetal heart movement is not diagnostic services and the practice of medicine;
- G. Fail to disclose that Respondent's prescription diagnostic ultrasound system is approved only for diagnostic ultrasound;
- H. Fail to comply with federal medical device reporting requirements, as required by 21 CFR § 803;
- I. Fail to disclose that prescription diagnostic ultrasound systems are only to be used under the written order and supervision of a practitioner licensed in Texas;
- J. Misbrand or adulterate prescription diagnostic ultrasound systems in commerce;
- K. Cause confusion as to the approval of a good by allowing consumers to purchase the use of prescription diagnostic ultrasound systems for keepsake purposes or emotional and maternal bonding; and

L. Fail to provide written notice to any agent, servant, employee, affiliate or representative at any of Respondent's locations of the existence and terms of these prohibited acts, and of their duty to comply with the terms set forth herein.

7. Respondent has read and understands this AVC; enters into it voluntarily, having been advised of the benefits of obtaining legal counsel; has chosen to represent herself in this matter; and acknowledges that she understands the meaning and effect of each provision of this AVC.

8. Respondent further agrees that the State's execution of this AVC does not constitute an approval by the State of Texas of any its practices and are not to make any representations to the contrary.

9. As set forth in TEX. BUS. & COM. CODE §17.58(c), notwithstanding any other provision of this AVC, Respondent acknowledges that unless this AVC has been rescinded by agreement of the parties, or voided by the Court for good cause, subsequent failure to comply with the terms of this AVC, is prima facie evidence of a violation of the DTPA and shall give rise to a right of action by the STATE OF TEXAS under the provisions of the Texas, Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN., §431.001, *et seq.* and the Texas Deceptive Trade Practices Act, TEX. BUS. & COM. CODE ANN. §17.41, *et seq.*

10. It is also agreed and understood that this AVC does not affect individual rights of action.

11. The acceptance of this AVC is conditioned upon payment by Respondent to the State of the sum of One Thousand Five Hundred Dollars (\$1,500.00) as attorneys fees and investigative costs under § 431.047 of the TFDCA and the TEX. GOVT. CODE § 402.006(c).

12. The acceptance of this AVC is conditioned upon payment by Respondent to the State of the sum of One Thousand Five Hundred Dollars (\$1,500.00) 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.

13. The State agrees, by its execution of this AVC, that if Respondent fully complies with the terms of the AVC that the State will not make any further claims or take any other enforcement action against Respondent with regard to the factual allegations contained in this AVC that occurred prior to the signing of this AVC.

14. All costs of court are adjudged against Respondent.

Signed this ____ day of _____, 2005.

Date: _____

Respondent MAUREE N. HOGGAN d/b/a FETAL FOTOS DALLAS

MAUREE N. HOGGAN
Owner and Director

STATE OF TEXAS

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