



authority granted him by §17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.21 *et seq.*, upon the grounds that GUIDANT has engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§17.46(a) and (b) of the DTPA.

3. Defendant GUIDANT CORPORATION is an Indiana corporation regularly conducting business within the State of Texas. At all times relevant to this petition, GUIDANT CORPORATION solicited consumers and businesses throughout the United States, including the State of Texas.

4. Defendant CARDIAC PACEMAKERS, INC., is a Minnesota corporation, regularly conducting business within the State of Texas. At all times relevant to this petition, CARDIAC PACEMAKERS, INC., solicited consumers and businesses throughout the United States, including the State of Texas.

5. Defendant GUIDANT SALES CORPORATION is an Indiana corporation regularly conducting business within the State of Texas. At all times relevant to this petition, GUIDANT SALES CORPORATION solicited consumers and businesses throughout the United States, including the State of Texas.

6. Because the marketing conduct alleged in this Petition concerns all Defendants, in this petition all defendants are collectively referred to as "GUIDANT."

#### VENUE

7. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA because the acts and practices that violate these statutes occurred in Dallas County, Texas.

## **PUBLIC INTEREST**

8. Because Plaintiff State of Texas has reason to believe that GUIDANT has engaged in, and will continue to engage in, the unlawful practice set forth below, Plaintiff State of Texas has reason to believe that GUIDANT has caused and will cause immediate and irreparable injury, loss and damage to the State of Texas, and its citizens, and will also cause adverse effects to business enterprises which conduct their trade and commerce in a lawful manner in Texas. Therefore, the Attorney General of the State of Texas believes and is of the opinion that these proceedings are in the public interest.

## **ACTS OF AGENTS**

9. Whenever in this petition it is alleged that GUIDANT did any act or thing, it is meant that GUIDANT performed or participated in such act or thing or that such act was performed by agents or employees of GUIDANT and in each instance, the agents or employees of GUIDANT were then authorized to and did in fact act on behalf of GUIDANT or otherwise acted under the guidance and direction of GUIDANT.

## **TRADE AND COMMERCE**

10. GUIDANT has, at all times described below, engaged in conduct which constitutes “trade” and “commerce” as those terms are defined by §17.45(6) of the DTPA.

## **NOTICE BEFORE SUIT**

11. GUIDANT was informed in general of the alleged unlawful conduct described below through Texas’ participation in a multistate investigation of GUIDANT and as may be required by §17.47(a) of the DTPA.

## FACTUAL ALLEGATIONS

12. GUIDANT is one of the world's largest manufacturers of implantable cardioverter defibrillators (ICDs).

13. An ICD is a medical device surgically implanted in a patient's chest to monitor for abnormal heart rhythms and if necessary, to deliver an electric shock to restore a normal rhythm. An ICD works as either a pacemaker to normalize the heart's rhythm or as a defibrillator to deliver an electrical shock to the heart muscle so that the heart returns to a normal beating rhythm. If an ICD fails to deliver a shock when needed, and the heart's normal rhythm is thus not restored, the patient could die.

14. GUIDANT manufactured and sold a specific implantable cardioverter defibrillator known as the Ventak Prizm 2 DR Model 1861 ("Prizm 1861 defibrillator" or "device") prior and subsequent to February, 2002.

15. In February of 2002, GUIDANT discovered a problem in the device's design which in some cases caused an electrical short. The Prizm's polyimide insulation could degrade and because a positively charged "feed through wire" was placed too close to a negatively charged "backfill tube header", a short circuit ("arcing") could, and in fact sometimes did, occur when the Prizm should have delivered a life saving shock. This rendered the device functionally useless for its intended purpose. The device's failure to work properly could lead to serious injury or death to the patient.

16. In an attempt to prevent this problem from occurring, GUIDANT made design changes to the Prizm 1861 defibrillator in April, 2002 and again in November, 2002. Notwithstanding these design changes, GUIDANT wrongfully continued to market and sell

devices from its inventory which did not have the April and November, 2002 design changes (the “fix”) incorporated.

17. GUIDANT further failed to notify the public, including doctors and patients, of the defect and the design changes made to correct it. GUIDANT did not even distinguish between the devices manufactured before the fix and those manufactured after the fix, and continued to call all of the devices, regardless of when manufactured, the Ventak Prizm 2 DR Model 1861.

18. GUIDANT did not disclose the defect and the fix until May 23, 2005, when it learned that the New York Times was planning to publicly disclose the defect, the non-disclosure of the defect by the company and that the company had continued to sell devices that did not have the fix incorporated into them even after the fix had been made.

19. GUIDANT continued to sell unmodified devices out of existing inventory without disclosing that the Prizm had been modified until July, 2005. Approximately 4,000 such devices manufactured before April, 2002, were sold after the fix had been made, but before GUIDANT stopped selling such units.

20. Prescribing physicians and unknowing patients were not formally notified of the defect until June 17, 2005, when the FDA issued a nationwide notification that GUIDANT had recalled the Prism 1861 defibrillators, manufactured before April 16, 2002.

#### **VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT**

21. GUIDANT, as alleged above in paragraphs 1 through 20, has in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in §17.46(a). Additionally, GUIDANT has violated §17.46(b) of the DTPA as follows:

- A. Causing confusion or misunderstanding as to the safety of the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002, in violation of §17.46(b)(2) of the DTPA;
- B. Representing that the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002, has benefits which it does not have, in violation of §17.46(b)(5) of the DTPA;
- C. Representing that the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002, is of a particular standard, quality, or grade, if it is of another, in violation of §17.46(b)(7) of the DTPA; and
- D. Failing to disclose that the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002, that was in its inventory did not have the April and November, 2002 design changes incorporated and therefore had a higher chance of malfunction, when such failure to disclose was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of §17.46(b)(24) of the DTPA.

### **INJURY TO CONSUMERS**

22. By means of the foregoing unlawful acts and practices, GUIDANT has acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

### **PERMANENT INJUNCTION**

23. The State alleges that by reason of the foregoing, GUIDANT should not continue to advertise, promote, or sell the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002, or any other device in violation of the laws of Texas. The interests of the State of Texas

require a permanent injunction to prohibit GUIDANT from advertising and selling its devices in Texas, unless GUIDANT is in compliance with the DTPA.

24. Unless injunctive relief is granted, GUIDANT will continue to violate the laws of the State of Texas to irreparable injury of the State of Texas and to the general public.

#### **PRAYER**

25. WHEREFORE, Plaintiff prays that GUIDANT be cited according to law to appear and answer herein; that after due notice and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining GUIDANT, its successors, assigns, officers, agents, servants, employees, and any other person in active concert or participation with GUIDANT from engaging in the following acts or practices:

- A. Marketing or selling the Ventak Prism ZDR Model 1861, manufactured prior to April, 2002;
- B. Making any false, misleading or deceptive representation regarding the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002 in violation of all applicable laws and regulations;
- C. Failing to comply with all applicable laws and regulations relating to the marketing, sale, and promotion of the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002;
- D. Causing confusion or misunderstanding as to the safety of the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002;
- E. Representing that the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002 has benefits which it does not have;

- F. Representing that the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002 is of a particular standard, quality, or grade, if it is of another; and
- G. Failing to disclose that the Ventak Prizm 2 DR Model 1861, manufactured prior to April, 2002 posed increased health and safety risks since the April and November, 2002 design changes had not been incorporated.

26. Plaintiff further prays that this court upon final hearing order GUIDANT to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$20,000.00 per violation of the DTPA.

27. Plaintiff further prays that upon final hearing that his Court order GUIDANT to restore all money or other property taken from persons by means of unlawful acts or practices, or, in the alternative, award judgment for damages to compensate for such losses.

28. Plaintiff further prays that upon final hearing that this Court order GUIDANT to pay to the STATE OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE §402.006( c).

29. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may show itself entitled.

Respectfully submitted,

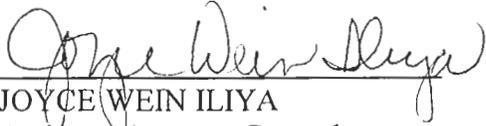
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