

## STATE COMMITTEE OF EXAMINERS IN THE FITTING AND DISPENSING OF HEARING INSTRUMENTS

## RECEIVED

AUG 18 2006

**OPINION COMMITTEE** 

1100 West 49th Street ● Austin, Texas 78756-318;
Phone: (512) 834-6784 ● Fax: (512) 834-6677
E-mail: fdhi@dshs.state.tx.us/fitters

August 10, 2006

The Honorable Greg Abbott Attorney General of Texas Office of the Attorney General P.O. Box 12458 Austin, Texas 78711-2548 FILE#<u>ML-44954-</u>D6 I.D.#<u>44954</u>

Re: Request for Opinion

Dear General Abbott:

RQ-0524-6A

This is to respectfully request your opinion pursuant to Article IV, Section 22, of the Texas Constitution and Chapter 402 of the Texas Government Code regarding the meaning and validity of certain provisions of the Occupations Code that relate to licensure and the sale of hearing instruments by mail.

## BACKGROUND

Chapter 402 of the Texas Occupations Code creates and governs the State Committee of Examiners in the Fitting and Dispensing of Hearing Instruments (the "Committee"). The Committee is part of the Department of State Health Services and was established to regulate the fitting and dispensing of hearing instruments. The Committee's responsibilities include enforcing its law against those persons or entities who engage in practices that are prohibited under the Act.

Occupations Code Section 402.451 provides:

Section 402.451 Prohibited Acts. (a) A person may not:

- (6) dispense or fit a hearing instrument on a person who has ordered the hearing instrument or device by mail unless the person dispensing or fitting is a license holder under this chapter or under Chapter 401; or
- (7) sell a hearing instrument by mail.

Under Chapter 402 of the Occupations Code, "sale" is defined as a "transfer of title or of the right to use by lease, bailment, or other contract. The term does not include a sale at wholesale by a manufacturer to a person licensed under this chapter or to a distributor for distribution and sale to a person licensed under this chapter. TEX. OCC. CODE § 402.001(7).

The Committee also defines the "selling of hearing instrument by mail" as "anytime a hearing instrument is not sold, fitted or dispensed in person by a licensee or permit holder." 22 TAC § 141.2(23).

Hearing Help Express (HHEx) and Lloyd Hearing Aid Corp. (Lloyds), both of which are Illinois corporations, advertise and promote hearing instruments in national magazines and the Internet, they sell these hearing instruments through the mail in all states including Texas. Although HHEx and Lloyd's are licensed in Illinois, neither company is licensed to fit and dispense or sell hearing aids in Texas by the State Committee of Examiners in the Fitting and Dispensing of Hearing Instruments (SCEFDHI), which is a part of the Texas Department of State Health Services. ("DSHS")

Hon. Greg Abbott August 10, 2006 Page 2

A DSHS investigator conducted an undercover purchase of a hearing aid from each company to obtain direct evidence that these companies are selling hearing instruments in Texas through the mail in violation of Occupations Code § 402.451(a)(6,7). A search on the Internet for sellers of hearing instruments reveals that there are hundreds of persons who are selling hearing instruments who are not licensed in Texas. HHEx and Lloyds are among the largest of the major dispensers.

SCEFDHI has previously requested that the Office of the Attorney General file lawsuits to enjoin these companies from selling hearing instruments by mail until they are licensed in Texas. Although lawsuits have been drafted and were approved on June 3, 2005, the United States Supreme Court decided <u>Granholm v. Heald.</u> 125 S. Ct. 1885, 1895 (2005) on May 17, 2005. This decision, along with the knowledge that there are several hundred of these types of sellers compels a re-examination of the statutes involved and a review of the decision to file these lawsuits.

## **ISSUES**

The SCEFDHI respectfully requests that your office review the pertinent statutes and provide guidance by addressing the following questions:

- 1. Whether Occupations Code, § 402.451(a)(6)(1999), which prohibits the fitting and dispensing of hearing instruments by anyone without a license, violates the "dormant commerce clause" of the U.S. Constitution, Art. I, § 8, Cl. 3?
- 2. Whether Occupations Code § 402.451(a)(7)(1999), which prohibits the sale by anyone from selling hearing instruments by mail, whether licensed or not, violates the "dormant commerce clause" of the U.S. Constitution, Art. I, § 8, Cl. 3?
- 3. Can the State of Texas justify the discrimination, both in terms of the local benefits flowing from the statute and the unavailability of nondiscriminatory alternatives adequate to preserve the local interests at stake?
- 4. Whether Occupations Code, § 402.451(a)(7)(1999), violates the "dormant commerce clause" because it imposes burdens on interstate commerce greater than the local benefits secured?
- 5. Whether Occupations Code § 402.451(a)(7)(1999) is arbitrary?
- 6. Whether the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. § 360(1976) and 21 C.F.R. §§ 801.420 and 801.421(2003) pre-empts Occupations Code, § 402.451(a)(6)(7)(1999)?
- 7. Does the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. § 360(1976) and 21 C.F.R. § 801.420 and 801.421(2003) provide for a cut-off date whereby a State can request an exemption from pre-emption, and does the failure to previously ask for pre-emption on the sales by mail issue preclude asking for an exception now?

Your opinion will help the Committee more efficiently administer its regulatory program in accordance with Occupations Code Chapter 402. We have already collected substantial research materials from both sides of the dispute and would be willing to provide your Opinions Committee upon request. Thank you for your time and attention to this matter.

Sincerely,

Ronald Ensweiler, President

State Committee of Examiners in the Fitting and Dispensing of Hearing Instruments