ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

March 6, 2007

Mr. Ronald Ensweiler, President
State Committee of Examiners in the Fitting
and Dispensing of Hearing Instruments
1100 West 49th Street
Austin, Texas 78756-3183

Opinion No. GA-0525

Re: Constitutionality of provisions of the Occupations Code, which prohibit the fitting and dispensing of hearing instruments ordered by mail by an unlicensed individual and the sale of a hearing instrument by mail (RQ-0524-GA)

Dear Mr. Ensweiler:

You ask several questions about two provisions in the Occupations Code governing hearing instruments.[1] As background you inform us that two Illinois corporations sell "hearing instruments through the mail in all states including Texas." Request Letter, *supra* note 1, at 1. You further inform us that though licensed in Illinois, neither company is licensed in Texas to "fit and dispense or sell hearing aids in Texas." *Id.* You ask:

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?

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[1] *See* Letter from Mr. Ronald Ensweiler, President, State Committee of Examiners in the Fitting and Dispensing of Hearing Instruments, to Honorable Greg Abbott, Attorney General of Texas, at 2 (Aug. 10, 2006) (on file with the Opinion Committee, *also available at* http://www.oag.state.tx.us) [hereinafter Request Letter].

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 [an exception] on the sales by mail issue preclude asking for an exception now?

Id. at 2.

The two state law provisions about which you ask are contained in section 402.451, Occupations Code, which pertains to prohibited acts for hearing instrument fitters and dispensers. *See* Request Letter, *supra* note 1, at 1; *see also* TEX. OCC. CODE ANN. § 402.451(a)(6)–(7) (Vernon 2004). Subsection 402.451(a)(6) prohibits a person from dispensing or fitting "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 [Chapter 402] or under Chapter 401." *Id.* § 402.451(a)(6). "Fitting and dispensing hearing instruments" is defined in relevant part to mean the "measurement of human hearing by the use of an audiometer or other means to make selections, adaptations, or sales of hearing instruments." *Id.* § 402.001(4); 22 TEX. ADMIN. CODE § 141.2(15) (2006) (State Comm. of Exam'rs in the Fitting & Dispensing of Hearing Instruments, Definitions). Through this definition of "fitting and dispensing hearing instruments" and the statutory requirements of subsection 402.451(a)(6), there is a requirement that a person licensed under Texas law perform an audiological exam on a person who has ordered a hearing aid by mail. Subsection 402.451(a)(7) prohibits the sale of a "hearing instrument by mail." TEX. OCC. CODE ANN. § 402.451(a)(7) (Vernon 2004). The "selling of a hearing instrument by mail" means "[a]nytime a hearing instrument is not sold, fitted or dispensed in person by a licensee or permit holder." 22 TEX. ADMIN. CODE § 141.2(23) (2006). Thus, at issue in this request are both the requirement of an audiological examination and the prohibition against hearing aids ordered by mail.

Several of your questions relate to the constitutionality of these two provisions. *See* Request Letter, *supra* note 1, at 2. A court will usually decide a constitutional question only when it cannot resolve the issue on nonconstitutional grounds. *See In re B.L.D.*, 113 S.W.3d 340, 349 (Tex. 2003). Because two of your questions are not related to the constitutionality of the Occupations Code

provisions but rather pertain to preemption issues concerning the two provisions, we will do likewise and consider them first.

You ask whether subsections 402.451(a)(6) and (a)(7) are preempted by federal legislation. *See* Request Letter, *supra* note 1, at 2. Under the Supremacy Clause of the United States Constitution, the laws of the United States are "the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. It is well settled that a state law conflicting with federal law is "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *Am. Cyanamid Co. v. Geye*, 79 S.W.3d 21, 23 (Tex. 2002). "Consideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.' Accordingly, '[t]he purpose of Congress is the ultimate touchstone' of pre-emption analysis." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citations omitted). Congressional intent with respect to preemption may be express or implied. *See Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985). State law is expressly preempted when Congress uses clear preemptive language in the federal statute or regulation. *See id.* (recognizing state laws can be preempted by federal regulations as well as by federal legislation). Absent express preemptive language, a federal statute or regulation impliedly preempts state law when the language indicates a Congressional intent to exclusively and completely occupy a legislative field. *See Cipollone*, 505 U.S. at 516. State law is also impliedly preempted when it actually conflicts with the federal law in such a way that "compliance with both federal and state regulations is a physical impossibility." *Hillsborough County, Fla.*, 471 U.S. at 713.

We need here consider only express preemption because there is an express preemption provision in the federal statute. *See* 21 U.S.C.A. § 360k(a) (West 1999); *see also Cipollone*, 505 U.S. at 517 ("When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a 'reliable indicium of congressional intent with respect to state authority'. . . 'there is no need to infer congressional intent to pre-empt state laws from the substantive provisions' of the legislation.") (citations omitted). In the Medical Device Amendment (the "MDA"), which gives the Food and Drug Administration (the "FDA") jurisdiction over medical devices, Congress preempted state laws that pertain to medical devices intended for human use and that impose any requirement:

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a) (West 1999); *see also* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. §§ 301–91); Federal Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906). A hearing aid is a "device" under the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C.A. § 321(h) (West 1999). Thus, we must

consider the scope of the express exemption in section 360k(a) and determine whether subsections 402.451(a)(6) and (a)(7) fall within the scope of that preemption. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996) ("While the pre-emptive language of § 360k(a) means that we need not go beyond that language to determine whether Congress intended the MDA to pre-empt at least some state law, we must nonetheless 'identify the domain expressly pre-empted' by that language.") (citation omitted); *cf. Smith v. Pingree*, 651 F.2d 1021, 1023 (5th Cir. 1981) (setting out method of analyzing state hearing-aid regulation).

The first prong of the preemption analysis inquires whether the two subsections impose requirements that are different from, or in addition to, requirements imposed under the MDA. In its hearing aid regulation adopted under the MDA, the FDA established "uniform professional and patient labeling requirements and conditions for sale of hearing aid devices." 42 Fed. Reg. 9286 (Feb. 15, 1977). The FDA rule contains a provision governing medical evaluations, which provides

> (1) General. Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.
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> (2) Waiver to the medical evaluation requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser [provides certain information and the specified waiver form].

21 C.F.R. § 801.421(a) (2006). The regulation restricts the sale of a hearing aid to an individual who has undergone a medical evaluation in the past six months, but allows a fully informed adult to waive the evaluation. In fact, the FDA entertained comments about the necessity of the waiver provision and determined that a waiver opportunity was necessary to protect the freedom of those who have religious or personal beliefs against a medical examination and for the circumstances where an individual would have great difficulty obtaining a medical examination. *See* 42 Fed. Reg. 9286, 9292–93 (Feb. 15, 1977). The FDA expressly decided to make the medical evaluation optional under the MDA. In contrast, subsection 402.451(a)(6) requires an evaluation but does not contain any provision authorizing a waiver of the evaluation. *See* TEX. OCC. CODE ANN. § 402.451(a)(6) (Vernon 2004). Under subsection 402.451(a)(6), the audiological evaluation is not optional. The state provision imposes a requirement that is different from, or in addition to, a requirement in the MDA.

Similarly, the federal hearing aid regulation does not contain a prohibition against the sale of hearing aids through the mail. *See* 21 C.F.R. § 801.421 (2006). And as it did with the medical

evaluation requirement, the FDA considered imposing a prohibition against mail ordered hearing aids but expressly rejected the idea. *See* 42 Fed. Reg. 9286, 9293 (Feb. 15, 1977) ("The Commissioner is not aware of any abuses in mail order sales of hearing aids . . . . The Commissioner has determined not to prohibit mail order sales provided that all the requirements of the regulation have been met."). On the other hand, subsection 402.451(a)(7) prohibits the sale of hearing aids by mail. Such a prohibition is a requirement that is different from or in addition to the requirements of the MDA.

The second prong of the preemption analysis requires consideration of the safety and effectiveness of the device. *See* 21 U.S.C.A. § 360k(a)(2) (West 1999). With respect to the audiological examination required by subsection 402.451(a)(6), the FDA has concluded that a state requirement of "audiological evaluation relates to the safety or effectiveness of hearing aids because it is intended to ensure that the purchaser is fitted properly with a hearing aid." 45 Fed. Reg. 67326, 67327 (Oct. 10, 1980) (final rule codified at 21 C.F.R. pt. 808). The FDA stated that an audiological exam aids in determining "the cause of, and pathology associated with, a patient's hearing loss" and is "based upon the recognition that an unnecessary or partially effective hearing aid device may be substituted for primary medical or surgical treatment, thus depriving the hearing impaired patient of benefit of appropriate medical diagnosis and care and resulting in a detriment to health." 42 Fed. Reg. 9286, 9287–88 (Feb. 15, 1977). Such considerations clearly pertain to the safety and effectiveness of a hearing aid.

The prohibition against mail-ordered hearing aids contained in subsection 402.451(a)(7) similarly relates to the safety and effectiveness of a hearing aid. The prohibition essentially requires the sale of hearing aids in person. *See* 22 TEX. ADMIN. CODE § 141.2(23) (2006) (defining "selling of hearing instrument by mail" as "not sold, fitted or dispensed in person"). In our opinion, a requirement that the sale of hearing aids be in person is a requirement designed to improve the effectiveness of the hearing aid and thus pertains to the safety and effectiveness of the hearing aid.

Because both subsections impose requirements that are different from, or in addition to, the federal requirements and because both relate to the effectiveness and safety of a hearing aid device, we believe the two subsections are expressly preempted by section 360k(a). Accordingly, we need not consider your questions pertaining to the constitutionality of these two sections. *See supra* at 2–3.

Your remaining question inquires whether the MDA and its regulations "provide for a cut-off date whereby a State can request an exemption from pre-emption, and [whether] the failure to previously ask for [an exception] on the sales by mail issue preclude[s] asking for an exception now." Request Letter, *supra* note 1, at 2. The MDA authorizes a state or political subdivision to seek an exemption from preemption. *See* 21 U.S.C.A. § 360k(b) (West 1999). The FDA by regulation, after notice and hearing, may exempt from preemption an applicable state requirement if

> (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

Id. The FDA regulations provide the procedures by which a state may seek an exemption. *See* 21 C.F.R. § 808.20 (2006). Neither the statute nor the regulations provide a cut-off date by which a state must apply for an exemption. *See* 21 U.S.C.A. § 360k(b) (West 1999); 21 C.F.R. § 808.20 (2006). While the FDA has not engaged in a formal rulemaking process on hearing aids recently, we see no express indication that a state could not now apply for an exemption. In the last rulemaking process, states were even encouraged to "remain active in regulating the hearing aid industry." 45 Fed. Reg. 67326, 67326 (Oct. 10, 1980). Moreover, the statute and the regulations have not been deleted or repealed for being unnecessary as would be expected if states were no longer permitted to apply for an exemption. For these reasons, we believe that there is no cut-off date by which a state or political subdivision must apply for an exemption. For the same reasons, we also believe that a state's failure to previously request an exemption does not preclude it from doing so now or in the future. We must point out, however, that the FDA has not construed the meaning of its own rule with respect to a cut-off date by which to seek an exemption. *See* 43 Fed. Reg. 18661 (May 2, 1978). Any reasonable interpretation of the rule by the FDA would, of course, be given deference over a state attorney general's opinion. *See Christensen v. Harris County*, 529 U.S. 576, 588 (2000) ("an agency's interpretation of its own regulation is entitled to deference").

S U M M A R Y

Subsections 402.451(a)(6) and 402.451(a)(7), Occupations Code, are preempted by the federal statutes and regulations governing hearing aid devices. However, no federal law or regulation imposes a cut-off date on a state's ability to request an exemption from preemption from the Food and Drug Administration (the "FDA"), although the extent to which such request receives consideration is subject to the FDA's discretion.

Very truly yours,

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