

# WISCONSIN DEPARTMENT OF REGULATION & LICENSING



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STATE OF WISCONSIN  
BEFORE THE DEPARTMENT OF REGULATION AND LICENSING

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IN THE MATTER OF A PETITION FOR	:	
AN ADMINISTRATIVE INJUNCTION	:	
INVOLVING	:	FINAL DECISION
	:	AND ORDER
HEARING HELP EXPRESS, INC.,	:	LS0612111UNL
JAMES HOVIS, CATHERINE HOVIS,	:	
AND LAURA STUEBING,	:	
RESPONDENTS.	:	

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Division of Enforcement Case No. 03UNL095

The State of Wisconsin, Department of Regulation and Licensing, having considered the above-captioned matter and having reviewed the record and the Proposed Decision of the Administrative Law Judge, makes the following:

ORDER

NOW, THEREFORE, it is hereby ordered that the Proposed Decision annexed hereto, filed by the Administrative Law Judge, shall be and hereby is made and ordered the Final Decision of the State of Wisconsin, Department of Regulation and Licensing.

The rights of a party aggrieved by this Decision to petition the department for rehearing and the petition for judicial review are set forth on the attached "Notice of Appeal Information."

Dated this 28<sup>th</sup> day of July, 2008.

Celia M. Jackson, Secretary  
Department of Regulation and Licensing

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IN THE MATTER OF A PETITION FOR AN :  
ADMINISTRATIVE INJUNCTION INVOLVING :  
 :  
HEARING HELP EXPRESS, INC. : PROPOSED DECISION  
JAMES HOVIS, CATHERINE HOVIS, : AND ORDER  
AND LAURA A STUEBING : Case No. LS0612111UNL  
RESPONDENTS. :  
 :

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[DOE Case No. 03UNL095]

The parties to this action are:

Hearing Help Express, Inc. et al.  
c/o Mr. Hal Harlowe  
Hal Harlowe & Associates  
519 North Pinckney Street  
Madison, WI 53703-1473

Department of Regulation & Licensing  
Division of Enforcement  
P.O. Box 8935  
Madison, WI 53708-8935

### **PROCEDURAL HISTORY**

A petition for an administrative injunction was sought against Hearing Help Express et al. In lieu of an evidentiary hearing, the parties requested that the matter be considered by the undersigned on the basis of the stipulated facts and supplemental briefs. Their request was granted. The Division of Enforcement appeared by attorney Sandra L. Nowack. Hearing Help et al., appeared by its attorney, Mr. Hal Harlowe.

Based on the entire record in this case, the undersigned administrative law judge recommends that the Department of Regulation and Licensing adopt as its final decision in this matter the following Findings of Fact, Conclusions of Law, and Order.

### **FINDINGS OF FACT**

1. Hearing Help Express, Inc. ("Hearing Help Express"), is an Illinois corporation located at 105 N. 1st Street, DeKalb, Illinois. James E. Hovis is Chairman of the Board; Catherine Hovis is Chief Executive Officer, and Laura C. Stuebing is President. Their business address is 105 N. 1st Street, P.O. Box 586, DeKalb, IL 60115.
2. Respondents are not licensed as hearing instrument specialists under s. 459.05, Wis. Stats., or as audiologists under s. 459.24(3), Wis. Stats. They have never been so licensed, nor do they have license applications pending. Respondents do not employ persons who are so licensed.
3. Respondent Hearing Help Express is licensed pursuant to Illinois statutes and the Illinois Hearing Instrument Consumer Protection Code contained in Part 682 of Subchapter J, Chapter IV, Title 77 of the Illinois Administrative Code. ILCS 50/6 specifically authorizes the sale of hearing aids through the mail. Sections 5 and 6 of the Illinois Hearing Instrument Consumer Protection Act, as codified at 225 ILCS 50/5, 50-6 state:  
**50/5. License required**  
§ 5. License required. No person shall engage in the selling, practice of testing, fitting, selecting, recommending,

adapting, dispensing, or servicing hearing instruments or display a sign, advertise, or represent oneself as a person who practices the fitting or selling of hearing instruments unless such person holds a current license issued by the Department as provided in this Act. Such person shall be known as a licensed hearing instrument dispenser.

Individuals licensed pursuant to the provisions of Section 8 of this Act shall be deemed qualified to provide tests of human hearing and hearing instrument evaluations for the purpose of dispensing a hearing instrument for which any State agency may contract. The license shall be conspicuously displayed in the place of business. Duplicate licenses shall be issued by the Department to licensees operating more than one office upon the additional payment set forth in this Act. Except for violations of the provisions of this Act, or the rules promulgated under it, nothing in this Act shall prohibit a corporation, partnership, trust, association, or other entity from engaging in the business of testing, fitting, servicing, selecting, dispensing, selling, or offering for sale hearing instruments at retail without a license, provided it employs only licensed individuals in the direct testing, fitting, servicing, selecting, offering for sale, or dispensing of such products. Each such corporation, partnership, trust, association, or other entity shall file with the Department, prior to doing business in this State and by July 1 of each calendar year thereafter, on forms prescribed by the Department, a list of all licensed hearing instrument dispensers employed by it and a statement attesting that it complies with this Act and the rules promulgated under it and the regulations of the Federal Food and Drug Administration and the Federal Trade Commission insofar as they are applicable.

#### **50/6. Mail order sales**

§ 6. Mail order sales. Nothing in this Act shall prohibit a corporation, partnership, trust, association, or other organization, maintaining an established business address, from engaging in the business of selling or offering for sale hearing instruments at retail by mail to persons 18 years of age or older who have not been examined by a licensed physician or tested by a licensed hearing instrument dispenser provided that: (a) The organization is registered by the Department prior to engaging in business in this State and has paid the fee set forth in this Act. (b) The organization files with the Department, prior to registration and annually thereafter, a Disclosure Statement containing the following:

(1) the name under which the organization is doing or intends to do business and the name of any affiliated company which the organization recommends or will recommend to persons as a supplier of goods or services or in connection with other business transactions of the organization;

(2) the organization's principal business address and the name and address of its agent in this State authorized to receive service of process;

(3) the business form of the organization, whether corporate, partnership, or otherwise and the state or other sovereign power under which the organization is organized;

(4) the names of the directors or persons performing similar functions and names and addresses of the chief executive officer, and the financial, accounting, sales, and other principal executive officers, if the organization is a corporation, association, or other similar entity; of all general partners, if the organization is a partnership; and of the owner, if the organization is a sole proprietorship, together with a statement of the business background during the past 5 years for each such person;

(5) a statement as to whether the organization or any person identified in the disclosure statement:

(i) has during the 5 year period immediately preceding the date of the disclosure statement been convicted of a felony, pleaded nolo contendere to a felony charge, or been held liable in a civil action by final judgment, if such felony or civil action involved fraud, embezzlement, or misappropriation of property, and a description thereof; or

(ii) is subject to any currently effective injunctive or restrictive order as a result of a proceeding or pending action brought by any government agency or department, and a description thereof; or

(iii) is a defendant in any pending criminal or material civil action relating to fraud, embezzlement, misappropriation of property or violations of the antitrust or trade regulation laws of the United States or any state, and a description thereof; or

(iv) has during the 5 year period immediately preceding the date of the disclosure statement had entered against such person or organization a final judgment in any material civil proceeding, and a description thereof; or

(v) has during the 5 year period immediately preceding the date of the disclosure statement been adjudicated a bankrupt or reorganized due to insolvency or was a principal executive officer or general partner of any company that has been adjudicated a bankrupt or reorganized due to insolvency during such 5 year period, and a description thereof;

(6) the length of time the organization and any predecessor of the organization has conducted a business dealing with hearing instrument goods or services;

(7) a financial statement of the organization as of the close of the most recent fiscal year of the organization. If the financial statement is filed later than 120 days following the close of the fiscal year of the organization it must be accompanied by a statement of the organization of any material changes in the financial condition of the organization;

(8) a general description of the business, including without limitation a description of the goods, training programs, supervision, advertising, promotion and other services provided by the organization;

(9) a statement of any compensation or other benefit given or promised to a public figure arising, in whole or in part, from (i) the use of the public figure in the name or symbol of the organization or (ii) the endorsement or recommendation of the organization by the public figure in advertisements;

(10) a statement setting forth such additional information and such comments and explanations relative to the information contained in the disclosure statement as the organization may desire to present.

(c) The organization files with the Department prior to registration and annually thereafter a statement that it complies with the Act, the rules issued pursuant to it, and the regulations of the Federal Food and Drug Administration and the Federal Trade Commission insofar as they are applicable. (d) The organization files with the Department at the time of registration an irrevocable consent to service of process authorizing the Department and any of its successors to be served any notice,

process, or pleading in any action or proceeding against the organization arising out of or in connection with any violation of this Act. Such service shall have the effect of conferring personal jurisdiction over such organization in any court of competent jurisdiction. (e) Before dispensing a hearing instrument to a resident of this State, the organization informs the prospective users that they may need the following for proper fitting of a hearing instrument:

- (1) the results of an audiogram performed within the past 6 months by a licensed audiologist or a licensed hearing instrument dispenser; and
  - (2) an earmold impression obtained from the prospective user and taken by a licensed hearing instrument dispenser.
- (f) The prospective user receives a medical evaluation or the organization affords the prospective user an opportunity to waive the medical evaluation requirement of Section 4 of this Act and the testing requirement of subsection (z) of Section 18, provided that the organization:

- (1) informs the prospective user that the exercise of the waiver is not in the user's best health interest;
- (2) does not in any way actively encourage the prospective user to waive the medical evaluation or test; and
- (3) affords the prospective user the option to sign the following statement:

"I have been advised by ..... (hearing instrument dispenser's name) that the Food and Drug Administration and the State of Illinois have determined that my best interest would be served if I had a medical evaluation by a licensed physician, preferably a physician who specialized in diseases of the ear, before purchasing a hearing instrument; or a test by a licensed audiologist or licensed hearing instrument dispenser utilizing established procedures and instrumentation in the fitting of hearing instruments. I do not wish either a medical evaluation or test before purchasing a hearing instrument."

(g) Where a sale, lease, or rental of hearing instruments is sold or contracted to be sold to a consumer by mail order, the consumer may void the contract or sale by notifying the seller within 45 business days following that day on which the hearing instruments were mailed by the seller to the consumer and by returning to the seller in its original condition any hearing instrument delivered to the consumer under the contract or sale. At the time the hearing instrument is mailed, the seller shall furnish the consumer with a fully completed receipt or copy of any contract pertaining to the sale that contains a "Notice of Cancellation" informing the consumer that he or she may cancel the sale at any time within 45 business days and disclosing the date of the mailing and the name, address, and telephone number of the seller. In immediate proximity to the space reserved in the contract for the signature of the consumer, or on the front page of the receipt if a contract is not used, and in bold face type of a minimum size of 10 points, there shall be a statement in substantially the following form:

"You, the buyer, may cancel this transaction at any time prior to midnight of the 45th business day after the date of this transaction. See the attached notice of cancellation form for an explanation of this right."

Attached to the receipt or contract shall be a completed form in duplicate, captioned "NOTICE OF CANCELLATION" which shall be easily detachable and which shall contain in at least 10 point bold face type the following information and statements in the same language as that used in the contract:

"NOTICE OF CANCELLATION

enter date of transaction

.....

(DATE)

YOU MAY CANCEL THIS TRANSACTION, WITHOUT ANY PENALTY OR OBLIGATION, WITHIN 45 BUSINESS DAYS FROM THE ABOVE DATE. IF YOU CANCEL, ANY PROPERTY TRADED IN, ANY PAYMENTS MADE BY YOU UNDER THE CONTRACT OR SALE LESS ANY NONREFUNDABLE RESTOCKING FEE, AND ANY NEGOTIABLE INSTRUMENT EXECUTED BY YOU WILL BE RETURNED WITHIN 10 BUSINESS DAYS FOLLOWING RECEIPT BY THE SELLER OF YOUR CANCELLATION NOTICE AND ALL MERCHANDISE PERTAINING TO THIS TRANSACTION, AND ANY SECURITY INTEREST ARISING OUT OF THE TRANSACTION WILL BE CANCELLED. IF YOU CANCEL, YOU MUST RETURN TO THE SELLER, IN SUBSTANTIALLY AS GOOD CONDITION AS WHEN RECEIVED, ANY GOODS DELIVERED TO YOU UNDER THIS CONTRACT OR SALE.

TO CANCEL THIS TRANSACTION, MAIL OR DELIVER A SIGNED AND DATED COPY OF THIS CANCELLATION NOTICE OR ANY OTHER WRITTEN NOTICE, OR SEND A TELEGRAM, TO (name of seller), AT (address of seller's place of business) AND (seller's telephone number) NO LATER THAN MIDNIGHT OF ..... (date).

I HEREBY CANCEL THIS TRANSACTION.

(Date)..... (Buyers Signature)" The written "Notice of Cancellation" may be sent by the consumer to the seller to cancel the contract. The 45-day period does not commence until the consumer is furnished the Notice of Cancellation and the address and phone number at which such notice to the seller can be given. If the conditions of this Section are met, the seller must return to the consumer the amount of any payment made or consideration given under the contract or for the merchandise less a nonrefundable restocking fee. It is an unlawful practice for a seller to: (1) hold a consumer responsible for any liability or obligation under any mail order transaction if the consumer claims not to have received the merchandise unless the merchandise was sent by certified mail or other delivery method by which the seller is provided with proof of delivery; (2) fail, before furnishing copies of the "Notice of Cancellation" to the consumer, to complete both copies by entering the name of the seller, the address of the seller's place of business, the seller's telephone number, the date of the mailing, and the date, not earlier than the 45th business day following the date of the mailing, by which the consumer may give notice of cancellation; (3) include in any contract or receipt any confession of judgment or any waiver of any of the rights to which the consumer is entitled under this Section

including specifically his right to cancel the sale in accordance with the provisions of this Section; (4) misrepresent in any manner the consumer's right to cancel; (5) use any undue influence, coercion, or any other wilful act or representation to interfere with the consumer's exercise of his rights under this Section; (6) fail or refuse to honor any valid notice of cancellation and return of merchandise by a consumer and, within 10 business days after the receipt of such notice and merchandise pertaining to such transaction, to (i) refund payments made under the contract or sale, (ii) return any goods or property traded in, in substantially as good condition as when received by the person, (iii) cancel and return any negotiable instrument executed by the consumer in connection with the contract or sale and take any action necessary or appropriate to terminate promptly any security interest created in the transaction; (7) negotiate, transfer, sell, or assign any note or other evidence of indebtedness to a finance company or other third party prior to the 50th business day following the day of the mailing; or (8) fail to provide the consumer of a hearing instrument with written information stating the name, address, and telephone number of the Department and informing the consumer that complaints regarding hearing instrument goods or services may be made to the Department. (h) The organization employs only licensed hearing instrument dispensers in the dispensing of hearing instruments and files with the Department, by January 1 of each year, a list of all licensed hearing instrument dispensers employed by it.

225 ILCS 50/5, 50-6.

4. Respondents Hovis and Stuebing are licensed hearing aid dispensers in Illinois, licensed pursuant to ILCS Ch. 225, ACT 50 (Hearing Instrument Consumer Protection Act), and the Illinois Administrative Code, Title 77 (Public Health), Chapter IV (Department of Public Health), Subchapter j (Vision and Hearing), Part 682 (Hearing Instrument Consumer Protection Code).
5. Illinois' licensing requirements for those who sell and distribute hearing aids are at least equivalent to Wisconsin's. The Illinois licensing requirements can be accessed at [www.ilga.gov/commission/jcar/admincode/077/07700682sections.html](http://www.ilga.gov/commission/jcar/admincode/077/07700682sections.html).
6. Wisconsin residents purchase hearing aids from Hearing Help Express, with products delivered via the U.S. mail or other delivery services.
7. Respondents maintain a website at <http://www.hearinghelpexpress.com> that provides a toll-free number for Hearing Help Express, at 1-800-221-2099. The website is accessible to consumers from within Wisconsin.
8. Respondents currently distribute marketing materials via the United States mail to addresses in all 50 states, including Wisconsin. Respondents advertise that they are engaged in the sale of hearing aids. Some of the materials are distributed through magazines that are circulated nationally or regionally, including in Wisconsin. Hearing Help Express's advertising materials are not tailored or targeted to any particular state; the advertisements do not specifically mention whether Hearing Help Express products are (or are not) available in any particular state.
9. The Respondents have used marketing materials mailed to Wisconsin addresses. The Division of Enforcement does not allege that the marketing materials are inaccurate or false.
10. If a Wisconsin resident, located in Wisconsin, wishes to purchase a hearing aid from Hearing Help Express, the resident contacts Hearing Help Express via the United States mail, telephone, or the internet at Respondents' Illinois location.
11. At the Wisconsin location, the consumer fills out an order form and elects to either (a) defer payment or (b) mail payment to Respondent's Illinois address in the form of cash, personal check, or credit card. Hearing Help Express allows all customers (with the exception of prisoners and some past customers with poor credit histories with Hearing Help Express) to elect to make deferred payments in four installments beginning 30 days after shipment; in such cases, Hearing Help Express ships its products in advance of receiving any payment.
12. Hearing Help Express processes order forms and receives customer payments at its Illinois location. Respondents require that a potential customer provide a prescription or documentation that he or she has had a professional hearing examination. Alternatively, the customer may provide Hearing Help Express with a written waiver acknowledging that the customer understands that such an examination is in his or her best interests and that he or she nevertheless desires to purchase a hearing aid without such an examination. Such written waiver must conform to the requirements of the FDA's 1977 Hearing Aid Rule, adopting 21 CFR Section 301.421.

13. The hearing aid is then packaged in Illinois and placed in the United States mail or with other delivery services for delivery to the Wisconsin addresses. Respondents do not process or pack items in Wisconsin. Shipped items do not originate in Wisconsin.
14. Hearing Help Express does not have facilities, employees, or distributors in Wisconsin.
15. Hearing Help Express does not deliver products to Wisconsin in vehicles owned or leased by Respondents.
16. Hearing Help Express does not refuse consumers' business on the basis of the consumers' location when the order is placed.
17. Consumer questions related to the selection of hearing aids are answered by persons licensed in the State of Illinois as hearing instrument dispensers.
18. Hearing Help Express warrants its products for one year from the date of sale.
19. When Hearing Help Express receives orders, whether through the United States mail, by telephone or through the internet, Respondents do not directly observe the ear canal of potential consumers, nor do Respondents prepare or fit ear molds, nor do Respondents measure mail-order customers' hearing by means of an audiometer or by any other means.
20. Respondents do not sell hearing aids to consumers under age 18 years.
21. The Division of Enforcement does not allege that Respondents conduct business in violation of Illinois and/or federal law, rules and regulations.
22. Wisconsin has never sought or obtained an exemption from the preemption requirement of the Medical Device Amendments to the Federal Food, Drug and Cosmetics Act.
23. The Division of Enforcement does not allege that any of Hearing Help Express's employees have ever traveled to Wisconsin in the ordinary course of Hearing Help Express's business.
24. The Division of Enforcement is not aware of nor does it allege that there have been any complaints related to Respondents' products or business practices by Wisconsin consumers who have done business with Respondents.

### **CONCLUSIONS OF LAW**

1. The Wisconsin Department of Regulation and Licensing has jurisdiction in this matter pursuant to s. 440.21, Wis. Stats.
2. Hearing Help Express, Inc., James Hovis, Catherine Hovis, and Laura C. Stuebing engaged in the advertising and selling of hearing aids in Wisconsin, without a valid credential as required under Chapter 459, Wis. Stats.
3. Pursuant to s. 440.21 (2), Wis. Stats., the Department of Regulation and Licensing may enjoin Hearing Help Express, Inc., James Hovis, Catherine Hovis, and Laura C. Stuebing from advertising and selling hearing aids in Wisconsin without valid credentials.

### **ORDER**

**NOW, THEREFORE, IT IS HEREBY ORDERED** that Hearing Help Express, Inc., James Hovis, Catherine Hovis, and Laura C. Stuebing are **ENJOINED** from advertising or selling hearing aids in Wisconsin unless and until they become licensed as audiologists or as hearing instrument specialists under Chapter 459, Wis. Stats.

### **OPINION**

Presently, Hearing Help Express, Inc., James Hovis, Catherine Hovis, and Laura C. Stuebing are not licensed as hearing

instrument specialists or as audiologists under §§ 459.05 and 459.24 (3), Wis. Stats. At issue in this case is whether they are required to obtain those credentials in order to advertise and sell hearing aids in Wisconsin.

Hearing Help Express, Mr. Hovis, and Mmes. Hovis and Stuebing (Hearing Help et al.) maintain that Wisconsin's licensing requirements are preempted by federal law, specifically by the Medical Device Amendments to the Federal Food Drug and Cosmetics Act. They also maintain that the licensing provisions place an undue burden on interstate commerce contrary to the Commerce Clause. Finally, they argue that Wisconsin's licensing requirements violate the First Amendment because they effectively ban the advertising of hearing aids by those who do not hold a license. Each of these issues will be addressed in turn.

Before considering the federal law, namely the Medical Device Amendments to the Federal Food Drug and Cosmetics Act, a review of sections 459.02 (1) and (2) of the Wisconsin Statutes is required. Section 459.02 (1) provides, in relevant part, that “[n]o person may engage in the practice of selling or fitting hearing aids or display a sign or in any other way advertise or represent himself or herself as a person who practices the fitting or sale of hearing aids unless he or she holds a valid license issued under this subchapter or a valid license or permit to practice audiology issued under subch. II . . .”

Additionally, section 459.02 (2) provides, in part, that “[n]othing in this subchapter or subch. II shall prohibit any corporation or mercantile establishment which maintains an established business address from engaging in the business of selling or offering for sale hearing aids at retail without a license, provided that for the purpose of selling and fitting hearing aids it employs persons licensed under this subchapter or persons issued licenses or permits to practice audiology under subch. II . . .”

These provisions provide that no one may sell or fit hearing aids or advertise that he or she practices fitting or selling hearing aids unless that person is licensed as a hearing instrument specialist or as an audiologist. They also provide that businesses are not required to obtain a license for selling or offering to sell hearing aids, if the business employs a licensed hearing instrument specialist or licensed audiologist.

The Division of Enforcement maintains that because Hearing Help et al., advertises in Wisconsin and sells hearing aids in Wisconsin, they are required to obtain a Wisconsin license. By its own admission, Hearing Help et al., acknowledges that they are engaged in the sale of hearing aids. They admit that they advertise their products in both national and regional magazines that are circulated in Wisconsin. They also maintain a website advertising their wares and have a toll-free number for customers to use throughout the country, including Wisconsinites. Wisconsin residents have purchased hearing aids from Hearing Help et al., and those products are either delivered via the U.S. mail or another delivery service.

Despite these obvious signs of advertising and sales, Hearing Help et al., argues that they do not engage in activities that require a Wisconsin license. They insist that because they only engage in sales, rather than the “practice of dealing or fitting” hearing aids, they are exempt from the licensing requirements. Their arguments are unconvincing. It appears as if Hearing Help et al., is confusing the qualifications that are required for licensure with the conduct for which licensure is required. Indeed, the issue is fundamentally whether Hearing Help et al., advertised and sold hearing aids in Wisconsin, not whether they meet the criteria for licensure.

Hearing Help et al., suggests that only those who sell hearing aids but who do not measure hearing are exempt from having to obtain a license. They argue that the Supremacy Clause of the United States Constitution preempts Chapter 459 from requiring credentials for those persons because federal law mandates that adults be allowed to purchase hearing aids without first submitting to a hearing examination. Their reading of Chapter 459 is misguided.

Section 459.02 (1), Wis. Stat., plainly states that a person who engages in the practice of selling *or* fitting hearing aids or who displays a sign or in any other way advertises that he or she is fitting or selling hearing aids must hold a valid license under Chapter 459 in order to do so. Unlike what Hearing Help et al., argues, the use of the word “or” in the statutes denotes a disjunctive term, meaning an alternative exists between “selling” and “fitting.” Therefore, a person need not both “sell” and “fit” hearing aids in order for the licensure requirement to apply. Rather, persons who either “sell” or “fit” hearing aids are required to obtain a license before engaging in either activity. But even if, *arguenda*, both elements were required for licensure, the position to which Hearing Help et al., subscribes nevertheless fails because s. HAS 5.02 (1) (d), Wis. Admin. Code, implicitly recognizes that a consumer may waive a medical evaluation under 21 CFR 801.421, and thereby avoid a hearing examination. Consequently, Wisconsin law does not require that adults obtain a hearing examination prior to being allowed to

purchase a hearing aid.

Hearing Help et al., also argues that they do not actually sell hearing aids in Wisconsin and that as a result they are not subject to the licensing provisions under Chapter 459. They maintain that because their “transaction” occurs in Illinois, they are not subject to the jurisdiction of the Hearing and Speech Examining Board or the Department of Regulation and Licensing. Their arguments are not persuasive. To begin, Hearing Help et al., utilizes a variety of publications within Wisconsin to induce sales within this state. They do not rely upon word of mouth to generate sales; instead, they explicitly attempt to make sales in Wisconsin through advertisements placed within this state. In addition, Wisconsin consumers initiate orders from within this state as well as tender payment from within Wisconsin. But Hearing Help et al., maintains that while they may advertise in Wisconsin, their transaction concludes in Illinois once the hearing aid is shipped to the purchaser. They therefore argue, unconvincingly, that they have engaged in a sale within Illinois, not Wisconsin. However, the more logical and persuasive conclusion is that the actual sale is complete upon delivery to the consumer which results in the sale of a hearing aid in Wisconsin, even if the transaction “originates” in Illinois. In short, it is mere folly to suggest, as Hearing Help et al., has, that they are not engaged in the “practice of selling” hearing aids. Because the inducement, offer, tendering of payment, and final delivery of the hearing aids all occur in Wisconsin, Hearing Help et al., is indeed engaged in the practice of selling hearing aids in Wisconsin as found in s. 459.02, Wis. Stats.

Nevertheless, Hearing Help et al., insists that Wisconsin’s licensing requirements are preempted by federal law, specifically by the Medical Device Amendments to the Federal Food Drug and Cosmetics Act. They further argue that the licensing provisions place an undue burden on interstate commerce contrary to the Commerce Clause. Finally, they claim that Wisconsin’s licensing requirements violate the First Amendment because they effectively ban the advertising of hearing aids by those who do not hold a license. As a consequence, they argue that imposing an injunction would be inappropriate as would requiring them to become licensed. Their arguments are without merit.

The Division of Enforcement’s action merely seeks to prevent Hearing Help et al., from practicing the sale of hearing aids, from representing themselves as selling hearing aids, and from engaging in any other act for which a license is required by the Hearing and Speech Examining Board. Hearing Help et al., argues, though, that the Supremacy Clause of the United States Constitution renders the Wisconsin licensing requirements unconstitutional because it is preempted by federal law, namely the Medical Device Amendments to the Federal Food Drug and Cosmetics Act. They rely upon a Missouri Attorney General’s opinion to support their position. However, they have presented no evidence that the Medical Device Amendments have ever been used to preempt a state’s exercise of its police powers by regulating the professionals who sell hearing aids.

Perhaps if the Division of Enforcement was seeking to control the conditions surrounding the sale of hearing aids, Hearing Help et al., would be on stronger footing with respect to its federal preemption argument. But instead, all that is being sought is for Hearing Help et al., to obtain a Wisconsin license in order to practice in this state. The Medical Device Amendments do not regulate professionals who sell hearing aids, nor do they prevent states from enacting laws that contain regulations that address the qualifications and licenses for professionals who sell hearing aids. The amendments do, apparently, prevent states from having requirements on hearing devices that are different from or in addition to the federal requirements. But the latter is not at issue in this case. Therefore, s. 459.02, Wis. Stats., is not subject to federal preemption in this instance.

Despite the request of Hearing Help et al., administrative agencies do not have the power to declare statutes unconstitutional. See *Metz v. Veterinary Examining Board*, 2007 WI App 220, ¶ 21, 305 Wis. 2d 788, 807, 741 N.W.2d 244 (Wis. Ct. App. 2007). It is solely within the province of the courts to interpret statutes and determine whether they are constitutional. See *Warshafsky v. The Journal Company*, 63 Wis. 2d 130, 147, 216 N.W.2d 197 (1974). Furthermore, despite its protests to the contrary, Hearing Help et al., does not have standing to challenge s. 459.02, Wis. Stats., ironically, because it is not licensed in Wisconsin. Because administrative agencies are unable to determine whether a statute is unconstitutional and because Hearing Help et al., does not have standing under s. 459.02, Wis. Stats., the undersigned respectfully declines to address whether ss. 459.02, Wis. Stats., is valid under the Commerce Clause and the First Amendment.

Hearing Help et al., is clearly attempting to evade having to become licensed in Wisconsin and thus avoid the state’s valid police power which allows it to require credentials for those persons wishing to engage in the sale of hearing aids. It has utilized a variety of arguments to buttress its claims, none of which are convincing. Hearing Help et al., argues that because it conducts its business in Illinois, it should not be subjected to Wisconsin’s regulations. But the fact remains, Hearing Help et al., advertises and sells hearing aids in Wisconsin too, not just in Illinois. Wisconsin citizens buy them in this state, pay for them

in this state, and receive them in this state. However, if a problem arises for Wisconsin citizens in connection with the sale of a hearing aid from Hearing Help et al., they have no recourse in this state because Hearing Help et al., is only licensed in Illinois, not Wisconsin. Any aggrieved Wisconsin citizen would therefore have to file a complaint and pursue any remedies against Hearing Help et al., in Illinois.

The state has a valid interest in seeking to protect Wisconsin consumers by requiring Hearing Help et al., to obtain the necessary licenses to operate in this state. Therefore, if Hearing Help et al., wishes to continue to engage in their existing activities, they must first obtain the required credentials in order to do so. In the absence of valid credentials, they are directed to cease and desist from engaging in the sale of hearing aids, from representing themselves as selling hearing aids, and from engaging in any other act for which a license is required by the Hearing and Speech Examining Board.

Dated at Madison, Wisconsin, this 24<sup>th</sup> day of June, 2008.

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Jacquelynn B. Rothstein  
Administrative Law Judge