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October 26, 2011

VIA OVERNIGHT MAIL

Lisa Tseng, MD, CEO
hi HealthInnovations
3022 Momentum Place
Chicago, IL 60689-5330

Re: hi HealthInnovations Internet Hearing Tests & Devices

Dear Dr. Tseng:

I am the General Counsel for the International Hearing Society. It has been brought to our attention that you are marketing a "hearing device" over the internet without, in our opinion, fully complying with the United States Food and Drug Administration's requirements for the sale of hearing aids. Further, we believe your organization's actions violate most individual State licensing laws regarding the sale of hearing aids. At this time we ask that you immediately cease and desist the sale of hearing aids through the hi HealthInnovations website.

Lisa Tseng, MD, CEO

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Food and Drug Administration

As you are no doubt aware, the FDA defines a hearing aid as “any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with, or compensating for, impaired hearing.”ⁱ It is clear that your product falls within the FDA’s definition of a hearing aid and thus falls under the purview of Federal and State regulatory and licensing agencies.

The FDA requires, in part, that a hearing aid dispenser “**provide**” a copy of the User Instructional Brochure (Brochure) to each prospective user,ⁱⁱ and that the hearing aid dispenser “**review**” the content of the Brochure with the prospective user and afford the prospective user an “**opportunity to read**” the Brochure “**prior**” to asking the prospective user to sign a medical evaluation waiver.ⁱⁱⁱ While it appears a consumer may be able to find product literature if they drill down to the correct page on your website, there is no evidence that you are actually **providing** product Brochures to all prospective purchasers prior to purchase, nor is there any evidence you are actually **reviewing** the brochure with the prospective customer, and doing so **prior** to the patient signing the medical evaluation waiver.

The FDA also requires that hearing aid dispensers abide by very specific labeling and warranty requirements, which are not evident on the hi HealthInnovations website. In addition, the FDA recommends that hearing professionals refer patients to licensed physicians when assessing a patient for a hearing aid and “red flag” signs of a potentially devastating condition are present. Based on our review of your website as well as our own participation in your online “hearing test,” it is evident that your program requires the consumer to do their own “red flag” testing.^{iv} This “self diagnostic” approach is not only inconsistent with the FDA’s directives and State Licensing laws, it unreasonably places the consumer at great risk.

State Licensing Laws

It is also our belief that hi HealthInnovations is violating most (if not all) State licensing laws by virtue of the fact that hearing is being tested, and hearing aids are being sold, by individuals who are not licensed by the state in which the end user resides. Most State Licensing laws contain language similar, if not identical, to the following:

*No person shall engage in the practice of fitting and selling hearing aids or display a sign or in any other way advertise or hold himself or herself as a person who practices the **dispensing** of hearing aids unless he or she is licensed in the State of _____.*^v

Dispensing includes but is not limited to administering hearing tests and selecting and fitting hearing instruments.

Duly licensed refers to a person who is licensed by a State's governing body to engage in the practice of dispensing hearing instruments.

By way of example, the State of California's Business and Professions Code Chapter 7.5, Article 3, reads as follows:

License Required

3350. It is unlawful for an individual to engage in the practice of fitting or selling of hearing aids, or to display a sign or in any other way to advertise or hold himself or herself out as being so engaged without having first obtained a license from the board under the provisions of this chapter. Nothing in this chapter shall prohibit a corporation, partnership, trust, association or other like organization maintaining an established business address from engaging in the business of fitting or selling, or offering for sale, hearing aids at retail without a license, provided that any and all such fitting or selling of hearing aids is conducted by the individuals who are licensed pursuant to the provisions of this chapter.

Unlicensed Practice

3427. It is unlawful to engage in the practice of fitting or selling hearing aids in this state without having at the time of so doing a valid, unrevoked and unexpired license or temporary license.

Practice Without a Business Address

3429. It is unlawful to engage in the practice of fitting or selling hearing aids without the licensee having and maintaining an established business address, routinely open for service to his clients.

A review of all 50 State's licensing laws has been performed and virtually every State licensing statute contains language similar to that found in California. It is our firm belief that these statutes expressly prohibit the sale of hearing aids to consumers in their State by individuals who are not, at a minimum, licensed in their State.

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Mail Order Hearing Aid Sales

In addition to State laws which require dispensing of hearing aids be performed by state licensed individuals, several states have adopted specific prohibitions which either ban mail order sales outright, or only allow these types of sales when there has been face to face contact, a prior fitting, or otoscopic examination by an individual licensed by that particular state. These states include California, Florida, Kansas, Missouri, Nevada, New York, Oregon, Texas, Washington, and West Virginia. Sales in these States is, in our opinion, a per se violation of their State laws.

Federal and State Consumer Protection Laws

The Federal Trade Commission, as well as most State consumer protection acts, prohibit unlawful, unfair, unconscionable, and/or deceptive trade practices. Failure to comply with State licensing laws is an unlawful practice and, in our opinion, a per se violation. Further, by omitting the fact that hi HealthInnovations is not (and does not employ) state licensed dispensers creates the misunderstanding by consumers that dispensers are not required to be licensed and that hearing aids are safe to be purchased through the internet. We believe this practice violates both the letter and the spirit of the FTC guidelines and State consumer protection laws.

The dispensing of hearing aids requires specific knowledge and skill to ensure that the interests of the hearing impaired public will be adequately served and safely protected. Appropriately selected and fitted hearing aids can give great satisfaction, improve quality of life, and protect public health. FDA requirements, State licensing laws, and Federal and State Consumer Protection laws, are designed to protect the public from harm. Unfortunately, your actions violate Federal and State laws and we must ask that you cease and desist.

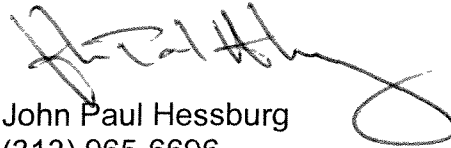
If you are unwilling to do so, we will have no choice but to pursue all legal remedies including but not limited to filing a complaint with the Federal Trade Commission, as well

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as pursuing action(s) at the State level for violating State licensing regulations and State consumer protection laws.

Should you wish to discuss IHS' position please do not hesitate to call me directly.

Very truly yours,



John Paul Hessburg
(313) 965-6696
john.hessburg@kitch.com

JPH:bkp

cc: Kathleen Mennillo, IHS Executive Director

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ⁱ 21 CFR 801.420.

ⁱⁱ 21 CFR 801.430(b)(1).

ⁱⁱⁱ 21 CFR 801.430(b)(2)-(3).

^{iv} The Food and Drug Administration's (FDA) Hearing Aid Rule (Rule) identifies several "red flag" medical conditions that a hearing professional should refer to a licensed physician:

- (1) Visible congenital or traumatic deformity of the ear;
- (2) Active drainage from the ear within the previous 90 days or history of this symptom;
- (3) Sudden or rapidly progressive hearing loss within the previous 90 days or history of this symptom;
- (4) Acute or chronic dizziness;
- (5) Unilateral hearing loss of sudden or recent onset within the previous 90 days;
- (6) Visible evidence of cerumen (earwax) accumulation or a foreign body in the ear canal;
- (7) Significant air-bone gap, when generally acceptable standards have been established;
- (8) Pain in the ear within the previous 90 days.

^v Due to the way your program is set up it is not possible to identify the specific individual who is "dispensing". However, shielding this person(s) identity behind the illusion that the transaction is with a "company" versus an "individual" in no way obviates your affirmative obligation to comply with State licensure laws. See for example, Alabama's licensing statute, Section 34-12-2(b) which states in pertinent part:

(b) Nothing in this chapter shall prohibit a corporation, partnership, trust, association, or other like organization maintaining an established business address from engaging in the business of selling or offering for sale hearing instruments at retail without a license; **provided, that it employs only properly licensed or permitted natural persons and that it shall have at least one licensed Alabama dispenser on its staff** to provide direct supervision of any licensed fitters or apprentices employed in the direct sale and fitting of such products. Such corporations, partnerships, trusts, associations, or other like organizations shall file annually with the board a list of all licensed hearing instrument dispensers, fitters, and apprentices directly or indirectly employed by them. Such organizations shall also file with the board a statement on a form approved by the board that they submit themselves to the rules and regulations of the board and the applicable provisions of this chapter. (Emphasis added.)