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**November 2, 2005**

Division of Dockets Management (HFA-305)  
 Food and Drug Administration  
 5630 Fishers Lane, Room 1061  
 Rockville, MD 20852

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**Re: Testimony Submission Docket No. 2005N-0354 Consumer-Directed Promotion of Regulated Medical Products**

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Please find the written testimony, submitted by the Hearing Industries Association (HIA) in response to **Docket No. 2005N-0354 Consumer-Directed Promotion of Regulated Medical Products.**

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2005N-0354

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## **TESTIMONY OF THE HEARING INDUSTRIES ASSOCIATION**

*Presented by*

Carole M. Rogin, Executive Director

Public Hearing: Consumer-Directed Promotion of Regulated Medical Products

November 1, 2005

Thank you for the opportunity to present the views of the Hearing Industries Association (HIA) at today's hearing. As an introduction, I am Carole Rogin and I have served the hearing aid industry for a number of years; our members manufacture hearing aids, hearing aid components and supplies such as batteries, and collectively, our HIA member companies produce most of the hearing aids sold in the United States on an annual basis.

Our products have a unique regulatory profile. Hearing aids, unlike many other medical devices, have a virtually unblemished safety record, as they are not the type of product that poses a health risk, especially in the context of the full array devices and drugs that FDA regulates. Further, hearing aids are dispensed directly to the consumer without the need for a prescription from a physician. They are dispensed by audiologists and hearing aid specialists who are trained in hearing health and licensed by the states in which they practice, with the only exception being the state of Colorado, which does not have a hearing aid licensure law.

Despite this safety record, the FDA has classified hearing aids as Class I "restricted devices" and, for many years, has paid special attention to how hearing aids are promoted to the public. A specific hearing aid rule delineates the way in which hearing aids are to be sold and, among other regulatory requirements, the restricted status of hearing aids provides the FDA with jurisdiction over the advertising of them.

While our members respectfully disagree with the need for such scrutiny, we have always sought to work with the FDA in a cooperative spirit to assure that our customers receive accurate and balanced information. We believe that the current regulatory scheme for hearing aids and hearing aid advertising is working, and we urge the Agency to preserve the ability of hearing aid manufacturers to provide information directly to consumers without additional regulations or requirements.

The importance of direct to consumer advertising to our companies and our customers cannot be overstated. As previously noted, hearing aids are not prescriptive devices, so consumers self-initiate hearing examinations – either because of their own concerns about their hearing, sometimes – but not often enough - at the suggestion of their primary care physician, but usually at the insistence of friends and family members who notice a loss of hearing. Consequently, the goal of our advertising has been not only to promote our products, but also and very importantly to educate consumers about the symptoms of hearing loss and help them understand that, for most people with hearing losses, the treatment of choice and, in fact, the only available treatment is hearing aids.

In addition to increasing awareness of hearing loss and hearing aids, direct to consumer hearing aid advertising differentiates today's hearing aids from less technologically advanced instruments of just a few years ago. Indeed, advertising not only reminds consumers that hearing aids are the treatment for most hearing losses, but it also enables them to learn about new, innovative products and features that can further improve their hearing.

Consumer-directed hearing aid advertising is essential because, despite our efforts, the percentage of people with hearing loss who use hearing aids is inexplicably low. Our surveys have been tracking the numbers for many decades, and they remain remarkably consistent. Of the 32½ million people in the United States with hearing loss, only about 23% currently use hearing aids.

This is unfortunate because today's hearing aids are very effective. While there are an array of advances in miniaturization, microphone technology and other elements, it is the incorporation of digital technology that has revolutionized our products. We all know someone – a parent, an aunt or uncle – who bought a hearing aid years ago and did not use it because it did not work in all environments. amplified sound inconsistently or was simply too difficult to use. With the advent of miniaturized digital technology, many of the problems have been addressed and eliminated, and satisfaction with today's hearing aids is at an all time high.

According to MarkeTrak, a longitudinal study of the hearing aid over the past 15 years, underutilization of hearing healthcare is due primarily to a lack of medical referrals and a key area addressed by advertising – stigma. While we do not even notice whether a person wears eyeglasses or not, and there is no stigma associated with declining vision, many people still feel stigmatized by hearing loss and its association with the aging process, or by wearing a hearing aid, which they remember to be big, bulky and very visible.

This stigma is a powerful disincentive to seeking hearing help, despite the fact that untreated hearing loss can be much more “visible” than a hearing aid when people don't hear accurately and respond inappropriately. As Dr. William Slattery of the world-reknowned House Ear Institute in Los Angeles, California noted in a *Newsweek* cover story article earlier this year, people with hearing losses who don't use hearing aids are “ afraid to look old, but they don't mind looking dumb.”

DTC hearing aid advertising addresses this problem in two ways: first by making clear that hearing loss is nothing to be ashamed of; it is often age related, but is also environmental in nature, as anyone who has grown up attending rock concerts or using hand-held hair dryers on a daily basis knows. Secondly, the advertising features today's hearing aids, which differ substantially and positively from many people's memories – today's hearing aids are now so small and fit so comfortably completely in the ear or behind it that they are essentially invisible.

The hearing aid industry has truly had what I call a "silent revolution" in technology, and we use our advertising and promotion to encourage people with a hearing loss to seek help. For people with hearing losses, hearing aids can truly enhance their quality of life and bring them back into families, groups, and workplaces from which their hearing losses have made them withdraw or totally disconnect. A recent report from the Better Hearing Institute (BHI) demonstrated that hearing loss is significantly related to income loss and, the greater the hearing loss, the greater the loss in income. On average, individuals who do not use hearing aids earn between \$1,000 and \$12,000 less annually and this translates into substantial income loss over a career; the cost to society as a whole, is huge.

I want to assure you that the hearing aid industry takes its advertising responsibilities extremely seriously. More than a decade has passed since FDA took enforcement action against our advertising. To augment cooperative actions by the Agency and our industry, HIA developed its own voluntary "Guidelines for Hearing Aid Manufacturers for Substantiation of Performance Claims" in November 2002 when the Agency's own guidance document was sunsetted. Additionally, in order to assure that our advertising standards are maintained, in 2003, HIA developed a voluntary review system that we call HEARS – it stands for Hearing Aid Advertising Review System. It is a process that all of our members agree to employ if advertising complaints or disputes arise. We are strong advocates for self-regulation of advertising, and endorse the efforts of trade associations in the drug industry, as well, to self-regulate.

In summary, HIA and, indeed, all in the hearing aid industry believe that direct to consumer hearing aid advertising serves an important public health function by helping people understand that hearing loss is nothing to be ashamed of, that it can be corrected with hearing aids, and that, in the words of Dr. James Furman, President and CEO of the National Council on the Aging, "untreated hearing loss is not a benign condition." Hearing aid advertising is often the only source

of information about hearing health available to people who have concerns about their hearing ability.

HIA believes that the advertising by our members is being done, uniformly, in a responsible way, and we have set up systems to assure that this sense of responsibility is maintained. Our association and our members intend to continue to work closely with the FDA to understand whatever concerns the Agency may have about medical device advertising, and to address those issues before they affect our industry.

HIA commends you for holding these hearings and looks forward to working with you in the years ahead. Thank you for this opportunity to present the views of the Hearing Industries Association.