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Comments Opposing the Etymotic and Gudhear Petitions
Docket Numbers 2003P-0362 and 2003P-0363

FDA Oversight of Hearing-Aid Technology Should Be Strengthened Not Weakened

Summary
This document is intended as a response to the petitions filed by Etymotic and Gudhear requesting that the FDA eliminate the requirement of a medical examination prior to the dispensing of a hearing aid and other measures that currently retard the sale of over-the-counter hearing aids. Although the goal of providing greater access to hearing-aid technology is a worthy one, the specific remedies proposed in the petitions are likely to be counter-productive and could conceivably hurt more individuals than would be helped. This document provides a detailed rejoinder to the arguments contained in the Etymotic and Gudhear petitions in an effort to help the FDA formulate a coherent policy regarding the oversight of hearing-aid technology in the United States.

Introduction
The petitions filed by Etymotic and Gudhear request that the FDA rescind requirement of a medical examination prior to the dispensing of a hearing aid. They argue that the current FDA requirement limits access to hearing-assistance technology because of the time and expense associated with a medical exam and fitting by a certified dispenser. The petitions liken hearing aids to reading glasses that can be purchased without prescription ("over-the-counter") in drugstores and supermarkets for approximately $10. They pose the following question – if reading glasses can be obtained without a medical or optometric exam, why can't hearing aids? In their view the ready availability of over-the-counter hearing aids would help millions of individuals with a hearing problem overcome their deficit at an affordable cost.

Providing greater access to hearing-assistance technology is, unquestionably, a laudable goal. Etymotic and Gudhear are to be commended for bringing this important issue to the attention of the FDA and the audiological community as a whole. Hearing impairment is one of the most important factors contributing to mental decline and depression among the elderly, and can wreak significant damage on both patients and their loved ones. Moreover, the ultimate cost of hearing impairment to the American economy and the

2003P-0363 C5

U.S. Government is close to $50 billion per year, due to the psychiatric and mental consequences of this profound communicative problem. By 2010, more than a quarter of the American population is likely to be older than 60 years of age, and many of these individuals will experience a serious deficit in hearing. Given the looming dominance of aging "baby boomers" in our population, it is imperative that the American government formulate a coherent strategy for ameliorating hearing loss among the elderly that is both effective and affordable – the only question is how?

The proposal of Etymotic and Gudhear, if adopted by the FDA, could potentially exacerbate, rather than ameliorate the current situation among the hearing impaired in the U.S. As a person's hearing-related deficit increases, without being diagnosed by a hearing professional, the risk of permanent hearing (and attendant cognitive) impairment increases (see "*Why is Hearing Loss So Serious*" below). The primary problem confronting this population is not the cost of the technology and fitting per se, but rather it is the deficient methods currently used to dispense hearing aids. More effective fitting procedures (as described below), combined with more stringent regulation of the hearing-aid industry, are likely to alleviate the plight of the hearing impaired to a far greater degree than could ever be accomplished by ready availability of inexpensive auditory prostheses. Moreover, the widespread adoption of inexpensive, non-customizable aids by the hearing impaired could actually result in an *increase* in hearing-related deficits, with a concomitant greater outlay of U.S. government and private funds for medical problems associated with a decline in communicative competence.

The remainder of this document addresses the issues raised in the Etymotic and Gudhear petitions in detail, and outlines a different course of action that should be undertaken by the federal government to alleviate the plight of the hearing impaired in the U.S. Because of the complexity of the issues raised by the Etymotic and Gudhear petitions we first present a brief primer concerning hearing impairment and hearing-aid technology in order to place our response in a context readily understood by those outside the audiological community. Immediately following the primer we address specific issues raised by the Etymotic and Gudhear petitions. In the final section we outline a strategy to improve the quality of services provided to the hearing impaired in this country.

Hearing Aid Primer

The overwhelming majority (ca. 95%) of individuals experiencing a hearing problem can trace their deficit to structural damage in the inner ear (i.e., sensorineural loss). Such damage affects not only the ability to detect sounds (audibility), but also and most significantly, the ability to process sound effectively and efficiently in a wide range of listening conditions. Verbal communication is often adversely affected because auditory dysfunction affects the ability to comprehend spoken language, particularly in public places with significant amounts of background noise and acoustic reflections (reverberation). Such a deficit often results in the hearing-impaired shunning social contact in order to avoid misunderstanding others during verbal interaction. This avoidance of social contact may constitute the first step in a long downward spiral in cognitive and affective states that ultimately ends in depression or even pre-mature senility and mental incapacitation.

In order to lessen the consequences of a hearing deficit of sensorineural origin it is essential to custom fit an aid to the individual's specific loss – no two individuals sustain the same pattern of damage. The hearing structures that remain intact interpret sound in a manner dependent on the individual needs and capabilities of the patient. Knowledge of these idiosyncratic patterns provides the key to fitting a hearing aid successfully and can only be accomplished through careful fine-tuning of the aid.

Further complicating the fitting process is the need to adapt the aid to the patient's ear canal. Each canal has a unique shape that must be taken into consideration when designing the mold used to place the aid in contact with the external ear. A poorly fit earmold or shell can cripple an otherwise excellent hearing aid through either unwanted acoustic feedback (often in the form of harsh whistling) or by changing the resonance characteristics of the aid, making it more difficult to understand spoken language. Moreover, the earmold, by virtue of its insertion into the canal, acts as a plug, blocking the passage of sound into the ear, and can distort the perception of the speaker's own voice unless special precautions are taken. If the earmold is fit incorrectly it can be improperly vented and thus lessen the hearing aid's efficacy.

Because of the highly technical nature of the hearing-aid fitting process it is difficult to achieve an optimum outcome in the absence of a careful, time-intensive evaluation that is accompanied by a fine-tuning of the aid's adjustable (software) settings. A typical fitting requires three to eight hours to perform, distributed over a period of six weeks. Key to a successful fit is the patient learning to adapt to the aid over the initial three to six months of wear. Often this adjustment process requires multiple adjustments of the hearing aid. Without such fine-tuning the patient is unlikely to wear the aid consistently and thereby achieve the optimum benefits provided by the device.

What are the consequences of a poorly fit hearing aid? A study published in 1984 by Silman and colleagues suggests that the absence of a properly fit aid can wreak enormous damage on an individual's ability to communicate (Silman et al., 1984). In that study the ability of 44 patients to understand speech was evaluated over a fifteen-year interval. Although both ears of the patient experienced a comparable deficit at the study's start, only a single aid was prescribed. The ear lacking the aid was far less capable of understanding speech at the study's conclusion than the aided ear (all other factors being equal). The absence of proper acoustic input appears to have lessened the ability of the auditory system and the brain to accurately process and decode speech. It is unclear whether such damage could be rectified, even with the most sophisticated hearing-aid technology. Thus, there is a risk of permanent hearing (and attendant cognitive) impairment in the absence of timely, well-executed intervention. This is an important consideration when evaluating the long-term efficacy of non-custom-fit, over-the-counter hearing aids, such as those currently marketed by Songbird and other companies.

What is Involved in Fitting a Hearing Aid?

The procedure for fitting a hearing aid is complex and time consuming if performed properly. It involves at least four separate stages of evaluation, analysis, tuning and adjustment.

First, the patient's hearing capabilities have to be evaluated and the etiology of the deficit determined. A detailed medical history is collected and a physical examination of the external and middle ear performed. Deficits of non-sensorineural origin (such as an acoustic tumor or infection of the middle ear) are referred to the appropriate clinician for consultation. The hearing evaluation consists of a number of audiometric tests, each designed to ascertain a patient's residual hearing capacity, as well as measure the ability to understand speech under controlled acoustic conditions. During this initial session a custom earmold impression is made.

The second visit focuses on how best to present sound (particularly speech) to the patient. Special tests are performed to assess the patient's auditory capabilities over a broad range of listening conditions using state-of-the-art digital technology. These tests provide an objective basis with which to select the type of hearing aid most likely to improve the patient's listening capabilities. This process is based on objective methods using sophisticated acoustic-measurement equipment, as well as subjective criteria that largely pertain to speech communication. The next stage in the fitting involves a demonstration and discussion of the relative merits of various types of hearing aid. This process often requires time and intricate adjustment to accomplish. The client becomes a knowledgeable participant in the appropriate choice of the hearing aid he/she will be wearing.

Once the hearing aid and earmold have been selected and properly fit it is necessary to fine-tune the aid and verify its efficacy. This third stage requires both objective and subjective methods of evaluation. First, it is necessary to determine audibility at different frequencies with the aid in place. Moreover, it is important to ensure that the subjective magnitude (loudness) of these frequencies is relatively equal and balanced across the spectrum. Second, the aid is evaluated with respect to how well the patient understands speech in a variety of listening situations representative of the real world. Speech intelligibility is assessed in both quiet and noisy conditions, with and without reverberation. In addition, the patient's reliance on visual speech cues (lipreading) is assessed independently, in order to adjust the spectral balance of the aid and optimize its performance in face-to-face interaction. It is also important to tune the aid so that sound seems natural and clear – otherwise, the patient is unlikely to wear the aid throughout the course of the day. This process of "customization" is crucial for the ultimate success of the hearing aid.

After this initial three-stage fitting procedure is completed the patient is ready to begin wearing the aid on a daily basis. However, the process of fine-tuning the aid is far from done. Over the next several weeks the patient evaluates the aid in a wide range of listening environments and works with the dispenser to optimize its performance during follow-up visits. This period of adjustment and fine-tuning is guided partly by the initial

hearing tests but is also influenced by the patient's feedback over the first few weeks' experience with the aid, as well as by his/her ability to adapt to changes in the way sound is perceived and interpreted.

The adjustment and adaptation period is crucial for the ultimate success of the fitting procedure, as it provides an opportunity for the dispenser to eliminate any distortion or imbalance associated with the initial fit. In addition, the dispenser uses fine-tuning of the aid to create a pleasant experience as a means of adapting the client to various types of sound in frequently encountered listening environments. This is accomplished by having the patient judge the naturalness of a broad range of sounds (including speech) in many different listening contexts. The experienced dispenser can use such information to adjust the spectral balance of the aid so as to optimize sound clarity and increase the likelihood of the patient using the aid on a routine, daily basis. The amount of time required to accomplish this fine-tuning varies from patient to patient. Often, the adjustment period extends over a period of weeks but can take as long as several months to complete. Many dispensers provide a no-risk guarantee so as to ensure the patient's complete satisfaction with the aid provided. Over-the-counter hearing aids do not afford the opportunity to customize the device to the patient's individual needs in the manner described in this primer and are therefore referred to as "non-customizable" in the present discussion.

Often, the hearing and cognitive capabilities, as well as the lifestyle of the patient, change over the course of several years, requiring additional adjustment of the aid to ensure optimum performance. In addition, the patient will be asked to visit the dispenser on a regular basis to ensure that the aid is continuing to work properly. With proper maintenance and care an aid should last between seven and ten years. Given the amount of time and attention required to optimize an aid's performance, the initial cost (generally $2,000-3,000) is relatively modest, particularly in view of the hardware's anticipated lifespan.

Why is Hearing Loss So Serious?

A hearing loss generally results from damage to those parts of the inner ear involved with the detection and analysis of sound. Far more than amplification is required to ameliorate the problem – the ability to effectively communicate is not predictable by audibility alone. For it is not only the inability to hear "soft" sounds that affects the speech comprehension capability of the hearing impaired. Their capability of understanding speech in noisy conditions is seriously undermined. Words appear to "blur" and lose their crispness. The listener is no longer confident of what is being said and loses the ability to verbally interact in a facile, spontaneous manner. Eventually, such a deficit can result in withdrawal from social interaction, with a concomitant decline in the individual's mental and emotional capabilities.

The ability to verbally interact involves far more than merely decoding the words spoken. It also entails attending to a speaker's voice in a complex background, filtering out extraneous sounds and voices, as well as anticipating what the speaker is going to say next. This capability is built upon an intricate interaction of auditory and cognitive processes operating in real time, requiring fast and accurate decoding of the speech

signal. The ability to understand spoken language among the elderly is particularly dependent on hearing acuity because of age-related changes in cognitive function. And yet it is among the elderly that hearing impairment is most common.

It is essential that this population have access to hearing-aid services capable of improving their hearing in order to maintain their cognitive and communicative capacities at a high level of function. For this reason the quality of the hearing aid and the manner in which it is fit provides a crucial means of maintaining the mental health of the elderly who have sustained a hearing loss.

Response to Specific Key Issues Discussed in the Etymotic and Gudhear Petitions

The central tenet of the Etymotic and Gudhear petitions concerns accessibility of hearing-assistance technology to the American population at large. In their opinion the primary barrier to widespread distribution of hearing-aid technology is cost and the time required to be examined by a physician and/or hearing specialist. They suggest that eliminating such barriers could ameliorate the functional deficit associated with hearing impairment to a significant degree.

Faulty Analogy Between Reading Glasses and Hearing Aids

Unfortunately, this perspective is based on a faulty analogy between sensorineural hearing loss and presbyopia, the difficulty visualizing objects (particularly text) close up that is particularly common among individuals older than 50 years of age. Inexpensive reading glasses of the kind discussed in the Etymotic and Gudhear petitions are designed to compensate for a change in the focus-accommodation capacity of the eye often observed among the middle-aged and elderly. Presbyopia is largely a mechanical problem affecting the elasticity of the eye's lens as well as the muscles controlling the positioning of the lens. Reading glasses are effective largely because the nature of the underlying problem is easy to compensate for with simple technology (i.e., adjustment of visual acuity through an external, artificial lens). There is no attempt to tailor the external lens to the specific visual impairment of the individual other than by adjustment of the refractive power of the eye (i.e., there is no attempt to correct for astigmatism and the like). Reading glasses are a simple "fix" for a relatively simple problem that works well under a very limited set of circumstances. Glasses designed for distance, particularly for driving and sports, are far more costly and require an optometric exam prior to making the corrective lenses. It is unlikely that the U.S. government will ever allow such corrective lenses to be sold over-the-counter because of the potentially harmful consequences of a grossly inaccurate prescription.

The structural and physiological bases of hearing impairment are far more complicated than those observed with most age-related problems of visual acuity. In myopia (i.e., near-sightedness) the focal length of the lens is set improperly. This can be compensated for either by corrective lenses or through laser surgery that alters the curvature of the lens. A corrective lens costs between $200 and $1,000, depending on the nature of the prescription, lens type and frame. Lasik (i.e., laser-guided) surgery typically costs between $1,000 and $3,000 per eye, and is chosen by millions of individuals each year in preference to corrective lenses despite its substantially higher cost.

In contrast to myopia and presbyopia, sensorineural hearing loss is not readily corrected through a simple application of technology. Hearing impairment usually originates in damage to the outer and inner hair cells of the cochlea. A certain proportion of the damage is age-related (as a consequence of repeated exposure to intense sounds), but many factors (including those pertaining to medications, genetics and lifestyle) influence the degree and form of impairment. Because of the complexity of sensorineural hearing loss – no two individuals manifest precisely the same deficit under a wide range of listening conditions – the technology required to ameliorate the deficit is costly, both to produce and to properly fit. For the present this situation is unlikely to change, and therefore only the most technically sophisticated aids, fit and fine-tuned as described in the Hearing Aid Primer above, are capable of truly helping those who need hearing assistance most.

Non-Customizable Hearings Aids Do Not Work Very Well for Those with a Hearing Impairment

The non-customizable aids (such as the Songbird) described in the Etymotic petition do not work nearly as well as implied by the study cited in that document (Moore et al., 2001). The Vallejo Hearing Aid Center, that I direct, was one of the principal sites for dispensing the Songbird device when it came on the market. Out of 36 individuals who were fit with the aid, only eight chose to continue wearing it after the first month of use – and only two of these eight purchased the aid more than twice. Twelve of the others opted for far more costly (and effective) hearing aids more suited to their specific form of hearing loss. Given the simplicity of the Songbird design (and other non-customizable, disposable aids), it is virtually impossible to achieve an adequate fit to the broad spectrum of listening conditions that most patients require. However, the Songbird *may* be an appropriate means of experimenting with hearing-assistance technology for those with a mild hearing loss who wish to try *some* form of hearing aid in advance of selecting more sophisticated technology or choose to defer hearing-assistance technology to a later date.

Even if the Songbird aid *were* to work as well as custom-fit and custom-tuned aids, it does not represent much of a significant cost saving over the anticipated lifespan of a first-class device. The batteries of the Songbird last approximately 400 hours, spanning an interval of approximately a month to six weeks (depending on use). After that period the aid is no longer effective and has to be replaced. Over the ten-year life span of a high-end aid an equivalent series of Songbirds would cost $2,400 – $3,600 ($20 – $30 per month per aid), approximately the same cost as a high-end digital aid.

What Proportion of the Hearing Impaired Population Uses Hearing Aids?

The Etymotic petition suggests that most of the hearing-impaired population in the U.S. has yet to wear a hearing aid. Many of these individuals could benefit significantly from the technology if only it were affordable and easy to obtain. Inexpensive hearing aids, combined with broad commercial distribution, is the answer to this vexing problem according to the petition.

A detailed analysis of the hearing-aid industry (Magilen, 1990a) suggests otherwise. The Marketing Edge newsletter of the Hearing Industry Association (HIA) reports that well over 50% of the 16+ million hearing impaired individuals in the U.S. do not intend to purchase a hearing aid. Most of these have only a mild loss in one or both ears and would not derive significant benefit from any form of hearing aid. Many of the remainder exhibit sensorineural or cognitive processing problems that cannot be effectively addressed with hearing aids. It is our belief that the actual market for hearing aids in this country is considerably smaller than that envisioned by the HIA, perhaps as few as 9 – 12 million individuals, and is largely saturated. Most individuals who truly need and can benefit from a hearing aid have either tried using one or are currently wearing one. The technology associated with the non-customizable hearing aids is unlikely to address the problems experienced by those with only a mild-to-moderate hearing loss, primarily because of annoying acoustic feedback and physical discomfort of the aid.

In our view, the primary problem is not the insufficient distribution of aids, but rather the inherent difficulty of addressing the needs of the mild-to-moderately impaired population, as well as the improper fitting of the moderate and profoundly hearing impaired. Many of the hearing impaired are dissuaded from purchasing a hearing aid by virtue of the technology's negative image. Hearing aids, as traditionally fit, often fail to deliver on the promise of enhancing speech communication. Over-the-counter, non-customizable aids are unlikely to improve either the image or success rate of the hearing-aid industry. Moreover, such aids could engender harm by dissuading a patient from seeking appropriate professional attention for what may turn out to be a serious hearing disorder.

Fitting is Key to Successful Hearing-Aid Technology NOT the Aid By Itself

The Etymotic petition points out that much of the cost associated with a sophisticated hearing aid is the dispenser's "mark-up." Eliminate the mark-up and the cost of the aid drops to a reasonable level. Unfortunately, in the absence of a proper fit, the hearing aid is unlikely to do the patient much good.

This is because there are two factors that largely determine the success (or failure) of a hearing aid. First, the aid must possess sufficient signal-processing capacity to precisely tailor sound to the needs of the patient. In practice this requires that the aid be capable of adjusting the amplification and degree of compression in many different frequency channels concurrently and in real time. Because each patient is unique, the hearing aid must be capable of making such adjustments in thousands of different ways. And because each aid has a unique constellation of strengths and weaknesses, an experienced dispenser is the person most capable of choosing the technology appropriate for the patient's hearing loss.

Although the most sophisticated hearing aids are able to provide enormous flexibility in sculpting the acoustic signal, it requires a great deal of experience and training to harness this power effectively. *A hearing aid can only perform well if properly fit to the patient's needs.* In practice it is exceedingly difficult to do so, for reasons described in the Hearing-Aid Primer. *The vast majority of patients fit with customizable hearing aids by traditional practitioners (i.e., dispensers and audiologists) have not had the intensive evaluation,*

analysis and fine-tuning described in the Hearing Aid Primer. For this reason, without a proper fit and tuning, even the most sophisticated aid is unlikely to benefit the patient, and may even do some harm. The sound level may be excessive in certain channels, insufficient in others, and the overall balance may be inappropriate for the patient to sustain significant benefit in real-world conditions. An improperly fit and tuned aid may discourage the patient from using the device because of discomfort or ineffectiveness. The absence of proper amplification may thereby indirectly hasten the deterioration of the patient's hearing capacity. *Moreover, the frequency with which hearing aids have been improperly fit and tuned has contributed to the general perception among the American public that this technology is incapable of providing the benefits claimed by manufacturers and is therefore not worth the amount of money commonly charged by practitioners for the aid and fitting.*

Contrary to the claims made by the Etymotic and Gudhear petitions, the current generation of over-the-counter aids is inherently incapable of providing significant benefit to the overwhelming majority of individuals sustaining a hearing loss – they lack the flexibility to fine-tune the amplification and compression characteristics to a patient's specific pattern of hearing loss. Even when such non-customizable aids are operating to their optimum capacity they fail to substantially improve speech comprehension in noisy and reverberant environments. Currently only the most sophisticated aids have the ability to significantly improve speech comprehension over a broad range of listening conditions typical of the real world. But in order to achieve their optimum potential these aids must be fit and tuned properly.

It is common in my practice for patients who have purchased a hearing aid from another dispenser to request a re-tuning of the device (because the original dispenser has been unable to satisfy the patient's listening requirements). Substantial improvement in the patient's speech comprehension is almost always observed after the aid has been properly re-fit and re-tuned. Such experiences have convinced me that a hearing aid's true capability and value can only be gauged using the most advanced fitting procedures. Under such conditions the non-customizable aids manufactured by Songbird and other companies do not come even close to providing the benefit afforded by more sophisticated digital aids. The outcome of the study cited in the Etymotic petition (Moore et al., 2001) was probably the result of inadequate fitting procedures that underestimate the capability of high-end digital aids.

Encouraging the sale of non-customizable hearing aids is likely to be counter-productive. These hearing aids are of very limited efficacy and may damage the patient's hearing even further by discouraging the appropriate use of hearing-assistance technology in patients who could demonstrably benefit from a properly fit aid.

The Patient is Not Necessarily the Best Judge of a Hearing Aid's Performance

The Etymotic petition appeals to the law of the market place in determining whether the sale of non-customizable aids should be encouraged (or not) – the patient is most capable of determining whether a hearing aid works well (or not), or is harmful to the individual

(or not). This logic is both flawed and potentially hazardous to the auditory capacity of the hearing impaired and other at-risk populations.

It is commonly observed in my practice that patients don't initially realize how poorly they're being served by a hearing aid fit by another dispenser. Sometimes the problem is with the aid itself, but often the problem originates in the manner in which the aid was originally fit. Only when given an opportunity to compare and contrast the original aid (and fit) with a more appropriate one does the patient fully comprehend how poorly he/she was hearing prior to re-fitting (or replacement of the aid). The signature of a well-fit hearing aid is ease of comprehension under a broad range of listening conditions. Unless the patient is allowed to compare a non-customizable aid with a properly fit sophisticated model it is unlikely that he/she will have an adequate benchmark with which to judge the efficacy of the over-the-counter product. Under such circumstances the patient may erroneously believe that the aid is doing all that is possible to do, when in fact this is not the case.

What Can Be Done to Improve Care for the Hearing Impaired in the United States?
Dissatisfaction with hearing aids is a matter of record and is common knowledge. The Etymotic petition points out that up to 30% of digital hearing aids dispensed in the U.S. are returned to the manufacturer. In addition, another 20% of the aids sold ultimately wind up not being used by the patient.

The problem lies not with the quality of hearing-aid technology per se, but with the procedures used to fit the aids. The fitting of a hearing aid, as currently practiced, is largely a hit-or-miss proposition. Without objective verification (as outlined in the Hearing Aid Primer) patient benefit and hearing-aid value is questionable. Most practitioners rely only on simple audiometric diagnostics to adjust the amplification and compression levels of the aid. Such audibility measures are often inadequate (by themselves) to compensate for a patient's impairment.

In my practice virtually none of the hearing aids dispensed are returned, despite an open-ended money-back guarantee and the fact that most of the devices sold are of the high-end, digital variety. This experience has convinced me that the key to patient satisfaction lies in the methods by which the aid is adjusted and tuned.

The FDA can ideally help improve the quality of care for the hearing impaired through stringent oversight of the technology used in hearing-assistance devices, as well as the procedures applied to fitting and evaluating the aids. Such improvements need to be effected within the constraints of the FDA's objectives and resources, and can be accomplished through the following measures:

(1) The FDA should develop a hearing-impairment awareness program to make clear to patients that hearing loss is complex in nature and reflects far more than a loss in audibility (and hence is not straightforward to treat). This educational program should be delivered through hearing professionals at the time a hearing aid is dispensed.

(2) The FDA should ensure that claims made by hearing-aid manufacturers are fair and accurate.

(3) The FDA should encourage the hearing-aid industry to develop objective hearing-loss correction measurements as a means of assessing a patient's potential for improvement with respect to speech comprehension in both quiet and noisy acoustic environments.

(4) The FDA should mandate the use of a 30-day trial period (at a minimum) on all hearing aids, with an individualized awareness program that informs the patient of both the benefits and limitations of the hearing-aid technology dispensed.

(5) The FDA should require that practitioners undergo a rigorous certification process that requires them to demonstrate proficiency in fitting digital hearing aids as a means of ensuring the highest possible standards of hearing aid delivery to the hearing impaired in this country.

Currently, there is no formal procedure for evaluating either the efficacy or safety of a hearing aid in the real world. It is difficult to know whether deterioration of an individual's hearing and cognitive capabilities is the result of an aid's improper performance or factors external to the device. Evidence from auditory deprivation studies suggest that unaided (or inadequately aided) ears may subject the patient to accelerated auditory and cognitive decline.

A Potential Role for Over-The-Counter Hearing Aids

Over-the-counter aids may potentially provide a certain amount of benefit for a particular segment of the patient population and in this way serve as an important means of educating the hearing impaired about the options available for treating their deficit. An informational booklet, similar to those routinely provided with medications, should be included with each device sold. The booklet should outline:

(1) The different varieties of hearing impairment

(2) Potential medical concerns and complications that could occur using over-the-counter hearing aids

(3) The importance of the aid's trial period and the need for objective verification of the device's performance and efficacy

(4) Realistic expectations for various types of hearing impairment

(5) The long-term consequences of not treating hearing loss properly

Key to improving the efficacy of hearing aid dispensing in the U.S is upgrading the training of audiologists and dispensers. Currently, most practitioners lack a

comprehensive background in hearing science and acoustics. Moreover, it is rare for a dispenser to have more than the barest understanding of signal-processing algorithms used in digital aids. Without the appropriate scientific and technical training it is difficult for the practitioner to objectively evaluate and fit a hearing aid. A veritable revolution in the training of hearing aid dispensers is required to provide the skills required to adequately care for the hearing impaired in this country.

Conclusion

Although the goal of providing greater access to hearing-aid technology is eminently worthwhile, the specific remedies proposed in the Etymotic and Gudhear petitions could conceivably hurt more individuals than would benefit by facilitating access to over-the-counter hearing aids in the manner outlined in their petitions. The FDA is urged to enhance (rather than reduce) oversight of the hearing-aid industry by establishing a hearing-impairment awareness program and by raising the standards and practices that govern the marketing and dispensing of hearing aids in the United States. Particular emphasis should be placed on the methods by which hearing aids are fit, as well as the technology used to evaluate and tune the devices. The ultimate objective should be to inform patients and to optimize the benefit afforded by the hearing aid so as to enable the patient to achieve the fullest possible communicative potential as a means of maintaining (or even enhancing) his/her quality of life.

About the Author

Gil Magilen received a Ph.D. in Biophysics from the University of California, Berkeley, as well as an M.S. in Biology from Long Island University and a B.S. in Natural Science from Iowa Wesleyan College. He has been at the forefront of clinical hearing-aid services since 1982, and currently owns and operates two dispensary clinics in the San Francisco Bay Area (one based in Walnut Creek, the other in Vallejo). Dr. Magilen established the Hearing Centers Network in 1990 to provide software and analytical reviews of industry practices to hearing-aid professionals. His publications span a broad spectrum of topics, ranging from methods for fitting, utilization and evaluation of hearing aids to market analyses. Dr. Magilen has recently received a patent from the United States Patent and Trademark Office pertaining to the objective clinical and technical evaluation of hearing aids for the hearing impaired. He can be contacted at: gilmagilen@aol.com. Additional information is available on the web site: http://www.hearingcentersnetwork.net.

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Respectfully yours,

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