



**AMERICAN ACADEMY OF
OTOLARYNGOLOGY—
HEAD AND NECK SURGERY**

November 02, 2011

Richard A. Justman, MD
National Medical Director
United Healthcare
5901 Lincoln Drive
Edina, MN 55436

Re: UnitedHealth Group's Announcement of Direct-to-Consumer Hearing Aid Sales

Dear Dr. Justman:

On behalf of the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS), I am writing to express our concern over a recent news release published by UnitedHealth Group (UHG) and hi HealthInnovations regarding the release of a new low-cost line of hearing aids complemented with a free online hearing test. We are writing to request a meeting with you and/or the appropriate UHG executives to further discuss our concerns so we can collaborate on appropriately treating hearing loss patients.

The AAO-HNS represents over 11,000 physicians in the United States who diagnose and treat disorders of the ears, nose, throat, and related structures of the head and neck. The medical ailments treated by this specialty are the most common that afflict all Americans, old and young, including hearing loss, balance disorders, chronic ear infection, rhinological disorders, snoring and sleep disorders, swallowing disorders, facial and cranial nerve disorders, and head and neck cancer.

Recently, the AAO-HNS learned of the endeavor of UHG and United Healthcare aimed at providing a direct-to-consumer, low-cost line of hearing aids, complete with a free online hearing test through UHG's new subsidiary, hi HealthInnovations. While we appreciate UHG's intentions to reduce costs, increase access to hearing assistance devices and testing, the AAO-HNS has serious concern regarding potential dangers, costs and unforeseen consequences for patients with a self-rendered, online hearing test and a "direct-to-consumer" line of hearing aids. The AAO-HNS readily acknowledges that many who could potentially benefit from an assistive hearing device do not have access to them due to high costs and/or a lack of benefit coverage.

In a recent press release, hi HealthInnovations CEO Lisa Tseng, M.D. stated, "*we really believe that audiologists, hearing instrument specialists, and ENTs are key. This is in no way intended as a replacement; this is just supplementing the work that they do.*" **While we appreciate this statement, due to some of the potential risks to patient safety and reduced quality of services in direct-to-consumer sales of hearing aids, we would like to collaborate with UnitedHealth Group (UHG) to**

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ensure appropriate otolaryngic physician oversight occurs – particularly for patient diagnoses and treatment, including referrals for appropriate audiologic testing and device fitting.

AAO-HNS policy encourages patients experiencing hearing loss to visit a physician, preferably an otolaryngologist-head and neck surgeon since many hearing problems can be corrected medically. It is especially important for a patient to see an otolaryngologist-head and neck surgeon if he/she is experiencing alternate symptoms such as ear pain, drainage, excess ear wax, hearing loss in only one ear, sudden or rapidly progressive hearing loss or dizziness, as these may be symptoms indicating a serious medical problem.

The AAO-HNS also strongly believes that an online hearing test is at best only an initial screening tool, and could provide misleading and potentially false results. For example, if a patient has a medically-correctable hearing problem such as cerumen impaction or a middle ear infection, this could present with a temporary conductive hearing loss documented by an online hearing test and a hearing aid may be unnecessarily dispensed.

Furthermore, hearing aids sold online and “programmed” based on online test results are sub-optimal and cannot be fitted appropriately, even if using a kit for taking mold impressions. In addition, a patient could easily miss, undervalue, or ignore “red flag” hearing health symptoms and issues when self-rendering an online hearing test. If a misdiagnosis is made, a patient may undergo unnecessary tests or be unnecessarily or inaccurately fitted for a hearing aid, resulting in increased expenses for patients and the overall healthcare system. Equally important to consider, referrals from the online hearing test could send a patient to a primary care provider office or other provider who is unskilled in hearing health, interpreting audiograms, evaluating hearing loss, and / or treating hearing loss. We recognize that there are selected cases of reduced access to hearing health care, or in instances where a consumer of hearing aids could do well without custom molds or fitting, this is much more affordable. However, if any of the negative issues mentioned above arise, this could lead to patient frustration and an overall cost escalation for treatment. We are interested to learn from UHG how patients will know that the plan will not be able to serve them if they have these types of medical issues and are not referred to an otolaryngologist-head and neck surgeon.

We are also curious how this new policy will be applied considering current federal and state laws pertaining to hearing aid dispensing. Pursuant to 21 C.F.R. §801.421, a patient is required to receive a physician evaluation prior to purchasing a hearing aid from a dispenser. If the patient is 18 years of age or older, they may sign a waiver to receive a hearing aid directly from a dispenser provided that the dispenser, “[d]oes not in any way actively encourage the prospective user to waive



*such a medical evaluation.*¹ We believe that this regulation is in place to encourage patients to seek proper evaluation to ensure that a hearing aid is medically necessary for his/her specific diagnosis.

Furthermore, we are concerned with the new policy's potential conflicts with state laws and the fact that such conflicts are not clearly evident to patients taking the at-home hearing test. Across the nation, there are a number of states that have recognized the importance of consumer protection and patient safety by placing restrictions on the dispensing of hearing aids by direct mail and/or the internet. These restrictions, in a number of states, will be in direct conflict with UHG's new approach of direct-to-consumer hearing aid dispensing. As an example; Florida², New York³, and Texas⁴ all provide that direct-to-consumer mail sales of hearing instruments are prohibited. In California, there are statutory conditions that must be met before a hearing aid may be dispensed by catalog or direct mail. The conditions include being licensed as a hearing aid dispenser in the state and that there is "no fitting, selection or adaptation of the instrument and no advice is given."⁵ The California laws would be in conflict with the UHG proposal in so much as advice would be given on the hearing instrument and would not be provided by a licensed hearing aid professional. Missouri law prohibits sales through the mail of hearing instruments without a prior fitting and testing by a hearing instrument specialist.⁶ Another example of restrictions put in place by the states to protect the patient is in Washington, where it is unlawful to dispense a hearing instrument in the state unless there has been face-to-face contact to test and determine the needs of the purchaser.⁷ ***The AAO-HNS would be interested in learning the specifics on how UHG plans to address the existing conflicts with state and federal laws for patients who wish to take the at-home hearing test and purchase a hearing aid through the mail.***

When warranted, otolaryngology and audiology oversight can be added to this low-cost hearing aid system. The hearing test could become an appropriate *screening tool* that motivates the hearing loss patients who currently do not seek attention to see an otolaryngologist-head and neck surgeon and receive specialized treatment, if necessary. Nonetheless, we submit that the test cannot itself be substituted for the clinical judgment of an ENT specialist. While cutting the otolaryngologist-head and neck surgeons, audiologists, and other hearing aid specialists out of the equation as "intermediaries" may drive short-run hearing aid costs down, it is at a severe expense and high risk to both the patient and general healthcare costs in the long-run. ***As such, the AAO-HNS respectfully requests that UHG reevaluate its marketing***

¹ 21 C.F.R. §801.421(a)(2)(ii)

² Fla. Stat. Ann. §468.1265 (2011).

³ N.Y. Gen. Bus. Law §798.17 (2011).

⁴ Tex. Stat. Code Ann. §402.451 (Vernon (2011)).

⁵ Cal. Bus. & Prof. Code Ann. §3351.5 (West (2011)).

⁶ Mo. Ann. Stat. §346.110 (West (2011)).

⁷ Wash. Rev. Code Ann. §18.35.175 (West (2011)).



efforts for the hearing test until further research can better clinically substantiate a self-rendered test.

The Academy is supportive of the advancement of technology in general to provide better access to healthcare to patients and lower costs. Advances in technology offer the promise to make hearing aid manufacture less costly and innovative fitting paradigms are being explored which may potentially further reduce costs by automating part or all of the fitting process. ***However, the latter must be demonstrated to have the same or improved net outcome for hearing impaired patients undergoing hearing aid placement. Therefore, we believe that hi HealthInnovations' advanced technology should be clinically researched further to satisfy this latter requirement.***

We appreciate the open communication our physician leaders recently have had with you and your colleagues. We look forward to your response to our comments and further discussion on this issue. Please contact Harrison Peery at hpeery@entnet.org or (703) 535-3728 to set up a time agreeable to you and your colleagues to discuss further. Thank you for your consideration.

Sincerely,

David R. Nielsen, MD
Executive Vice President/CEO