Livingston HEARING AIDS

5303 50th Street • Lubbock, Texas 79414
p: (806) 799-8950 • f: (806) 799-8939

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Public Comments: Richard Davila, II

I am a practicing Hearing Instrument Specialist in Lubbock, Texas. I have been licensed to fit and dispense hearing aids for 25 years. I am Board Certified in Hearing Instrument Sciences and I completed the Audioprothology Study class in 2001. I am a member of the Texas Hearing Aid Association and International Hearing Society. I have testified before the Texas Sunset Commission. I was appointed by Texas Governor Rick Perry to serve a six year term (2003 – 2009) on the State Board of Examiners in the Fitting and Dispensing of Hearing Instruments. In 2015 I was appointed to the Texas Fitting and Dispensing Advisory Board. I am a hearing aid practice owner with over 200 employees in 70 locations in Texas, New Mexico and Colorado.

This letter expresses my concerns regarding recommended regulatory changes in hearing healthcare. It is my belief that the recent President's Council of Advisors on Science and Technology (PCAST) recommendations contain key inaccuracies that decision-makers should be made aware of before moving forward with regulatory changes in the hearing healthcare delivery model.

"PCAST believes that cost is the largest barrier to hearing technology adoption." (PCAST letter page 1). Although the cost of hearing aids may be an obstacle, it is not the largest obstacle. In countries where hearing aids are offered for free to those who could benefit from them e.g., Switzerland, Germany, France and Italy, the hearing aid adoptions rates are 38.8%, 34.0%, 30.4% and 24.6% respectfully. The highest adoption rate for hearing aids when they are free to those who could benefit from them is in Norway at 42.5%. The afore mentioned hearing aid global adoption rates reveal that 57.5% to 75.4% of people choose not to get hearing aids for a reason other than cost; therefore cost could not be the "largest barrier". Any recommendations or changes made or proposed based on the supposition that cost is the largest barrier to hearing technology adoption would be based on a distortion of the facts.

"PCAST concludes that Americans would be better served if non-surgical air conductive devices intended to address bilateral, gradual-onset, mild to moderate age-related hearing loss (referred to here as "basic" hearing aids) were available over the counter. (PCAST letter page 5). This recommendation is rooted in a position which contends that because older Americans have been able to mistakenly purchased over the counter eyeglasses that they should be given the same opportunity to mistakenly purchase an over the counter hearing aid (or two). This logic is unsound. Also older Americans in greater number would mistakenly purchase over the counter hearing aids because self-verification of benefit is more difficult to determine. For reading glasses a prospective candidate need only grab a magazine and look for the glasses that make the words the clearest. For hearing aids there is a difference between hearing (hearing thresholds) and understanding (word recognition potential) so it would be almost impossible to determine if they are benefiting the most or at all with an over the counter product.

"PCAST concludes that it is unclear how well the current distribution options available are helping consumers find hearing aids that improve hearing. (PCAST letter page 4). PCAST sites data regarding misfit hearing aids from a 2009 Consumer Report article to support the conclusion. The published data reveals that actual hearing aid wearers have no such difficulty finding hearing aids that improve their ability to hear and understand. The latest MarkeTrak data reveal that 95% of hearing aid owners are satisfied with the care and service they have been provided within the last five years. This is another example of recommendations made based on key inaccuracies.

There are more than 40 million Americans living with hearing loss. Although hearing aids are not currently available as over-the-counter (OTC) products, the Over the Counter Hearing Aid Act (S.670/ H.R. 1652) would direct the FDA to establish an OTC hearing aid category for mild-to-moderate hearing loss. This proposed federal regulation poses a threat to consumer choice and hearing healthcare access because the language in the bill will most likely prompt insurers to drop doctors' visits to diagnose and treat hearing loss, to drop audiology screenings and to drop hearing aid fittings. In addition, OTC hearing aids would require self-diagnosis which presents a big risk to the consumer because of the increasing chance for missed and delayed diagnoses of medically-treatable conditions like otitis media or life threatening very serious medical conditions (for which hearing loss is a symptom) such as tumors, brain lesions, mastoiditis, autoimmune inner ear disease, and advanced infections. Finally, the lack of diagnosis and treatment presents a risk to the consumer for inaccurate fitting, worse quality of hearing, low satisfaction levels and the potential to cause further damage to their hearing.

Senators Elizabeth Warren (D-MA), Charles Grassley (R-IA), Maggie Hassan (D-NH), and Johnny Isakson (R-GA) introduced S. 670, the Over the Counter Hearing Aid Act of 2017, which is a special-interest backed bill to introduce FDA regulations for over-the-counter hearing devices. The stated goal of the legislation is to "increase access" to hearing devices. However, in practice, the bill would drastically disrupt the doctor-patient relationship and incentivize states to drop hearing aid and audiology coverage. This bill increases FDA regulations and eliminates states' rights to govern their Medicaid systems as they see fit. The correct conservative policy outcome is to leave regulation of such matters at the lowest practical level of government, the states.

The FDA Safety & Effectiveness Standards for over-the-counter products states: 1) incorporate the same standards as prescription drugs (standards for safety and efficacy, good manufacturing practices (inspections), and labeling), and 2) stipulate that consumers must be able to self-diagnose, self-treat, and self-manage, which can be assessed through label comprehension studies and actual use studies. Bypassing the current FDA standards for OTC determination would disregard the long-standing policy that ensures patient safety and efficacy in the delivery of health care, and create a dangerous new precedent that would place consumers, especially seniors, in harm's way.

In conclusion, I would like to express my strong opposition to the recommendations to create an over-the-counter (OTC) classification for hearing aids for people with mild to moderate hearing loss. Creation of such a class would bypass the necessary screening mechanism and involvement of a licensed hearing aid provider, who can insure that the patient is a candidate for hearing aids or whether medical intervention by a physician is necessary. Such a class would create patient confusion and mistrust, as well as eliminate important state and federal consumer protections, including those that ensure providers are competent and accountable.

As an industry, we appreciate all that the FDA has done to encourage the proper evaluation and treatment for hearing impaired individuals and to protect consumers from harmful hearing aid sales practices. The FDA has once before rejected this type of proposed OTC legislation. Approval of these proposed regulatory changes would be a step backward for consumer safety and protection resulting in lower adoption rates and promoting the masking of more serious retro cochlear conditions. I urge the FTC & FDA to reject these over the counter proposals.

Thank you for your time and consideration.

Respectfully submitted,

Richard R. Davila II BC-HIS, ACA
Board Certified in Hearing Instrument Sciences