

“Examining Improvements to the Regulation of Medical Technologies”

Testimony of

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Chairman Burgess, Ranking Member Green, and Members of the Subcommittee:

Thank you for inviting me here today. My name is Frank Lin, and I'm an Associate Professor in the Departments of Otolaryngology-Head & Neck Surgery and Geriatric Medicine at the Johns Hopkins School of Medicine and in the Departments of Epidemiology and Mental Health at the Johns Hopkins Bloomberg School of Public Health. From a clinical perspective, I'm a board-certified otolaryngologist with fellowship training in otology, and I am an expert in the medical and surgical management of hearing loss and other conditions affecting the ear. From a research perspective, I am a public health expert on the impact that hearing loss has on older adults and society. My interest in and testimony on the Over-the-Counter Hearing Aid Act (H.R.1652) stems directly from this background.

The OTC hearing aid act introduced by Representatives Blackburn and Kennedy directly reflects the earlier recommendations made by 2 expert committees—the President's Council of Advisors on Science and Technology issued a report in October 2015¹, and this was then followed by a National Academies consensus study report² on Affordable and Accessible Hearing Care for Adults in June 2016. I advised PCAST on their report and was a member of the National Academies expert committee. Both of these expert bodies concluded that the creation of an FDA regulatory classification for OTC hearing aids would immediately benefit public health and Americans.

The importance of the present bill instructing that the FDA carry out this recommendation is immense for public health. Over the past several years, research from Johns Hopkins as well as from other academic institutions has demonstrated that hearing loss, while being a usual process of aging for nearly all Americans, is not without consequence. These studies have demonstrated that individuals with hearing loss are at a greater risk of developing dementia³⁻⁵, having falls^{6,7}, becoming hospitalized^{8,9}, and having greater health care costs¹⁰. These research studies also clearly suggest that hearing loss treatments such as using hearing aids and other forms of amplification could potentially decrease these risks and lead to real and tangible benefits for individuals, families, and society. And yet, presently, <20%¹¹ of the nearly 38M Americans¹² with a significant hearing loss currently has access to hearing aids.

The reason for this low rate of use stems largely in part from a current regulatory framework that only allows for a one-size-fits-all model of obtaining hearing care—that is, for an American to obtain hearing aids, he or she has to make repeated trips back and forth to a licensed hearing professional who serve as the gatekeepers to consumers being able to obtain hearing aids. While this model is appropriate for those with more complex hearing losses, this model is extremely expensive and is clearly not needed by every one of the 38M Americans with hearing loss. At present, the average cost of obtaining 2 hearing aids in the U.S. under this model is approximately \$4700² which means that for the average American a pair of hearing aids could be their third largest material purchase in life after a house and a car.

The passage of the OTC hearing aid bill would allow for hearing aids meeting explicit performance standards that would ensure safety and effectiveness to be directly available to consumers. Based on the scientific literature¹³, such devices could safely provide levels of amplification that would be effective for those individuals with mild-to-moderate hearing losses. Both established hearing aid manufacturers as well as innovative new startup companies and consumer technology companies that have economies of scale in manufacturing would then be able to enter the marketplace to sell devices directly to consumers that will come at a lower cost as many more are sold. At present, with current regulations prohibiting direct access to consumers and 98% of the world's hearing aid marketplace being controlled by 6 companies, there is little incentive or ability for innovation and for new companies to enter the market.

Importantly, the availability of OTC hearing aids does not in any way preclude the invaluable services in counseling, education, and programming that a hearing professional could provide. One would expect that many adults would in fact still want to seek out a hearing professional to learn how to use these devices and customize the device to their hearing needs, while others may learn to use these devices on their own much like any other consumer electronic. The important point is that the availability of OTC hearing aids would bring hearing technologies out from under the explicit control of a group of individuals (such as me) and allow consumers to choose what level of hearing care best meets their needs and priorities.

I should note that some critics of OTC hearing aids raise concerns about the safety of these devices for consumers without having a professional exam, the risk of children using these devices, and the suitability of these devices for mild-to-moderate hearing loss. While as a medical and surgical expert on hearing loss, I can appreciate where these concerns are coming from, these concerns are misguided and more often than not are being raised by parties who are more interested in preserving the status quo rather than in improving the lives of Americans with hearing loss and advancing public health. These latter priorities are what mainly concern me and what also concerned PCAST and the National Academies in their recommendations that serve as the basis of the present OTC hearing aid act.

Possible concerns raised about OTC hearing aids

Device safety One of the most important aspects of the current legislation is that the FDA would establish evidence-based performance standards for OTC hearing aids to ensure that they are both safe (e.g., maximum sound output levels) and effective. At present and without this regulatory classification, the market is awash with unregulated hearing devices (i.e., personal sound amplification devices) commonly found in drugstores and advertised in magazines that make wild and unsubstantiated claims about performance and many of which have unsafe sound output levels. Consumers seeking out more affordable hearing technologies often turn to these devices, but without proper FDA regulation, they have no way of knowing which devices could in fact benefit them. FDA re-regulation would bring clarity to the marketplace ensuring that consumers could have access to safe and effective devices.

Consumer safety Some clinicians make the argument that obtaining a hearing aid without first having a medical exam is unsafe. While this argument is sound for children, it doesn't make sense for adults where 2 of every 3 adults over 70 years have a hearing loss¹⁴. In the absence of signs such as a draining ear, sudden hearing loss, etc. (all of which would be listed as warning signs to see a doctor for in the labelling of an OTC device), the chances of missing important clinical diseases are minute ² (e.g., an acoustic neuroma [a benign hearing nerve tumor] is diagnosed in ~0.001% of people per year) and far outweighed by the benefits of ensuring access to hearing technology

for the millions of people who currently do not seek help for their hearing loss. By the same extension, we as a society have long accepted the risk and benefits of OTC reading glasses (despite the fact that poor vision could be from glaucoma which is prevalent in 5% of older adults) or OTC aspirin for headaches (despite the fact that headaches may be masking neurologic conditions or that aspirin can and does occasionally lead to fatal internal bleeding). In both of these latter cases and as with OTC hearing aids, the benefit of access to these OTC products for society far exceeds any theoretical risks.

More importantly, there is an even greater likelihood that the availability of OTC hearing aids will intensify awareness of hearing loss in society and lead even more (rather than fewer) Americans to seek a hearing professional's evaluation of hearing once affordable OTC hearing aids are known to be available. At present, many consumers avoid seeking out professional hearing evaluations because of the perceived lack of affordable treatment options for hearing loss.

Device effectiveness for mild-to-moderate hearing loss and consumer ability to self-diagnose and self-fit hearing aids: The strongest scientific study to date consisting of a definitive NIH-funded randomized controlled trial¹³ demonstrated that consumers can self-fit OTC hearing aids and that these devices benefit consumers with a mild-to-moderate hearing loss. There is absolutely no medical reason or rationale to consider limiting the intended use of OTC hearing aids (and hence the FDA performance standards of these devices) to only those individuals with a mild hearing loss.

Risk to children Some individuals have raised the concern that children with hearing loss may be given OTC hearing aids by their parents rather than being taken for medical and audiological evaluation. As a medical and surgical expert in hearing loss, I agree that this would not be in the child's best medical interest, but any concern that I have is tempered by the actual circumstances concerning how pediatric hearing loss is already managed in the U.S. Presently, universal newborn hearing screening and school-age hearing screening programs have long been active in all states, and children are thereafter referred appropriately for follow-up. For low-income families with children qualifying for Medicaid, the Early and Periodic Screening, Diagnosis, and Treatment

Program under Medicaid already mandates coverage of all medically-necessary hearing aid services and hearing aids for children. As such, it is highly unlikely that a significant hearing loss in a child would go unrecognized in the current environment such that a parent would take it upon themselves to feel compelled to self-diagnose and treat their child without consulting with a medical and/or audiological professional.

As a society, we have also long ago accepted that many OTC products could theoretically be inappropriately used by children and cause harm, but that the overall benefits to society far outweigh these theoretical risks. For example, using the case of aspirin discussed above, when given to children recovering from viral illnesses aspirin can increase the risk of Reye's syndrome, a potentially fatal condition involving brain swelling. However, with proper labelling instructing parents to avoid giving aspirin to children with viral-like illnesses, this condition remains very rare, and we continue to recognize the benefits to society of having OTC aspirin widely available despite the theoretical risks.

Conclusion

The OTC hearing aid bill under consideration by Congress would enable the FDA to sensibly re-regulate hearing aids to ensure that 38M Americans with hearing loss have access to safe and effective OTC hearing technologies that can enable them to communicate and fully engage in society. The benefits of OTC hearing aids for improving public health, promoting innovation in the hearing technology marketplace, and lowering costs are substantial and profound. Passage of this bill represents a 'win-win' for the 38M Americans¹² with hearing loss (in particular American seniors of whom nearly 2 of 3 have a significant hearing loss¹⁴), hearing health professionals who will have a wider range of hearing technologies to choose from with which to help their patients, and both established hearing aid and other technology companies who will now be able to develop innovative new hearing technologies that can be offered directly to American consumers.

Thank you for the opportunity to present my views to you today. I am happy to happy to answer any questions that you may have.

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