January 13, 2022

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
RE: Docket No. FDA-2021-M-0555, RIN 0910-AI21
Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

Dear Dr. Woodcock:

Thank you for the opportunity to comment on the Proposed Rule *(Medical Devices; Ear Nose, and Throat Devices; Establishing Over-the-Counter (OTC) Hearing Aids)* and for your attention to the needs of the hard of hearing and for the I am writing to express my personal opinion on the Over the Counter (OTC) Hearing Aid Act of 2017 Proposed Rule. My views are mine alone and do not represent those of any professional organization or association.

I am an audiologist and have been involved, for at least the last 15 years, in the disruptive technology and hearing aid delivery change movement and an early advocate of the utility of over the counter and direct to consumer solutions to hearing loss. The Proposed Rule actually cited a paper I co-authored several years ago. While I am strong advocate in the role of audiologists in the hearing loss identification and amplification processes, I am an EQUALLY ardent supporter of increased and improved patient access to self-assessment and over the counter and direct to consumer amplification and assistive technologies. For me, the risks of non-treatment are now significantly greater than the potential risks of less than “gold standard” evaluation and treatment. I also have yet to see any data supporting true or significant safety issues or negative outcomes from over the counter or direct to consumer delivery versus provider delivered care.

I FIRMLY believe that my role, as an audiologist, is to assist the hard of hearing in gaining access to sound and communication. I want to help individuals hear more and fall less. My goal is to improve consumer access and adoption and, potentially, increase competition and affordability. As I do not own or operate a clinic or practice or have employee relationship with any manufacturer of any product, I am able to view the Act and the Proposed Rule objectively rather than with emotion and bias.

Stakeholder groups joined together and created a Consensus Paper on over the counter hearing aid classification. While I agree with and appreciate some of their findings, I find most to be totally self-serving and based on cherry picked evidence that met their narrative. The gain and output limits were questionably conservative. I find it incredibly disingenuous that, now that an amplification device “looks” like a hearing aid, traditional stakeholders are now suddenly concerned about gain and output limits, given that almost no one in the industry has truly carried about or advocated against the gain and output of headphones, earbuds or audio equipment. I agree with the language outlined in the Proposed Rule that did not place gain limits on the OTC class of hearing aids but limited output. In my opinion, the goal of “limits” is to “limit” access to over the counter solutions and reduce competition from new entrants in the marketplace. Limits make the hearing aids less accessible to those with more moderate hearing losses.

As the Proposed Rule pertains to the new class of OTC hearing aids, I believe that the FDA should consider the following in its regulations:

- No restrictions on the dispensing of this class of aids by licensed professionals, such as audiologists. The regulatory environment for the sale and dispensing of OTC aids should be the same for retailers and licensed professionals. This is unclear in Proposed Rule. Anything else again reduces access to innovative, affordable, accessible hearing solutions from licensed professionals.
- Return for credit privileges. I fear that, without return for credit privileges, many consumers will be hesitant to purchase an OTC aid, especially if they have had no prior experience with amplification. Return for credit allows for the market itself, in the absence of consistent oversight and audit, to weed out questionable products.
- Language removing all existing state pre-emptions that apply to adult (18 and older) hearing aid users.
- Package labeling requirements as outlined in the Proposed Rule, with the addition of Consumer Ear Disease Risk Assessment (CEDRA) OR the addition of acute or chronic tinnitus as a red flag and the typing of time periods to the specific red flag rather than moving to a uniform six month time period. For example, sudden or rapid progressive hearing loss should be a 14-day time period. Overall, these appear to be comprehensive, clear, concise and practical for the purchaser.
- No medical waiver, medical clearance or medical evaluation or hearing test requirements, as outlined in the Proposed Rule for anyone 18 years of age or older. This change will make amplification more accessible.
- Lay user controls as outlined in the Proposed Rule. It is vital that the purchaser have control over the performance of the OTC hearing aid.
- Electroacoustic performance requirements as outlined in the Proposed Rule. These requirements are important, especially if the purchaser experiences difficulties with the aid and needs to seek the guidance and support of a licensed professional. Access to the electroacoustic performance data will be invaluable in determining the efficacy of the OTC aid and if the OTC aid is functioning appropriately. This data should be publicly available on their website in order to make it possible to aid purchasers when they seek professional support.
- Design requirements as outlined in the Proposed Rule, with the addition of a triggered warning when the result of a self-assessed or entered audiogram or audiometric configuration exceeds those of a mild to moderate hearing loss. The "trigger" could read: "Your test results are indicative of a hearing loss that is possibly greater than moderate. We recommend a complete audiologic evaluation prior to pursuing an over the counter hearing aid to confirm type and degree of hearing loss".
- Addition of a design requirement requiring creation and hosting of online video training tools on the appropriate insertion and use of their OTC aid.
- Conditions for sale, as outlined in the Proposed Rule, restricting sale of OTC aids to adults 18 years of age and older and the lack of requirements for verifying age. If you add a verification of age requirement for hearing aids, you should also add one for personal audio devices as their output can be even more dangerous and damaging if used inappropriately.
- Exemptions from existing and proposed Food and Drug Administration (FDA) 510(k) requirements, including those proposed for self-fitting, air conduction hearing aids. You stated in the Proposed Rule that "OTC hearing aids are those that use the same fundamental scientific technology as air-conduction hearing aids". So, given this statement, I see no reason for the need for FDA 510(k) requirements for OTC hearing aids that do not exist for air-conduction, prescription hearing aids. 501(k) requirements for the OTC class of hearing aids restricts new entrants into the marketplace and stifles competition. Competition is required in this industry in order to lower the cost of amplification to consumers.
    - Instead, I propose the addition of:
        - An FDA registration requirement,
        - Self-regulation by manufacturers, with requirement to supply clinical efficacy data upon audit and request,
        - Federal Trade Commission (FTC) regulated return for credit processes, and an
        - FTC consumer complaint hotline and enforcement process.

As the Proposed Rule pertains to the redefined Prescription class of hearing aids, I believe this class and its associated regulations should have more clarity. I recommend consideration of the following:

- Addition of another category of hearing aid, titled "Software-Based Hearing Aid". This category would encompass software driven, rather than merely hardware driven, hearing aid solutions. Some existing examples of this technology are Apple Live Listen, Jacoti, Mimi and EarMachine. These technologies allow for the MOST accessible, affordable hearing aid solutions. Without classification such as this, these technologies, which are evidence based, could be relegated solely to a personal sound amplification product (PSAP) classification, rather than in the hearing aid marketplace, where they more appropriately belong. In your Proposed Rule, you cited my work on over the counter solutions. For example, EarMachine was included in this paper and has been found to effectively remediate mild to moderate hearing loss as part of a free IPhone application. I refer individuals to this application often and most, ultimately, transition to traditional hearing aids following the use experience.
- A requirement for an audiologic evaluation and resulting prescription, provided by a licensed audiologist or physician, consistent with the FTC Contact Lens Rule and set forth and regulated by the FTC. As allowed by technology, the audiologic evaluation should be provided via telepractice or face to face encounter with a licensed audiologist or physician and should include, at a minimum, a hearing handicap inventory, pure-tone air conduction testing, and speech in noise testing. The test design, specifications and protocol should be based upon peer reviewed literature and the illustrate reliability and sensitivity to hearing loss and communication difficulties.
- Consistent with the FTC Contact Lens and Eyeglass Rules, the addition of a requirement for licensed audiologists or physicians to provide consumers with a copy of their audiologic evaluation, even if the audiologic evaluation was provided at no charge and even if the consumer does not opt to purchase hearing aids from the said licensed audiologist or physician. This requirement should be set forth and regulated by the FTC.
- The ability for consumers to take their prescription and purchase prescription hearing aids from any licensed hearing professional, including licensed hearing aid dispensers, licensed audiologists, or licensed physicians. These aids should be able to be delivered online and dispensed via telepractice or face to face encounters. Manufacturers of the prescription class of hearing aids should not be able to restrict the sale and distribution of prescription hearing aids and related supplies delivered directly to the patient and fit via telepractice as long as the fitting is the result of an appropriately obtained hearing aid prescription. Without the engagement of the FDA and/or FTC, there will be a flurry of state hearing aid dispensing bills emerge restricting the dispensing of prescription hearing aids to face to face, brick and mortar only evaluation and delivery, which has never existed (as mail order hearing aids have been dispensed, with few significant issues, since the 1960s).
- Federally codifying regulations for the sale of prescriptive hearing aids to anyone under the age of 18 years of age, including medical clearance requirements and a Federal prohibition on a medical clearance and/or medical waiver for anyone 18 years or older.
- The addition of requirements for an open access, programming software platform, where no prescription hearing aid is allowed to be proprietarily locked and, as a result, can be programmed or adjusted by any licensed hearing professional. If this is not achievable, the fact that the aid(s) are proprietarily locked should be divulged, in writing, to the consumer as a condition of sale. This was outlined by both the President's Council of Advisors on Science and Technology (PCAST) and National Academies of Science, Engineering and Medicine (NASEM). This should be set forth and regulated by the FTC.
- Tinnitus maskers or tinnitus masking features available on many prescriptive hearing aids needs to be addressed and clarified by the FDA as it pertains to 1) the classification of tinnitus makers and/or tinnitus masking features which exist on prescriptive devices, 2) who can diagnose tinnitus, 3) who can prescribe this type of device and/or device feature and 4) who can fit these tinnitus masking devices and/or tinnitus device features.
- The addition of requirements of federally mandated, itemized bill of sale or receipt, with the costs of the device separated from the costs of evaluation, fitting, and long-term service outlined as well as the return for credit and warranty terms. This was outlined by the National Academies of Science, Engineering and Medicine (NASEM). This should be set forth and regulated by the FTC. Right now, there are states that do not require that a purchase agreement or receipt be provided.

Hearing aids, which would now meet the classification of Prescription hearing aids, have been sold via mail order and now online retailers since the 1950s. There is no documented evidence of consumer harm. There needs to be clear guidance on the availability of this class of devices through mail order and online channels, especially given the growth and demand for telehealth. So, as it pertains to both the OTC and Prescription classes, I would like to see more

definition and clarity around the role and scope of state pre-emptions. I expect that, if the Final Rule does not go the way of industry, that there will be an onslaught of state pre-emption requests and state legal actions to restrict, as much as possible, the sale and distribution of OTC and Prescription hearing aids through online, direct to consumer and mail order channels. I respectfully request clear, concise guidance on the roles and limitations of state hearing aid and consumer protection laws on the sale and distribution of both the OTC and Prescription hearing aid classes.

I would like to see significantly more engagement by the FTC in the regulation of the SALE and DISTRIBUTION of both the OTC and Prescription classes of hearing aids. It is my opinion that the FDA should regulate the medical device itself, as they do other medical devices, and that the FTC should regulate the sale and distribution of the hearing aid, as they do contact lenses and eyeglasses. FTC engagement in this industry is sorely needed to better protect consumers from potentially unfair, deceptive, or fraudulent business practices, to promote competition and allow for new entrants into the marketplace, and to monitor instances of anti-competitive, collusive behaviors. For example, there are manufacturers who offer direct to consumer (DTC) prescription hearing, purchased by and fit to the consumer via the internet and telehealth without a brick and mortar location, that do not allow audiologist or hearing instrument specialist providers to provide similar prescription hearing aids in this manner. I do not understand how the latter is not a restriction of trade.

The Right To Repair movement and its resulting legislative and regulatory requirements should also be addressed by the FDA and FTC. Its applicability to all classes of hearing aids is not defined. Currently, five legacy hearing aid manufacturers control every aspect hearing aid repair and adjustment, including software and hardware. As I indicated prior, when the software is proprietarily locked and/or the hearing aids are private label, non-franchised or non-member licensed hearing aid providers cannot adjust or repair these hearing aids in their offices. They cannot get access to replacement parts. Hearing aid owners often do not have access to even low cost and/or disposable repair parts, such as receivers, battery chargers, domes, wax filters, wax guards. Licensed hearing aid providers are often prohibited by the hearing aid manufacturer from offering these items direct to consumer in their e-commerce sites or through online means. The FDA and FTC should clearly define how much access consumers and even some licensed providers have to repair parts, hardware and software.

There needs to be more transparency at every level of this industry and service delivery processes. The FTC could provide much needed regulation and oversight. The legacy hearing aid manufacturers and hearing aid clinic ownership groups have been fighting OTC hearing aids at every level since the legislation was initially proposed. They have been flooding the marketplace with potentially deceptive information on the OTC legislation and the hearing aids themselves and soliciting stock, potentially misleading, mass comments to the OTC Proposed Rule. These behaviors should be investigated to determine if they violate any FTC regulations or guidance and safeguards should be considered to stop the flood of potentially negative communications that may emerge from competitors once the OTC hearing aids officially hit the market. There is also some extremely misleading “marketing” being put forth with the Campaign for Better Hearing. This looks, to consumers, like a non-profit; instead, it is a for-profit sales venture that being propagated by a hearing aid manufacturer through their owned clinics.

In closing, I want to see accessible, consumer centric products and transparent, ethical hearing pricing and delivery. The vertical integration that has been allowed to grow, unfettered, in this industry needs to be explored. It impedes access and affordability to hearing care and I want to see more individuals have access to communication. We, as providers, need to think differently and evolve our practices to the new realities of technology and healthcare. Federal oversight and regulations can help frame that. These changes have been required by all retail and healthcare industries. Hearing healthcare should be no different.

Respectfully,

Kim Cavitt

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