Industry, Reg Expert To FDA: Regulate OTC Hearing Aids As 510(k) Devices

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The hearing aid industry and a regulatory expert are pressing FDA and White House officials to apply FDA's 510(k) device premarket review and enforcement oversight to over-the-counter hearing aids, coming as President Joe Biden presses HHS to, by November, propose a rule that allows hearing aids to be sold OTC.

A leading hearing aid lobby group and regulatory expert recently met with White House regulatory affairs officials and FDA to make a case that OTC hearings aids should be subject to FDA premarket review requirements because they will incorporate technology similar to that of the already-existing category of self-fitting hearing aids. The regulatory expert also said FDA should require that consumers take a self-administered hearing test before purchasing OTC hearing aids.

FDA has missed several deadlines for issuing the proposed OTC hearing aid rule, "Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations," which is expected to lay out safety, labeling and manufacturing standards for OTC hearing aids.

The agency is now facing increased pressure from the Biden administration and lawmakers who want FDA to release the proposal as soon as possible.

Biden in July issued an executive order directing HHS to, within 120 days, publish the proposed OTC hearing aid rule for notice-and-comment. Under that directive, the agency has until November to issue the rule.

FDA sent the proposed rule to OMB for review Aug. 18.

Jim Tozzi, head of the Center for Regulatory Effectiveness and a former White House Office of Management and Budget official, and Kate Carr, president of the Hearing Industries Association, met with OMB's Office of Information and Regulatory Affairs and FDA on Sept. 13 and Sept. 28, respectively.

In his presentation materials, Tozzi asserts that OTC hearing aids should be subject to FDA's 510(k) premarket notification requirements because they will be similar to the already-existing category of self-fitting hearing aids. In 2019, Tozzi explains, FDA established a new generic category of self-fitting air-conducting hearing. FDA said in its Final

Order that manufacturers of devices that similarly incorporate self-fitting technology, including software, could use the 510(k) process to obtain premarket clearance.

"Because OTC hearing aids will incorporate technology analogous to the De Novo device, they too should be subject to a 510(k) premarket notification requirement. This will serve as the basis for a strong enforcement program," Tozzi says.

FDA also needs to update its hearing aid prescription regulations to make sure traditional hearing aids are only sold by licensed professionals, including ear specialists, audiologists or hearing aid dispensers who are licensed under state, local or tribal law, Tozzi says.

Traditional and OTC hearing aids are different types of devices that are regulated distinctly and are intended to treat different conditions in different patient populations, he explains. For example, traditional hearing aids may be prescribed to both adults and children who suffer from a wide range of hearing impairments, whereas OTC devices are intended only for adults who have mild-to-moderate hearing impairment.

"[U]nless the FDA updates its hearing aid dispensing regulations, consumers are not going to be able to disentangle traditional hearing aids from OTC hearing aids from non-medical [personal sound amplification products], all of which are going to be similarly marketed to people," Tozzi wrote.

FDA already has the authority to impose the licensure requirement, Tozzi says. The agency needs to make minor revisions to its hearing aid labeling and condition for sale regulations under 21 CFR 801.420 and 21 CFR 801.421 to establish the requirement. Under the updated regulations, consumers would continue to be able to purchase traditional hearing aids through a direct-to-consumer process, but would also be able to have trained, licensed hearing care professionals available to help them purchase the device.

FDA needs to establish a requirement that consumers take a self-administered hearing test before purchasing OTC hearing aids, Tozzi says. Such a test could be available as a smartphone app or incorporated into the OTC device itself and used for self-fitting and calibration. If the device is not right for the consumer, the potential user would then be allowed to return the device and get a full refund.

Adult consumers who have mild-to-moderate hearing loss would be given an assessment of their hearing and informed that an OTC hearing aid might be right for them.

If the self-administered hearing test shows a consumer's hearing is not impaired, the consumer would be informed that there's no need for a hearing aid, Tozzi says. Conversely, consumers who are found to have above-moderate hearing impairment would be told the OTC hearing aid device is not intended for them and that they should seek help from a licensed hearing care professional.

"It is important to note that a self-administered hearing test that uses a smartphone app or a testing capability built into OTC hearing aids is fully consistent with the FDARA requirement

that the devices be available 'without the supervision, prescription, or other order, involvement, or intervention of a licensed person….,'" Tozzi wrote. "By instituting a pre-purchase hearing test requirement, the FDA will protect consumers while improving public health."

FDA should limit the output and gain for OTC hearing devices, Tozzi says. Output is the upper limit of amplification measured in sound pressure level (SPL). Gain is the difference between the SPL of the incoming sound and the output for OTC hearing devices.

Putting in place technical limitations will help ensure OTC hearing aids will not be used by individuals suffering from hearing impairment that exceeds a moderate level, Tozzi wrote.

Tozzi says that, based on peer-reviewed information, FDA should establish an output SPL limitation of 110 decibels and a maximum gain limitation of 25 decibels.

"This is confirmed by real-world data from audiograms of over 28,000 adults that show commercially available hearing aids programmed according to parameters typical of those used for individuals with mild-to-moderate hearing loss yield output and gain levels that are well within the recommended limits," Tozzi wrote.

Tozzi notes the 110-decibel SPL output and 25-decibel gain measurements fall in line with recommendations from the four leading professional hearing care associations.

Specifically, the American Academy of Audiology, Academy of Doctors of Audiology, American Speech-Language Hearing Association, and International Hearing Society proposed the SPL and gain limits in a broader consensus paper, published in 2018, that laid out the organizations' OTC hearing aid recommendations.

The Hearing Industries Association endorsed those recommendations in 2018 and still believes those requirements are in the best interest of consumers, Carr told *IHP*. She highlighted the 2018 consensus paper in her meeting with FDA and OMB. Carr also emphasized the need for strong regulation and enforcement.

The 2018 paper recommends that the new category of OTC hearing aids maintain the same risk classification as air conduction hearing aids -- that is, class I for self-fit OTC hearing devices and class II for wireless self-fit OTC hearing aids.

Like Tozzi, the paper asserts that the first OTC hearing device marketed by each manufacturer should be required to undergo the 510(k) processes. Any 510(k) exemptions should be limited to devices that have already received a first-time FDA marketing authorization, the industry groups wrote.

The paper also recommends FDA define concise, outside-of-the-box labeling and comprehensive inside-the-box labeling.

Outside-the-box labeling should include the name of the OTC hearing aid category, the intended use, and a notice that explains hearing loss is a medical condition best addressed with a licensed professional and includes a list of "red flags."

The inside labeling should include a warning that the device is not intended for children, a notice that lets users know for how long they should use the device each day and other special care instructions, and a notice alerting users that lack of benefit from the device could indicate a more severe or complex type of hearing loss.

The 2018 paper also urges FDA to define the OTC category in a way that consumers can easily comprehend and that's in line with risk class requirements for safety and effectiveness.

Similar to Tozzi's recommendations, the 2018 paper says FDA's hearing aid guidance should clarify four key elements -- the name of the device category, intended use, conditions for sale and risk classification -- to help differentiate between OTC hearing devices, traditional hearing aids and personal sound amplification products.

The segmentation between the three product categories must be clearly distinguishable and easily comprehended by the average consumer in all elements, including name, intended uses and delivery model, the hearing care associations wrote in 2018.

FDA also should coordinate with the Federal Trade Commission to establish strong consumer protection regulations and put in place adequate processes and resources to enforce those regulations. The organizations recommended that return-and-refund policies be defined for the OTC hearing aid category and that the agencies pay attention to product category claims.

FDA and FTC should put a process in place to ensure that all claims are substantiated by data, scientific evidence or clinical studies, the consensus paper says.

The Hearing Loss Association of America, AARP and Bose Corporation also met with OMB and FDA on Sept. 14. It's unclear what they discussed at the meeting, but HLAA has previously advocated for hearing aids and services to be provided by state-licensed audiologists and hearing aid specialists.

HLAA also has called for people with moderate-to-severe to profound hearing loss to be covered by Medicare.

"Keep in mind that cochlear implants are already reimbursed by Medicare. Given the high cost of coverage for hearing, vision and dental, people with mild to moderate hearing loss will likely be recommended to seek an over-the-counter product, not reimbursed by Medicare," HLAA wrote on its website. -- *Beth Wang* (bwang@iwpnews.com)

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