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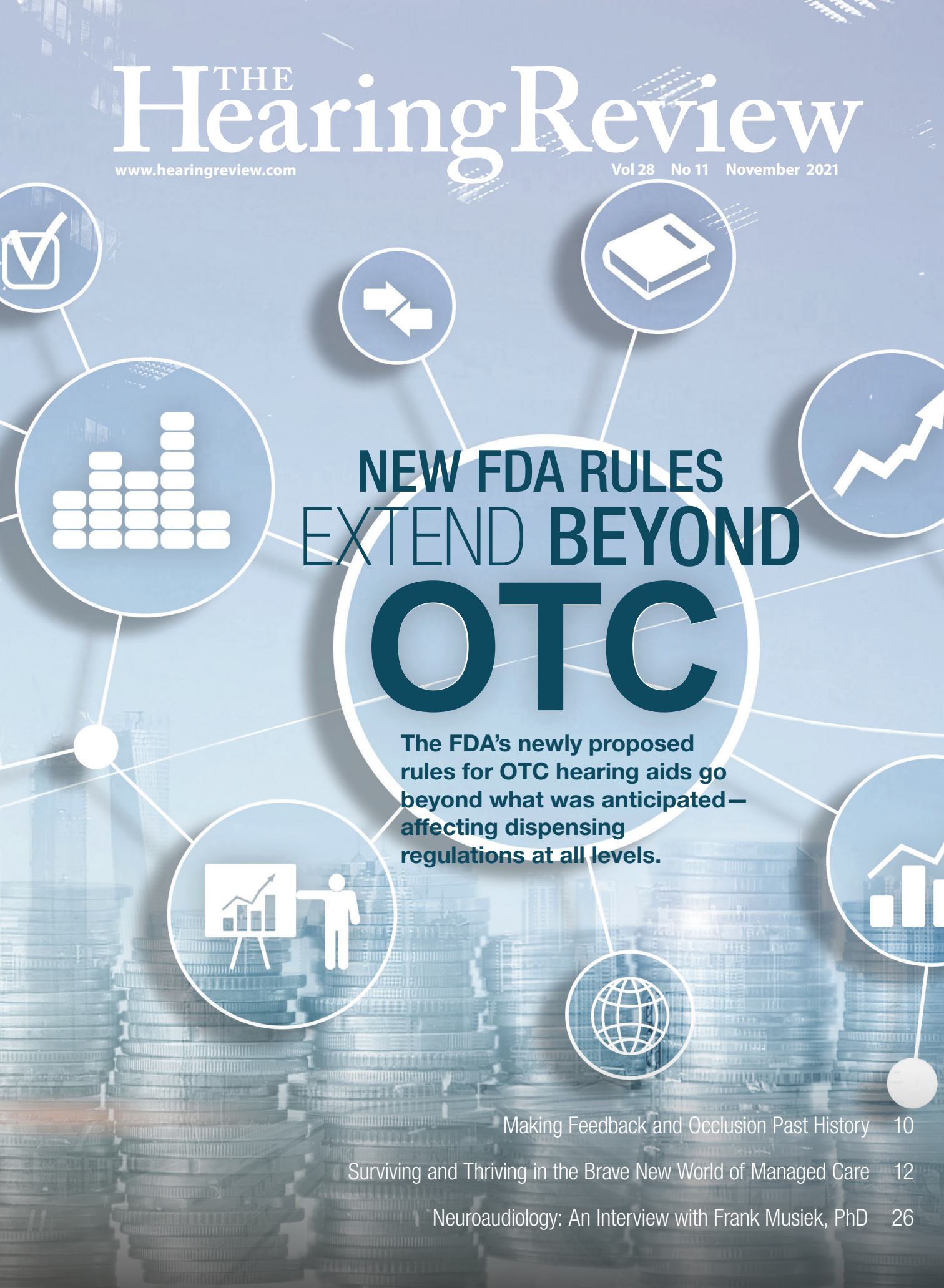

NEW FDA RULES EXTEND BEYOND OTC

The FDA's newly proposed rules for OTC hearing aids go beyond what was anticipated—affecting dispensing regulations at all levels.

Proposed OTC Hearing Aid Regulations Extend Beyond OTC

As noted in this column last month, we expected the US Food and Drug Administration (FDA) to roll out their proposal for a new class of over-the-counter (OTC) hearing aids in October. They did that—and much more—on October 20 in the *Federal Register*.

Designed to make hearing aids more affordable and accessible for people with mild-to-moderate hearing loss, the new proposed regulations are *a lot* more far-reaching than expected—essentially separating hearing aids into two categories for the purpose of dispensing: "OTC hearing aids" and "prescription hearing aids" (professionally dispensed aids). The regulations are crafted to create a new OTC class of hearing aids that could be sold directly to consumers in stores or online without a medical exam or fitting by a hearing care professional (HCP). Mandated by the *FDA Reauthorization Act of 2017* (FDARA), the FDA says it also wishes to increase competition while ensuring the safety and effectiveness of both OTC and prescription hearing aids.

The 114-page rules document, *Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids*, covers most aspects related to OTC hearing aid manufacturing, electroacoustic requirements, packaging and labeling, returns, and conditions for sale. In an effort to promote more consistency in the regulations and enforcement of hearing aid manufacturing and distribution, the FDA is also proposing several important changes that would affect the industry and state-wide hearing aid dispensing. In fact, it appears that the FDA wishes to remove professionally dispensed hearing aids from its list of "restricted devices." It states:

This rulemaking also affects other existing regulations that apply to hearing aids. FDA has established device restrictions for hearing aids that include labeling requirements as well as conditions for sale. We are proposing to remove these device restrictions for hearing aids, and establish a new regulation for prescription hearing aid labeling. Further, FDA has by regulation granted or denied exemptions from Federal preemption for State requirements pertaining to hearing aids. The removal of the device restrictions on hearing aids, as well as certain provisions of FDARA, *impact most of these previous exemption decisions, for example, by altering their scope. We are proposing to remove the regulations codifying these decisions and establish other regulations clarifying some of the effects of statutory preemption under* FDARA.

In the document, FDA refers repeatedly to the President's Council of Advisors for Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NASEM) reports. However, at least when it comes to the vital issue of output levels—which largely determines the range and market scope of OTC devices—the Agency sided with positions advocated by the Consumer Technology Association (CTA) instead of those promulgated by the OTC Hearing Aid Consensus Statement published by AAA, ADA, IHS, and ASHA and endorsed by the Hearing Industries Association (for a summary, see the October 2018 *Hearing Review*, pgs 8-9). With the 120 dB SPL output limit proposed for the new OTC devices, a closed-fit OTC hearing aid could creep into the severe hearing loss range.

Additionally, FDA refers to the new device category as "OTC hearing aids" whereas it had been recommended by the consensus statement they be called "self-fit over-the-counter hearing devices" so as not to cause any further confusion among consumers.

OTC hearing aid manufacturers would be given a pass by FDA when it comes to product returns if the new regulations go unchanged; however, state or local requirements for returns would continue to apply provided they don't conflict with the FDA's final rulemaking. Additionally, manufacturers need to describe their return policy (or lack thereof) on the product packaging.

Importantly, the OTC Hearing Aid regulations, in accordance with the *FDARA of 2017*, would preempt any state or local requirements specifically related to hearing products that "would restrict or interfere with commercial activity involving OTC hearing aids, including any state or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids," according to the document.

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That means non-professionals and professionals alike can dispense OTC hearing aid products; however, the regulations are not meant to interfere with or preempt state requirements regulating professional services of audiologists, hearing aid specialists, or speech pathologists.

Consolidating Hearing Device Categories

Over the years, FDA has created different regulations for the variety of hearing devices as technology and use-cases evolved. FDA would now like to realign and recategorize its hearing aid regulations by "sound-conduction mode." It proposes combining non-wireless ("legacy") and wireless hearing aids, as well as self-fit hearing aids (eg, Bose Self-fitting Hearing Aid), into an "air conduction hearing aid" class, and include OTC hearing aids as a separate subset. It would also retain the classification for bone-conduction devices. FDA says this realignment would not affect the device class or premarket notification exemption status (ie, 510(k) filing requirements) of any existing device. Additionally, for the sake of consistency, some special controls for wireless hearing aids would be removed and replaced by the proposed labeling requirements for both OTC and prescription hearing aids.

As noted above, FDA is calling for something of a "clean slate" when it comes to the agency's previous decisions about state and local exemptions on conditions for sale of hearing aids. Over the past four decades, FDA has granted or denied hundreds of state exemptions pertaining to hearing aids, with some exemptions pre-empting others in confusing ways. The Agency is now proposing removal of these decisions and establishment of other regulations, along with a more transparent system that would better clarify the rules in each state for all stakeholders.

A Deeper Dive into Some Specifics in the Proposed OTC Regulations

Loudness limits. In the *FDARA of 2017*, Congress mandated that the new OTC classification be intended for mild-to-moderate hearing losses, typically defined from 20-55 dBHL. The proposed rule is *very liberal* in its allowance of output, with a maximum OSPL90 of 120 dB SPL for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control (VC), and a 115 dB SPL for those that do not.

These proposed 115-120 dB SPL limits substantially exceed those recommended by the OTC Hearing Aid Consensus Statement, and could push a closed-fit OTC hearing aid into the severe hearing loss category. In the consensus paper, the four national hearing care organizations recommended OTC devices to be intended only for mild-to-moderate hearing losses of 26-55 dB HL with a 110 dB max output (26 dB max HFA-FOG), while offering input compression and volume controls.

FDA is proposing not to restrict loudness levels for OTC hearing aids based on gain.

Electroacoustic requirements. The proposed regulations include a subset of tests and specifications adopted from the ANSI/CTA-2051, including tests for distortion control limits, self-generated noise limits, latency limit, and frequency response bandwidth and smoothness. As reported by *Hearing Review*, inclusion of electroacoustic tests and performance standards for OTC hearing aid regulation was a hotly debated subject at the NASEM Dissemination Meeting in June 2017 (see July 2017 *HR* news, pgs 8-10, 49). There was a wide range of opinions on what to include in the standards or even if a voluntary standard, as advocated by CTA at the earlier FTC Workshop, would better serve consumers.

Other OTC hearing aid design requirements. Other proposed design requirements to ensure proper physical fit and prevent user injury involve an eartip insertion depth and material specs, proper physical fit, and requirements for tools and software for the lay user to control and customize the device.

Returns-for-credit. Manufacturers of OTC hearing aids would not need to offer returns-for-credit, although state or local requirements for returns would continue to apply provided they do not conflict with the final rule based on this rulemaking. FDA is seeking comments on this issue.

Labeling on outside package. On the OTC hearing aid packaging, the FDA is proposing a warning that the device is not for users younger than 18 years old; symptoms of perceived mild-to-moderate hearing loss (with examples); considerations for seeking a consultation with a hearing healthcare professional, and a modified version of the red flag conditions.

Under the new regulations, the outside packaging would also need to include a web address and phone number to access the more detailed inside-the-package information via a digital or mailed printed copy. The labeling would not require cellphone compatibility or battery information. The packaging also needs to disclose its return policy and if the product was reused/rebuilt.

Inside-package labeling. Inside the OTC hearing aid packaging, manufacturers would be required to include a wide range of cautions, illustrations of the controls and product features, descriptions of accessories, and directions for use of the product. The agency is also proposing some technical specifications to allow users, prospective users, and others to evaluate and compare the performance of OTC hearing aids, as well as anything that users might need to know about side effects associated with using the OTC hearing aid, etc.

The report says FDA is still considering inclusion of other information, including technical information similar to that required for hearing aids which can be useful for HCPs in the selection and servicing of the devices.

Quality systems controls and good manufacturing practices. This is an area for which the agency is gathering more data.

Other Proposed Changes for Professionally Fit Hearing Aids

As noted, the FDA would no longer view hearing aids as "restricted devices." The new rules would also eliminate the requirement of a medical evaluation prior to obtaining professionally dispensed ("prescription") hearing aids. Essentially, the requirement of a "physician/medical waiver" is now up to state and professional licensing boards.

To more closely match safety measures with the new OTC regulations, the proposed rules would require professionally dispensed hearing aid labeling to include warnings about underlying pathological conditions, use in people younger than 18, and potential injury from high outputs. The proposed regulations also call for the disclosure by manufacturers of certain technical specifications necessary for appropriate selection and fitting by HCPs.

Timeline to the Finalized Rules

A 90-day comment period will be in effect, and this is typically followed by a 180-day period during which FDA reviews comments received, makes changes to its proposed rules, and obtains the necessary sign-offs. Once finalized, the rule would be effective 60 days after publication in the Federal Register. That means, barring an accelerated timeline, it will be at least another 11 months before the final rules go into effect, or around September 2022.

Comments can be submitted electronically at: https://www.regulations.gov.

The above is condensed from a comprehensive report available at hearingreview.com.