Canadian Audiologist
The Official Publication of the Canadian Academy of Audiology

Hearing Aid Dispensing Groups Back New FDA Restrictions On PSAPs; HLAA Does Not

Published March 4th, 2016

Originally posted at HHTM *On January 19, 2016*. Reprinted with permission.

The following post was originally published on February 5 and updated on February 6.
By David H. Kirkwood

ROCKVILLE, MD –Three more organizations concerned with hearing submitted comments to the U.S. Food and Drug Administration (FDA) this week on the agency's submitted comments to the U.S. Food and Drug Administration (FDA) this week on the agency's proposed guidance document, which would tighten existing restrictions on the marketing of personal sound amplification products (PSAPs).

The International Hearing Society (IHS) and the Academy of Doctors of Audiology (ADA) sent responses to the agency just before the February 5 deadline, strongly supporting FDA's efforts to further distinguish PSAPs from hearing aids. However, the Hearing Loss Association of America (HLAA) raised concerns about the agency's document, which it said contained "confusing language" and was "unhelpful," and it urged FDA to seek more input to come up with a better guidance document.

As reported by this blog earlier, FDA's proposed document holds that PSAPs, which are not regulated devices, must not be marketed as a treatment for hearing loss. That, says the agency, differentiates them from hearing aids, which are FDA-regulated medical devices that are intended for people with hearing loss.

In embracing FDA's revision of its earlier (2009) document on PSAPs, IHS and ADA joined the Hearing Industries Association (HIA), whose comment to the agency was reported here last month. Their position statements fit into an overall pattern: Organizations whose members manufacture or dispense hearing aids want FDA to prevent PSAPs from being sold as an alternative to hearing aids. On the other hand, PSAP makers and other advocates, such as RightToHear.Org, want FDA to loosen or eliminate restrictions on the marketing of PSAPs.

"A STRONG STEP IN THE RIGHT DIRECTION"

In her letter to the FDA, Kathleen Mennillo, executive director of IHS, called the agency's proposal "a strong step in the right direction" and applauded its efforts "to ensure that consumers are best protected."
Noting an "influx of new personal sound amplifier retailers in the marketplace," Mennillo wrote that "it is clear that many (if not most) of these retailers are marketing their devices to hearing-impaired consumers." She added, "This creates a very real health risk for the public, who may unknowingly forgo recommended medical intervention."

IHS's letter went on to suggest some changes to "strengthen the guidance." One is that FDA should consider restricting PSAP marketing that, even if it is not explicitly directed at people with hearing loss, implies that PSAPs will address hearing loss.

Mennillo also recommended that PSAP labeling be required to "clearly state that the device is a personal sound amplifier, not a hearing aid, and that it is not meant to be used by people with hearing loss."

SUPPORT FROM ADA

In his letter to the FDA, Brian Urban, AuD, president of ADA, stated that his organization "strongly supports the 2013 Draft Guidance and recommends that the FDA finalize the guidance as soon as feasible. Based on our observation, the PSAP market continues to expand, as do PSAP marketing claims that they can be used to treat hearing loss."

Urban also addressed the issue of enforcement, writing, "According to FDA, when PSAPs are marketed for the treatment of hearing loss, they become hearing aids by virtue of their intended use. Once that line is crossed, we presume that these de facto hearing aids are held to the same regulatory standards as all hearing aids. As such, ADA encourages swift and consistent enforcement of existing hearing aid regulations as it applies to these devices."

The ADA president's letter also had two other recommendations for the agency.

One asked it to consider requiring PSAP manufacturers to add labels warning that their products "are not intended for use in treating…hearing loss and that doing so could pose serious health and safety risks."

The other was to send letters to companies that are illegally marketing PSAPs advising them that they are violating FDA regulations.

HLAA CALLS GUIDANCE "VAGUE AND UNCLEAR"

Writing for HLAA, an advocacy organization of and for people with hearing loss, Executive Director Anna Gilmore Hall found fault with FDA's attempt to differentiate hearing aids from PSAPs based on their intended use.

Hall wrote, "Attempting to draw a distinction based upon 'listening situations' provides vague and unclear guidance to consumers. FDA's examples create confusion by depicting situations where amplification of sounds would benefit both individuals with and without hearing loss. Yet FDA's draft guidance would require PSAP manufacturers to use language in their advertising that might deter consumers with hearing loss from using their products."

She continued, "Many people with hearing loss do not obtain hearing aids for reasons of cost or fear of being stigmatized. While HLAA is working to overcome these barriers, we believe that, under current circumstances, some of these individuals could benefit from PSAPs, and there is no reason to erect a barrier to preclude this from happening."

In concluding, the HLAA leader said, "Too much of the new language [in the draft guidance] is confusing, resulting in an overall unhelpful change to the 2009 guidance. We respectfully request that the FDA seek input from a broad range of stakeholders to work together to craft a document that is helpful to industry, providers, and consumers alike and provide for greater education of consumers."

MORE RESPONSES TO COME

The American Academy of Audiology and the American Speech-Language-Hearing Association were also expected to submit comments on the PSAP issue to FDA, but they were not available before this post was published.

A SECOND CITIZEN PETITION FILED

On a related note, Mead Killion, PhD, founder and chief technology officer of Etymotic Research, submitted a citizen petition with the FDA on January 28 asking that it "refrain from taking any actions that interfere with the free and unfettered availability of an unregulated consumer product that the agency refers to as 'Personal Sound Amplification Products' or 'PSAPs.'"

In his 22-page petition, Killion said that the "over-riding argument is that the current FDA regulations governing hearing aids are outmoded, ineffective, and excessively burdensome, and do nothing more than unduly and unnecessarily restrict the availability of hearing aids through labeling requirements and arcane conditions of sale. FDA's regulations severely limit competition, and they make no meaningful contribution to protecting public health."

Killion's submission follows a citizen petition sent to the FDA on January 16 by Gail Gudmundsen, AuD, managing director of the audiology division of Etymotic, asking the FDA commissioner to instruct the Center for Devices and Radiological Health (CDRH) to withdraw its draft PSAP guidance document.

Killion and Gudmundsen have a long history of petitioning FDA to make amplification products more easily accessible to consumers. In August 2003, the two audiologists sent separate petitions to the agency. Killion asked for the creation of a separate category of non-custom hearing aids with a peak output of 115 dB that could be sold to consumers over the counter. Gudmundsen's petition asked FDA to eliminate the requirement that adults get a medical evaluation (or sign a waiver in lieu of an evaluation) before purchasing a hearing aid.

The FDA rejected their requests in February 2004.