



STATE OF NEW JERSEY
OFFICE OF THE ATTORNEY GENERAL

January 18, 2022

Via Federal eRulemaking Portal

The Honorable Janet Woodcock
Acting Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Comments on *Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids*, 86 Fed. Reg. 58,150 (Oct. 20, 2021), Docket No. FDA-2021-N-0555

Dear Acting Commissioner Woodcock:

We, the Attorneys General of New Jersey, Delaware, the District of Columbia, Illinois, Maryland, Massachusetts, Michigan, Nevada, New York, and Rhode Island, write to strongly support the Food and Drug Administration's (FDA) proposal to create a regulated market for over-the-counter (OTC) hearing aids. As sovereign states responsible for safeguarding our residents' health and wellbeing, we have an interest in ensuring that residents with mild to moderate hearing loss have access to hearing aids—a critical treatment option. The reality today, however, is that many of our residents who could benefit from hearing aids are shut out of the marketplace. Hearing aids are prohibitively expensive—the average cost today is \$4,700 per pair—and while several factors impact price, an important contributing factor is the FDA's longstanding rule requiring consumers to complete a medical evaluation prior to purchasing hearing aids. While consultation with a licensed professional may well be the right choice for some consumers, others who would benefit from hearing aids may not want or be able to afford this initial evaluation. Under the FDA's current rule, however, they generally must undergo an evaluation before buying hearing aids. Additionally, some consumers are charged a bundled price for the hearing aid and the required consultation and related services, such that the hearing aid itself accounts for a fraction of the total cost to the consumer. In this way, FDA rules have contributed to keeping prices high enough that most adults with hearing loss who would benefit from hearing aids cannot afford them and instead live with untreated hearing loss. The consequences for public health are dire: with more than 28 million Americans today suffering from hearing loss, approximately 75 percent of adults who would benefit from hearing aids do not use them, often due to the prohibitive cost. Those adults

suffer from an impaired ability to communicate and face higher risks of dementia, depression, and injuries related to falls.

The FDA's Proposed Rule offers critical relief to these individuals by making it easier for them to find affordable hearing aids. Establishing a regulated OTC market would bring an influx of competition to an industry currently dominated by a small number of manufacturers, driving down prices and spurring innovation. In doing so, the Proposed Rule would also reduce demand for largely unregulated personal sound amplification products (PSAPs), which are not meant to treat hearing loss but are often misleadingly advertised as a lower-cost substitute for hearing aids. Our residents are increasingly turning to PSAPs simply because they cannot afford hearing aids. The existence of affordable OTC hearing aids would pull those consumers into a regulated market and away from PSAPs which, if not used properly, can be harmful to patient health. We commend the FDA for this much-needed rulemaking.

I. Existing Regulations Contribute to the Prohibitive Cost of Hearing Aids.

Hearing loss affects more than 28 million Americans and can upend a person's quality of life.¹ Untreated hearing loss impairs one's ability to communicate, can cause social isolation, and has been linked to depression, dementia, cognitive decline, and injuries resulting from falls.² The risks go beyond physical and cognitive health; hearing impairment is also associated with reduced income and higher rates of unemployment.³ Hearing loss is especially prevalent in older age, with approximately 25 percent of adults aged 65 to 74 and half of adults 75 and over suffering disabling hearing loss.⁴ Indeed, age-related degenerative processes are "[t]he leading cause of adult-onset hearing loss."⁵ Not only are older adults acutely at risk, but age-related hearing loss is expected to rise as the Baby Boomer generation enters old age.⁶

¹ PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY, AGING AMERICA & HEARING LOSS: IMPERATIVE OF IMPROVED HEARING TECHNOLOGIES, at 1 (2015), <https://tinyurl.com/2p8t2ubk> ("PCAST"); NAT'L ACADS. OF SCIENCE, ENG'G & MED., HEARING HEALTH CARE FOR ADULTS: PRIORITIES FOR IMPROVING ACCESS AND AFFORDABILITY, at 1 (2016), <https://www.nap.edu/read/23446/chapter/1> ("HEARING HEALTH CARE FOR ADULTS"); NAT'L INST. ON DEAFNESS & OTHER COMM'C'N DISORDERS, *Quick Statistics About Hearing*, <https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing> (last updated Mar. 25, 2021).

² PCAST, *supra* note 1, at 1; HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 3; Lisa L. Cunningham et al., *Hearing Loss in Adults*, 377 NEW ENG. J. MED. 2465, 2465 (2017).

³ HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 3; *Hearing Loss in Adults*, *supra* note 2, at 2465.

⁴ *Quick Statistics*, *supra* note 1; *see also* HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 1 (finding 45 percent of adults aged 70 to 74 and "more than 80 percent" of adults aged 85 and older have hearing loss); PCAST, *supra* note 1, at 1 (over half of adults aged 70 to 79 years and approximately 80 percent of those over age 80); *Hearing Loss in Adults*, *supra* note 2, at 2465 (half of adults aged 60 to 69 years and 80 percent of those over age 85).

⁵ *Hearing Loss in Adults*, *supra* note 2, at 2466.

⁶ HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 1; PCAST, *supra* note 1, at 1; Frank R. Lin et al., *Hearing Loss Prevalence in the United States*, 171 JAMA INTERNAL MED. 1851, 1851 (2011), <https://tinyurl.com/2p8ueuku>.

But while the burdens and prevalence of hearing loss are clear, only a small proportion of affected adults use hearing aids. Approximately “67 to 86 percent of adults who may benefit from hearing aids do not use them.”⁷ The rate of adoption is alarmingly low among older adults, perhaps the demographic most vulnerable to the health risks associated with hearing loss: less than 30 percent of adults 70 and over who could benefit from hearing aids have ever used them.⁸ The problem is especially acute for communities of color, who have traditionally lacked access to hearing aids. Among older adults with hearing loss, African Americans and Mexican Americans are significantly less likely—58% and 78% less, respectively—than white adults to report using hearing aids.⁹

Public health experts point to a number of explanations for this—such as difficulties with comfort and fit, and a stigma associated with being hard of hearing—but a significant barrier to using hearing aids is their staggeringly high price.¹⁰ A pair of hearing aids costs on average \$4,700, making hearing aids the third largest purchase for most Americans, after a house and car.¹¹ And most consumers must pay the entire price out of pocket, because many private insurance and Medicare plans do not cover the costs of the device or the fitting.¹² It is no surprise then that most individuals with hearing loss simply go without hearing aids and adjust to life with untreated hearing loss.

Several characteristics of the hearing aid market contribute to high prices, but some of these problems are exacerbated by the FDA’s requirement that consumers seek a medical evaluation before purchasing hearing aids.¹³ To be sure, some consumers prefer to undergo an audiologic evaluation, during which a licensed professional assesses the magnitude and cause of hearing loss, before deciding whether hearing aids are appropriate.¹⁴ Moreover, some individuals may decide they would benefit from a fitting, adjustment of the hearing aid, or other services provided by a

⁷ HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 1; *see also* PCAST, *supra* note 1, at 1.

⁸ *Quick Statistics*, *supra* note 1.

⁹ Carrie L. Nieman et al., *Racial/Ethnic and Socioeconomic Disparities in Hearing Health Care Among Older Americans*, 28 *J. Aging & Health* 68 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4826391/>; *see also* HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 113.

¹⁰ PCAST, *supra* note 1, at 1; HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 7; *Hearing Loss in Adults*, *supra* note 2, at 2471.

¹¹ GLOBAL PARTNERSHIP FOR ASSISTIVE TECHNOLOGY, *A MARKET LANDSCAPE AND STRATEGIC APPROACH TO INCREASING ACCESS TO HEARING AIDS AND RELATED SERVICES IN LOW AND MIDDLE INCOME COUNTRIES*, at 15 (2019), <https://tinyurl.com/ycktpfb> (“INCREASING ACCESS TO HEARING AIDS”); *see also* HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 207; PCAST, *supra* note 1, at 1-2 (explaining that most users of hearing aids require a device in both ears, which doubles the cost).

¹² PCAST, *supra* note 1, at 2.

¹³ 21 C.F.R. § 801.421(a). Patients aged 18 or older can sign a waiver of the evaluation requirement, but FDA rules require hearing aid dispensers to admonish the patient that doing so “is not in the user’s best health interest.” *Id.*

¹⁴ *See* HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 85-86.

licensed professional. But many consumers who could benefit from hearing aids do not require these services and may be unable to afford them on top of the cost of the hearing aid. Indeed, many patients are charged a bundled price—a single up-front fee for a professional evaluation by a licensed audiologist, hearing aids, a follow-up appointment, and any adjustments after an initial period of use.¹⁵ This can result in a markup of up to 120 percent of the wholesale device price, so that “less than half” of what the consumer pays is for the hearing aid itself.¹⁶ The remainder of the up-front cost accounts for rehabilitative and fitting services—which can range from \$1,900-2,100 per hearing aid—that not all patients find necessary.¹⁷ If an OTC option existed, consumers could choose for themselves whether and when to seek these professional services, a choice that for many could be the difference between whether they can afford hearing aids or not.

Further, hearing aid manufacturers have structured their distribution channels in such a way that some consumers relying on a licensed professional may be aware of only a limited range of products.¹⁸ The five largest manufacturers control more than 90 percent of the market, and through vertical integration—in which the manufacturer owns or has a financial stake in the retailers distributing its goods—these suppliers seek to prevent hearing aid dispensers from offering competitors’ products.¹⁹ For example, these manufacturers own or affiliate with chains of audiologist and dispenser practices who may then favor (or exclusively sell) the parent company’s brand; manufacturers also offer exclusive contracts to independent dispensers to similar effect.²⁰ Similarly, most manufacturers use proprietary fitting software, which can discourage audiologists from switching suppliers because doing so would entail a time-consuming learning process.²¹ As a result, roughly 20 percent of dispensers sell only one brand of hearing aids; even where multiple brands are available, dispensers recommend a single brand to about 75 to 80 percent of their patients.²²

These manufacturers’ business structures keep prices artificially high by blocking new entrants into the market, who would otherwise compete on price but are excluded from key distribution channels.²³ Moreover, consumers who are presented with only a small number of

¹⁵ PCAST, *supra* note 1, at 3; INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 15; *Hearing Loss in Adults*, *supra* note 2, at 2471.

¹⁶ PCAST, *supra* note 1, at 3; *see also* HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 208.

¹⁷ PCAST, *supra* note 1, at 3 (finding over 80 percent of hearing aid dispensers use bundled pricing structures); INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 15.

¹⁸ PCAST, *supra* note 1, at 3; INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 15.

¹⁹ INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 15; PCAST, *supra* note 1, at 2-3; HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 207.

²⁰ INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 15; PCAST, *supra* note 1, at 3.

²¹ INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 15.

²² PCAST, *supra* note 1, at 3.

²³ *Id.*

options will likely be unaware of lower-priced products available elsewhere, another way in which the largest manufacturers insulate their products from the downward price pressure they would face in a more open market. These same forces help to explain the relative lack of innovation in the hearing aid industry, which has seen far fewer “dramatic reductions in price and increases in features” than other consumer electronics.²⁴ Indeed, “the unnecessarily high price of hearing aids” and “conspicuously slow pace of innovation by their manufacturers” are “consequences of a concentrated and increasingly vertically integrated incumbent industry.”²⁵ If a regulated OTC market existed, consumers could opt to bypass this business structure entirely and instead shop in the OTC market. That could eliminate or at least substantially reduce incentives for companies to rely on these types of exclusive distribution structures, which would increase competition and thus exert greater downward pressure on prices.

States are increasingly concerned that their residents cannot afford hearing aids and are expanding efforts to improve access for individuals with hearing loss. A number of states have established a state agency devoted to services for the deaf and hard of hearing, several of which manage programs designed to expand access to hearing aids.²⁶ New Jersey’s Division of the Deaf and Hard of Hearing (NJDDHH), for example, administers a program that provides a cash reimbursement to eligible low-income seniors to offset the purchase of new hearing aids. In 2021, Governor Murphy’s administration increased the reimbursement amount for the first time since the program’s creation in 1987, from \$100 to \$500 per hearing aid, with a potential of up to \$1,000 in total.²⁷ The NJDDHH also provides free refurbished hearing aids to eligible low-income seniors.²⁸ While these programs offer critical support to eligible residents, the fact that hearing aids are so expensive to begin with limits the ability of such programs to make hearing aids affordable across the board. States cannot solve this problem on their own, and the nationwide nature of the problem requires a federal response.

II. The Proposed Rule Would Bring Much-Needed Reform to a Market that Has Kept Hearing Aids Unaffordable for Most Adults with Hearing Loss.

After years of efforts by advocates to expand access to hearing aids, Congress acted in August 2017 and passed the bipartisan Over-the-Counter Hearing Aid Act.²⁹ The Act specifically

²⁴ *Id.*; see also David Lim, *Why political contributions linked to a little-known hearing aid firm topped medtech giants*, MEDTECH DIVE (Nov. 29, 2018), <https://tinyurl.com/bd9y65m2>.

²⁵ PCAST, *supra* note 1, at 9.

²⁶ See, e.g., MO. COMMISSION FOR THE DEAF & HARD OF HEARING, <https://mcdhh.mo.gov/hadp/>; N.J. DIVISION OF THE DEAF AND HARD OF HEARING, <https://www.nj.gov/humanservices/ddhh/>; N.C. SERVICES FOR THE DEAF AND THE HARD OF HEARING, <https://www.ncdhhs.gov/divisions/services-deaf-and-hard-hearing>.

²⁷ Press Release, Dep’t of Human Servs., NJ Human Services Announces Increased Hearing Aid Assistance & Enhanced Deaf and Hard of Hearing Equipment Distribution (July 12, 2021), <https://tinyurl.com/2m5hdnte>.

²⁸ N.J. DIVISION OF THE DEAF AND HARD OF HEARING, Hearing Aid Project, <https://tinyurl.com/5622uwf3>.

²⁹ FDA Reauthorization Act of 2017, Pub. L. No. 115-52, § 709, 131 Stat. 1005 (2017).

requires the FDA to establish a category of OTC hearing aids as well as certain design and performance requirements to ensure the OTC devices are safe and effective to use.³⁰

The Proposed Rule does precisely that. The Rule would establish a new category of OTC hearing aids, defined as air-conduction hearing aids that are intended for use only by adults with mild to moderate hearing loss.³¹ These devices could be purchased over-the-counter with no physician evaluation/intervention or prescription required. The Rule also establishes the design, labeling, output limits, conditions of sale, and other specifications required by Congress, so that users can be assured these devices offer a basic level of hearing technology.³² In particular, the Rule appropriately proposes a host of conspicuous warnings that would require prompt consultation with a “licensed physician, preferably an ear specialist” where certain conditions (e.g., pain in the ear, vertigo, or a visible deformity) are present.³³ And the Rule would impose a flat ban on the sale of OTC hearing aids to anyone under the age of 18.³⁴ While the 2017 Act already preempted state and local requirements for the intervention of a licensed professional to sell the new category of OTC hearing aids, the Proposed Rule notes that preemption would not apply to prohibitions on deceptive trade practices or other generally applicable regulations that apply to any business that sells goods or services.³⁵ Further clarification regarding the scope of the Act’s preemptive effect would ensure that States retain their authority to regulate the hearing aid market to protect consumers.

The Rule would expand access to hearing aids and thus improve hearing health across the country. Most notably, establishing an OTC market “would increase competition by bringing in new players among established technology companies such as Apple, Samsung, and Bose, all of whom are expected to participate.”³⁶ It would do this by helping to dismantle the dominant manufacturers’ control of the market, which, as explained above, hinges on the vertically integrated structures they have established in reliance on current regulations.

More competition would lead to lower prices—as low as \$500 per pair, as one comprehensive study of the hearing aid market predicted.³⁷ In part that is because an OTC market would “disrupt the current bundled pricing model” and thus “improve price transparency by

³⁰ See 86 Fed. Reg. 58,151.

³¹ *Id.*; 86 Fed. Reg. 58,177 (proposed definition of “over-the-counter hearing aid”).

³² See 86 Fed. Reg. 58,151, 58,158-67.

³³ 86 Fed. Reg. 58,178-81.

³⁴ 86 Fed. Reg. 58,165-66.

³⁵ 86 Fed. Reg. 58,166-68.

³⁶ INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 25; *see also* Lim, *supra* note 24.

³⁷ INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 26; *see also* PCAST, *supra* note 1, at 8-9; *Hearing Loss in Adults*, *supra* note 2, at 2471.

informing customers on device costs unbundled from services.”³⁸ In doing so, the Rule would make hearing aids more affordable for the millions of adults with hearing loss who may not be able to afford the products on the market today. This would especially benefit communities of color, who have traditionally had less access to hearing aids in part due to their high cost.³⁹ Merely by creating the conditions for lower prices, the Proposed Rule would likely facilitate higher rates of hearing aid use in these communities. And the expected influx of competing manufacturers could rapidly increase the pace of innovation in this industry which has seen far fewer improvements than analogous digital technologies.⁴⁰

There is already ample evidence that hearing aids could be profitably sold at a fraction of today’s prices. Costco, the second-largest provider of hearing aids in the United States, charges a bundled price of as low as \$1,499 per pair—about one-third of the typical retail price—which includes the cost of a fitting.⁴¹ It is able to offer those cost savings by, among other things, buying products from the leading manufacturers that are often one generation behind and utilizing its bulk purchasing power. If Costco is able to profitably sell hearing aids at that price even when it procures its product line from the dominant manufacturers, consumers should see even greater cost savings and product choice once the OTC market is established.

Notably, the Proposed Rule would also mitigate some of our serious concerns surrounding PSAPs. These products have proliferated in some states, in part due to regulatory uncertainty stemming from how the FDA distinguishes PSAPs from hearing aids. As defined by the FDA, PSAPs are wearable electronic products intended for users without hearing loss to amplify sounds in certain recreational settings, such as hunting and bird watching, but are not intended to treat or compensate for impaired hearing.⁴² By contrast, a “hearing aid” is “designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.”⁴³ As a result, PSAPs are exempt from the FDA’s suite of strict regulatory controls applicable to hearing aids so long as they are not offered for the purpose of treating hearing loss.⁴⁴

But few consumers fully grasp that distinction, and many companies have taken advantage of the resulting confusion by marketing the lower-cost PSAPs, either explicitly or implicitly, as a substitute for hearing aids.⁴⁵ Unable to afford hearing aids, many consumers have accepted those

³⁸ INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 26.

³⁹ HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 114-15.

⁴⁰ PCAST, *supra* note 1, at 1-2, 8-9; Lim, *supra* note 24.

⁴¹ INCREASING ACCESS TO HEARING AIDS, *supra* note 11, at 17; PCAST, *supra* note 1, at 2-3.

⁴² 86 Fed. Reg. 58,154; PCAST, *supra* note 1, at 4.

⁴³ 21 C.F.R. § 801.420(a)(1).

⁴⁴ See PCAST, *supra* note 1, at 4; HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 189.

⁴⁵ HEARING HEALTH CARE FOR ADULTS, *supra* note 1, at 189; Jeff Craven, *FDA issues proposed OTC hearing aid rule*, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Oct. 19, 2021), <https://tinyurl.com/5xyx8a46>.

dubious advertising claims and purchased PSAPs, mistakenly believing them to be a lower-cost treatment for hearing impairment.⁴⁶ In other words, the absence of an affordable, OTC option is helping *create* demand for the largely unregulated PSAPs, products whose intended uses are not always clearly understood by consumers. By establishing a market for OTC hearing aids that must meet basic safety and quality standards, the Proposed Rule would pull consumers into a regulated market and sap demand for those unregulated products. Far from deregulating hearing aids, the Proposed Rule would bring clarity to the marketplace by providing an assurance of safety and effectiveness that is missing with many of the direct-to-consumer products available today.

III. In Addition to Establishing a Regulated OTC Market for Hearing Aids, the FDA Should Consider Stronger Enforcement of Existing Rules.

Although the Proposed Rule removes a significant obstacle to improving hearing health in our States, it does not respond to other problems in the hearing aid market that we believe pose a risk to patient health. In particular, the Proposed Rule expressly declines to regulate PSAPs as hearing aids and maintains the FDA’s position that these products are not subject to medical device regulations as long as they are not offered to treat or compensate for hearing loss.⁴⁷ The Proposed Rule adds that “merely calling a product something besides ‘hearing aids’ would not” allow it to escape regulation as such if the product label makes clear “the product was intended to compensate for hearing loss.”⁴⁸ But that admonishment provides little reassurance when many companies today market PSAPs in ways that, to a layperson, make them indistinguishable from hearing aids. And despite the Proposed Rule’s strong words, there is little evidence the FDA is enforcing its existing hearing aid regulations against PSAPs distributors when they cross that line.⁴⁹ To be sure, establishing a regulated OTC market for hearing aids would direct consumers seeking a low-cost treatment for hearing loss away from PSAPs, which, in itself, goes a long way toward addressing our concerns. But there will still be bad actors who, emboldened by the current lax enforcement, may improperly offer PSAPs as a substitute for hearing aids. Therefore, we urge the FDA to step up enforcement of existing hearing aid regulations against PSAPs manufacturers and retailers who improperly offer these products to treat or compensate for hearing loss.

IV. Conclusion.

We commend the FDA for carrying out Congress’s mandate to allow consumers to purchase affordable hearing aids in a regulated OTC market. The Proposed Rule would increase competition in a highly concentrated industry, spur innovation, and ultimately reduce prices, thus

⁴⁶ See, e.g., Press Release, Office of the Attorney General, Attorney General Bonta Issues Consumer Alert on Hearing Aids Sold Online or Over-the-Counter (Aug. 4, 2021), <https://tinyurl.com/y287pkwz>.

⁴⁷ 86 Fed. Reg. 58,154.

⁴⁸ *Id.*

⁴⁹ See Transcript of FTC Workshop, Now Hear This: Competition, Innovation, and Consumer Protection Issues in Hearing Health Care, at 101 (Apr. 18, 2017), <https://tinyurl.com/yckw8bt3>.

expanding access for millions of adults with hearing loss. And it would do so while ensuring these OTC hearing aids meet basic standards for safety and effectiveness, so that consumers who cannot afford premium hearing aids can still access this crucial treatment for hearing loss.

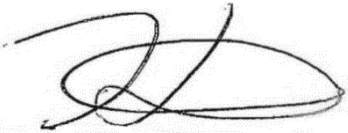
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