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Office of Policy Planning
Bureau of Economics
Bureau of Competition

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Docket No. FDA-2021-N-0555

Attention: Food and Drug Administration
Dockets Management Staff (HFA-305)
Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids, Proposed Rule

The staff of the Federal Trade Commission (“FTC” or “Commission”) Office of Policy Planning, Bureau of Economics, and Bureau of Competition (“FTC staff”)¹ appreciate the opportunity to respond to your request for comments on the Proposed Rule, RIN 091-AI21, Establishing Over-the-Counter Hearings Aids, implementing pertinent provisions of the FDA Reauthorization Act of 2017.² We write to express our support for the proposed rule, given the benefits to competition and health care consumers that the rule would likely promote.

As noted in the Notice of Proposed Rulemaking (“NPRM”) – and in reports from the National Academies³ and other authorities⁴ – tens of millions of US consumers suffer hearing loss, resulting in significant associated health problems; yet most hearing-impaired persons lack hearing aids due, in no small part, to the high price of hearing aids and related services, such as assessment and “fitting” of hearing aids.⁵ The proposed rule implements bipartisan legislation that seeks to reduce the burden on hearing-impaired patients by permitting the sale of Over-the-Counter (“OTC”) hearing aids.⁶ By establishing a category of OTC Hearing Aids and preempting contrary state laws and regulations, the proposed rule is likely to foster the following procompetitive benefits:

- The development and entry of lower-priced safe and effective hearing aids; and, as a related matter, the ability to market such products as hearing aids to those subject to mild-to-moderate hearing loss.
- New channels of distribution for hearing aids.

- The increased availability and diversity of lower-priced bundles of hearing aids and services for consumers for whom price or access to services is a barrier to acquisition and use of hearing aids.
- The development and entry of remote and web-based ancillary tools for hearing aids.
- Increased competition and innovation in legacy hearing aids, given a supply expansion for both lower-cost alternative hearing aids and new channels of distribution.

As explained below, these benefits are likely to improve competition and innovation in hearing aids, with potential benefits to millions of American consumers. With increased access to a greater variety of hearing aids, many consumers could obtain much needed hearing aids more conveniently, and at lower prices, than they can now.⁷

Interest and Experience of the Federal Trade Commission

The FTC is charged under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.⁸ Promoting free and fair competition has long been core to America's economy,⁹ and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, more choices, and greater innovation. Because of the importance of health care competition to the economy and consumers, anticompetitive conduct in health care markets has long been a key target of FTC law enforcement,¹⁰ research,¹¹ and advocacy.¹²

In particular, the FTC has more than three decades of regulatory and research experience regarding barriers to competition and consumer access to medical devices, including barriers like those that motivated the pertinent provisions of FDARA and the Proposed Rule.¹³ The FTC has facilitated consumer access to other medical devices through regulations designed to increase competition for prescribed products. For example, the Commission enforces the Eyeglass Rule,¹⁴ which was initially promulgated in 1978, and the Contact Lens Rule,¹⁵ which implements the Fairness to Contact Lens Consumers Act:¹⁶ these rules enhance consumer access to optical goods by fostering competition in retail sales of eyeglasses and contact lenses.

For decades, the FTC has taken steps to prevent unfair conduct by hearing aid manufacturers and to help consumers better understand their options for hearing products. For example, in 1981, a report prepared for the FTC's Bureau of Competition examined vertical restraints in the hearing aid industry.¹⁷ The Commission has also brought enforcement actions against hearing aid manufacturers for violating the FTC Act and other laws and regulations enforced by the Commission;¹⁸ and the FTC has published various consumer guides about purchasing hearing aids.¹⁹

Spurred in part by a 2016 report issued by the National Academies of Sciences, Medicine, and Engineering (“National Academies”)²⁰ and 2015 and 2016 reports from the President’s Council of Advisors on Science and Technology (“PAST”),²¹ the Commission hosted a workshop to examine competition and consumer protection issues in hearing health care, with participation from FDA, the Centers of Disease Control, academic medicine and audiology, practitioners, consumer groups, and industry.²² Topics explored at the workshop included, among others, data regarding hearing loss, innovations in hearing technology, innovations in hearing health delivery, the costs and benefits of hearing health care regulations, consumer information and choice.²³ Participants across all panels at the workshop discussed the potential benefits of an OTC category of hearing aids. As discussed below, consistent with the recommendations of the National Academies²⁴ and PCAST reports,²⁵ the record from this public event supports the FDA’s efforts to make hearing products more accessible as one way to improve competition and lower prices.²⁶

Statutory Background and the NPRM

In August 2017, Congress enacted the FDA Reauthorization Act of 2017 (“FDARA”).²⁷ Section 709 of FDARA provides, in pertinent part, for the promulgation of regulations “to establish a category of over-the-counter hearing aids.”²⁸ The statute also requires, *inter alia*, that such regulations “provide reasonable assurances of safety and effectiveness of [OTC] hearing aids . . . [and] include requirements that establish or adopt output limits appropriate for [OTC] hearing aids.”²⁹ Section 709 establishes the conditions “under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.”³⁰ It also contains an express preemption clause.³¹

The NPRM describes those hearing aids to be regulated as OTC hearing aids, sets forth the technical requirements, labeling requirements, and conditions of sale for OTC hearing aids, and establishes federal preemption of contrary state laws, as stipulated in FDARA. The NPRM also sets forth considerable background regarding its consideration of hearing aid regulations and the potential for OTC hearing aids, both in prologue to FDARA’s enactment and FDA’s rulemaking process. In drafting the NPRM, FDA appears to hew to the statutory directives and purpose; that is, to enhance access to hearing health care by regulating OTC hearing aids in a way that balances consumer protection and competition interests: on the one hand, truthful and non-misleading marketing of safe and effective devices; on the other hand, improved competition and access to hearing aids via the introduction of low-risk, low-cost, OTC hearing aids.

On balance, we anticipate that the Proposed Rule, if adopted, would reduce regulatory costs for a significant range of hearing devices, with benefits accruing to health care consumers. Consumers with hearing loss who presently face limited access to hearing aids may benefit the most.

Discussion

There appears to be substantial unmet medical need for hearing aids.³² While extrapolation of commercial demand from data regarding untreated hearing loss is not necessarily straightforward, it appears that many more consumers would purchase hearing aids were it not for certain barriers to hearing aid sales and acquisition. As noted in the literature, those barriers are complex; at least some seem unnecessary and due, in part, to a combination of federal and state regulations that impede more varied and efficient channels of distribution.³³ The 2015 PCAST Report, for example, argues that “[c]urrent distribution channels create barriers to access . . .” and that “[c]omplex State regulations restrict the distribution channels for hearing aids.”³⁴ Because the proposed rule promises to reduce or remove some of those barriers, it is likely to foster a supply expansion for hearing aids; and that should lead to lower average prices for hearing aids. In addition, because the proposed rule would provide for the sale of hearing aids “without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online,” it should foster more widespread access to lower-cost unbundled hearing aids, and to new channels of distribution, for consumers who do not yet have access to these options.

FTC staff notes, at the outset, that the central pro-competitive provisions of the Proposed Rule are required by statute: establishment of a regulatory category of OTC hearing aids,³⁵ streamlining of regulations for hearing aids,³⁶ and preemption of contrary state laws.³⁷ We note, further, that the preemption provision of FDARA expressly protects access to OTC hearing aids “through in-person transactions, by mail, or online,” among other things.³⁸ Those statutory mandates, as FDA proposes to implement them, should work in concert to foster more competitive hearing aid markets.

A. High Prices and Other Barriers put Hearing Aids out of Reach for Many in Need

As we noted above, tens of millions of Americans suffer hearing loss. A 2011 clinical study estimated that 30 million Americans suffered bilateral hearing loss and 48.1 million suffered unilateral hearing loss.³⁹ As the CDC noted in 2020, “[a]bout 40 million US adults aged 20-69 years have noise-induced hearing loss.”⁴⁰ In addition, numerous serious health problems are associated with hearing loss.⁴¹ Yet while hearing aids can be effective – mitigating both hearing deficits⁴² and the broader harms associated with untreated hearing loss⁴³ – most hearing loss remains untreated or unmitigated.⁴⁴ While extrapolation of demand from data regarding untreated hearing loss is not necessarily straightforward, it appears demand may be unduly suppressed by barriers to hearing aid sales and acquisition.

1. Price: One chief reason for the gap between medical need (or potential demand) for hearing aids and other hearing health care is the high price of hearing aids.⁴⁵ Recent reports note prices for a single hearing aid ranging from approximately \$1,600 for “entry level” models to more than \$2,000 for mid-level hearing aids and more than \$2,600 for premium models.⁴⁶ Both the National Academies and PCAST reports note that most consumers must bear these costs out of pocket, given a lack of coverage under Medicare and many private health insurance policies.

Some portion of the average price may be due to factors other than the cost of the hearing aids themselves, such as inefficient channels of distribution and diminished competition. For example, it has been reported that the U.S. Department of Veterans Affairs procures hearing aids for its beneficiaries – approximately 20 percent of the U.S. hearing aid market – through volume contracts with manufacturers.⁴⁷ And “[a]ccording to one report published in early 2014, the VA paid an average of \$369 per hearing aid, while one vendor’s retail price for a similar hearing aid in the open market was \$1,400–\$2,200.”⁴⁸ While few vendors can match the negotiating position of the VA, or of large national retailers such as Costco, and many may pay significantly higher prices to acquire hearing aids for resale,⁴⁹ the differential is striking.⁵⁰ And, as discussed below, consumer access to larger vendors or alternative channels of distribution may be constrained by extant regulations.

2. **Bundled Pricing:** Hearing aids are commonly sold as part of a bundle that includes both the hearing aids and varying forms and amounts of follow-up services. A significant portion of the average retail price appears to be due to the cost of bundled services many consumers may not want or be likely to use, and not simply higher wholesale prices paid by smaller vendors. One participant in the FTC Workshop reported that approximately one third of the cost of providing typical hearing aid bundles is associated with the devices, while two thirds of the cost stem from the services bundled with the hearing aids.⁵¹ Surveys have found that a large majority of audiologists – licensed vendors in many states – use bundled rather than itemized pricing.⁵²

Moreover, although alternatives to relatively high-priced hearing aids and bundles exist in some markets, not all consumers have access to such alternatives.⁵³ Rural and other underserved areas may offer few vendors or hearing health care providers; and low-income and older consumers, who suffer disproportionately from hearing loss,⁵⁴ may face additional challenges travelling for hearing assessment, purchase, or adjustment of hearing aids. Further, as noted by the National Academies and PCAST reports, consumers’ access to hearing aids may be limited by various state laws or regulations, as many states restrict the conditions under which hearing aids are sold or who can sell them.⁵⁵ Such restrictions may include, *inter alia*, requirements of a hearing evaluation or exam prior to sale of a hearing aid, licensing requirements for vendors or dispensers of hearing aids, or the prohibition of hearing aid sales by mail or via the internet.⁵⁶ Such restrictions can also limit consumer access to telehealth or online hearing services, such as the remote follow-up, tuning and adjustment program offered by the VA⁵⁷ or the remote hearing assessment tool that the AARP offers its members.⁵⁸

Although ancillary services bundled with hearing aids can have some benefits for some consumers,⁵⁹ bundled pricing, coupled with specialization of vendors, as well as increasing vertical integration, can impede comparison shopping and can raise tying or lock-in concerns.⁶⁰ Moreover, as noted at the FTC Workshop, common bundled hearing pricing requires that consumers pay up-front for future care and services that they may or may not use.⁶¹ A survey conducted by Consumer’s Union indicated that, while many consumers paid for a long-term series of follow-up services “most people didn’t go back for

more than two visits.”⁶² The survey evidence also suggests that a quarter of hearing aid consumers never use a single follow-up appointment.⁶³

3. Search and Information Costs:

An additional barrier to access for consumers are high information costs or search costs. PCAST, the National Academies, and workshop participants all noted a lack of transparency in hearing aids and hearing health care markets.⁶⁴ Consumers have difficulty researching prices and features of hearing aids, and with making “apples-to-apples” comparisons between various models and varied bundles of hearing aids and ancillary services, such as hearing aid adjustments by audiologists.⁶⁵ While the FTC and organizations such as Consumer Reports⁶⁶ and AARP⁶⁷ provide consumer education materials on shopping for hearing aids, many consumers are only able to shop for hearing aids through particular prescribers or dispensers of hearing aids. In many cases, such limits are caused or exacerbated by limitations on sales imposed by state laws and regulations.⁶⁸ In addition, most vendors carry a limited selection of hearing aids, and many specialize in the sales and fitting of a single brand.⁶⁹ Consumers in states that restrict mail-order sales and telehealth support may have difficulty entering the market through alternative types of vendors; and consumers who learn about their retail options via such vendors may learn relatively little about alternatives in the market. Further, systematic evidence on the likely benefits of various models and features is limited, and several studies have failed to find superior results or effectiveness associated with more expensive or “premium” hearing aids.⁷⁰

B. OTC Hearing Aids Will Reduce Barriers to Access and Spur Competition from new Lower Cost Devices

The NPRM’s provisions regarding OTC hearing aids, the conditions of sale for OTC hearing aids, and the streamlining of the mix of federal and state regulations will likely work in concert to foster greater competition and innovation in hearing aids and greater access to hearing aids for consumers with mild-to-moderate hearing loss.

First, because the proposed definition of OTC hearing aids comprises devices that use “the same air-conduction technology as hearing aids [currently] regulated under [21 CFR] §§ 874.3300 and 874.3305,”⁷¹ we anticipate not just the introduction of new devices, but the near-term marketing of certain extant Class I and Class II hearing aids as OTC hearing aids. Moreover, to the extent that the current supply of such devices is demand constrained, due to limited channels of distribution, the ability to sell such hearing aids “without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online”⁷² is likely to incent a supply expansion, as internet retailers, pharmacies, big box stores, and other vendors and would-be entrants may demand these devices where they were previously barred or otherwise restricted from selling them. Such products may also appeal to retail outlets unprepared to invest in the fixed costs associated with providing a wider range of hearing health care services. As a general matter, such a supply expansion will tend to lower prices.

Reducing bottlenecks to entry should enhance the supply expansion as new products and manufacturers enter the market, as they seem poised to do.⁷³ At the FTC Workshop, several participants discussed emerging “hearables” and other sound amplification devices being developed by large consumer electronics firms, including audio equipment manufacturers.⁷⁴ One participant noted the development of products that “have hearing aid functions incorporated into them . . . [that] can be sold at consumer prices,” while noting regulatory barriers that prevent firms from marketing such products to people with hearing loss.⁷⁵ Removing some of those barriers and reducing others should incent further development of such products. And while unregulated personal sound amplification devices (“PSAPs”) represent a heterogenous range of (nonmedical) devices of varying quality, several studies suggest that at least some currently marketed PSAPs can be beneficial for patients with mild or mild-to-moderate hearing loss.⁷⁶

New channels of distribution may be especially helpful for the development and marketing of new low-cost safe and effective hearing aids, not least because relatively low-priced products may appeal to new hearing aid consumers who cannot afford the bundles of hearing aids and services that dominate traditional channels of distribution. In addition, such consumers may benefit from the provision of relatively low-cost follow-up services via internet or telephony, along the lines of the ERTHI services the VA already provides to its audiology patients.⁷⁷

A supply expansion comprising both extant devices made more widely available and new devices may have wider competitive benefits still, as the presence of lower-priced and more convenient alternatives could exert competitive pressure on legacy devices and established channels of distribution. Potential effects include lower prices for some legacy devices and increased availability of unbundled pricing (or more varied bundles).⁷⁸ Without suggesting that any particular product-plus-services bundle is optimal for all hearing aid consumers,⁷⁹ where devices are established as safe and effective, competition within and across bundles and models of distribution may best meet the demands and budget constraints of varied health care consumers.

Streamlined and clarified regulations – and more uniform national regulations – should further serve to lower regulatory costs (and potential liability), expand supply, and, hence, to increase access. Along those lines, we note a specific aspect of the proposed regulatory simplification. Whereas most hearing aids are not, strictly speaking, prescription devices, extant regulations require that a prospective purchaser must either present to a dispenser (vendor) a signed statement of medical evaluation from a physician or, in the alternative, waive the medical evaluation requirement by signing a formal statement with a prescribed advisement.⁸⁰ Extant regulations also require that dispensers retain a copy of the medical evaluation or signed waiver for three years.⁸¹ FDA proposes to strike that requirement for OTC hearing aids and we concur with FDA’s proposal. As the NPRM notes, “[a]fter a review of the literature and relevant clinical databases from the U.S. Department of Defense and the U.S. Department of Veterans Affairs, NASEM [the National Academies] concluded that . . . [the exam or waiver requirement] provides no clinically meaningful benefit, and the waiver presents a barrier to access with no substantial enhancement of patient safety.”⁸² At the very least, striking the waiver and document

retention requirements should reduce regulatory costs imposed upon hearing aid vendors and dispensers.

C. Regulatory Streamlining:

We noted above that the Proposed Rule is likely to reduce regulatory costs for a broad range of hearing aids by clarifying both federal regulations and the interaction between federal and state regulations. As a related matter, we support FDA's proposed rescission of "most of the current regulations codifying previous decisions for exemption . . . for certain States" under 21 CFR Part 808.⁸³ Rescinding those exemptions seems necessary to preserve the preemptive force of FDARA Section 709⁸⁴ and the proposed OTC hearing aid regulations, as most of the exemptions address hearing aid sales and distribution, and as many expressly permit State restrictions that would impede or even bar the sale of OTC hearing aids.⁸⁵

In addition, we note two aspects of the NPRM's treatment of labeling regarding return policies. First FDA proposes "to require that the manufacturer disclose its return policy or, if none, state that it does not accept returns."⁸⁶ Given extant and proposed labeling requirements, this may be a low-cost addition of potential benefit to consumers, as it may provide material information to some consumers and help alleviate confusion regarding return policies for those consumers who expect them, due to either extant state regulations or commercial practices. Second, FDA seeks comment on the question whether a State or local requirement that retailers accept returned OTC hearing aids "would promote, rather than restrict or interfere with, commercial activities involving OTC hearing aids." FDA takes the preliminary position that such requirements would likely promote—rather than restrict or interfere with—commercial activity involving the devices by reducing the financial risk to purchasers.⁸⁷ That may be correct. Staff have no doubt that return policies may be of value to many consumers and, indeed, that some retailers or manufacturers may provide them voluntarily as a non-price means of competition. At the same time, we note that honoring liberal return provisions entails costs; some of these costs may be passed along to consumers. Hence, there is an open question whether some State or local requirements may, however inadvertently, restrict commercial OTC activity more than they enhance it. Staff suggest no alternative approach, but we commend FDA staff for seeking input on this question, and for its proposed attention to the effects of particular requirements going forward.

Conclusion

FTC staff commend FDA for its proposed implementation of Section 709 of FDARA to permit the marketing of OTC hearing aids. We believe that the proposed rule would, if adopted, serve to enhance competition and innovation among hearing aid retailers and manufacturers. Most important, as a result, enhanced competition and innovation will make lower-priced hearing aids available to the millions of American health care

consumers who live with untreated hearing loss. For those reasons, we support the adoption of the Proposed Rule.

¹ These comments reflect the views of FTC staff. They do not necessarily represent the views of the FTC or of any Commissioner; the Commission has, however, voted to authorize staff to submit these comments.

² Establishing Over-the-Counter Hearing Aids, 86 Fed. Reg. 58150 (proposed Oct. 20, 2021) (to be codified at 21 CFR Parts 800, 801, 808, and 874) [hereinafter NPRM].

³ See, e.g., Nat'l Acads. Scis., Engineering, & Med., Hearing Heath Care for Adults: Priorities for Improving Access and Affordability (2016), [hereinafter NASEM].

⁴ See, e.g., Ctrs. for Disease Control (CDC), Vital Signs, Too Loud! For Too Long! (2020), <https://www.cdc.gov/vitalsigns/hearingloss/index.html> (“About 40 million US adults aged 20-69 years have noise-induced hearing loss. More than 1 in 2 US adults with hearing damage from noise do not have noisy jobs.”); Jennifer H. Maddens, Julie D. Weeks, & Nazik Elgaddal, CDC Nat'l Ctr. for Health Stats., Data Brief No. 414 (2021), <https://www.cdc.gov/nchs/products/databriefs/db414.htm>; President's Council of Advisors on Science and Technology, Report to the President: Independence, Technology, and Connection in Old Age (2016), [hereinafter PCAST 2016]; President's Council of Advisors on Science and Technology, Letter Report: Aging America & Hearing Loss: Imperative of Improved Hearing Technologies (2015), [hereinafter PCAST 2015].

⁵ NASEM, *supra* note 3; PCAST 2016, *supra* note 4.

⁶ NPRM, *supra* note 2, at 58151; 115 P.L. 52, 131 Stat. 1005, 2017 Enacted H.R. 2430, 115 Enacted H.R. 2430 [hereinafter FDARA or FDARA Section 709] (pertinent provisions are at Section 709(b)(1)).

⁷ We express no views on the proposed technical requirements, such as the maximum output levels for OTC hearing aids, and for OTC hearing aids that implement input-controlled compression and user-adjustable volume controls. We also express no views on the specific labeling requirements in the draft NPRM, although we note, in broad terms, potential advantages to the proposed clarification of labeling requirements for hearing aids generally, and to the streamlined labeling requirements proposed for OTC hearing aids.

⁸ Federal Trade Commission Act, 15 U.S.C. § 45.

⁹ See, e.g., National Society of Professional Engineers v. United States, 435 U.S. 679, 695 (1978) (“The heart of our national economy long has been faith in the value of competition.”).

¹⁰ See generally, e.g., FED. TR. COMM'N [FTC], FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2021), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_of_ftc_actions_in_health_care_services_and_products.pdf; see also Competition in the Health Care Marketplace: Cases, <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care>.

¹¹ See, e.g., FED. TR. COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Chapter 7 (2004), <https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf>.

¹² FTC and staff advocacy may comprise letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, or reports. *See, e.g.*, FTC Staff Comment to the Dep't Veterans Affairs (VA) Concerning Authority of VA Professionals to Practice Healthcare (2021), <https://www.ftc.gov/policy/advocacy/advocacy-filings/2021/01/ftc-staff-comment-department-veterans-affairs-concerning>.

¹³ FED. TR. COMM'N, THE STRENGTH OF COMPETITION IN THE SALE OF RX CONTACT LENSES: AN FTC STUDY, 45-46 (2005), available at <http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf>.

¹⁴ Advertising of Ophthalmic Goods and Services, Statement of Basis and Purpose and Final Trade Regulation Rule, 43 Fed. Reg. 23,992 (June 2, 1978). The Eyeglass Rule was revised in 1992, with the revisions codified at 16 C.F.R. § 456. FED. TR. COMM'N, 16 C.F.R. § 456, Ophthalmic Practice Rules, 57 Fed. Reg. 18822 (May 1, 1992).

¹⁵ Contact Lens Rule, 69 Fed. Reg. 40482 (July 2, 2004) (Contact Lens Rule) (codified at 16 C.F.R. pts. 315 and 456).

¹⁶ Fairness to Contact Lens Consumers Act, Pub. L. No. 164, 117 Stat. 2024 (codified at 15 U.S.C. §§ 7601-7610 (2003)).

¹⁷ HOWARD P. MARVEL, VERTICAL RESTRAINTS IN THE HEARING AID INDUSTRY, REPORT PREPARED FOR THE FTC'S BUREAU OF COMPETITION (1981).

¹⁸ Fed. Trade Comm'n, Staff Summary of Federal Trade Commission Activities Affecting Older Americans During 1995 and 1996, <https://www.ftc.gov/reports/staff-summary-federal-trade-commission-activities-affecting-older-americans-during-1995-1996> (Describing a 1994 order enforcement action against hearing aid manufacturer Dahlberg, Inc. for making false and unsubstantiated claims and a 1996 case, brought in federal court, alleging that hearing aid manufacturer Telebrands had exaggerated benefits of its hearing aid, in violation of Section 5 of the FTC Act, and had violated the Commission's Mail or Telephone Order Rule, 16 CFR Part 435).

¹⁹ *See, e.g.*, Fed. Trade Comm'n, Ideas for Buying Hearing Aids (2021), <https://www.consumer.ftc.gov/articles/ideas-buying-hearing-aids>.

²⁰ *See* NASEM, *supra* note 3.

²¹ PCAST 2016, *supra* note 4.

²² FTC Workshop: Now Hear This: Competition & Consumer Protection Issues in Hearing Health Care (2017). Links to the workshop agenda, transcript, public comments, and other materials on the workshop web page at <https://www.ftc.gov/news-events/events-calendar/2017/04/now-hear-competition-innovation-consumer-protection-issues>; *see also* Tara Isa Koslov & Daniel J. Gilman, Turning up the Volume on Hearing Care, Fed. Trade Comm'n, Competition Matters Blog Post (2017), <https://www.ftc.gov/news-events/blogs/competition-matters/2017/04/turning-volume-hearing-care>.

²³ *Id.*

²⁴ NASEM, *supra* note 3, at 8 ("The Food and Drug Administration (FDA) should establish a new category of over-the-counter (OTC) wearable hearing devices.")

²⁵ PCAST 2015, *supra* note 4, at 8 (Recommendation 1: FDA should establish a class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser. FDA should also approve for OTC sale, both in stores and on-line, tests appropriate to the self-fitting and adjustment of these OTC devices by the end user.")

²⁶ Potential advantages to an OTC category of hearing aids were discussed throughout the FTC workshop, as well as potential issues regarding implementation. For advantages with regard to price and access, *see, e.g.*, FTC Workshop, Testimony of Frank Lin, pp. 110-111 (noting advantages of OTC category and endorsing "Warren-Grassley" bill that would form basis of FDARA Section 709); Testimony of Jani Johnson, p. 45; Testimony of Stavros Basseas, pp. 46, 58; Testimony of Rupa Balachandran, p. 58.

²⁷ 115 P.L. 52, 131 Stat. 1005, 2017 Enacted H.R. 2430, 115 Enacted H.R. 2430.

²⁸ *Id.* at § 709(b)(1).

²⁹ *Id.* at § 709(b)(2).

³⁰ *Id.* at § 709(b)(2)(d).

³¹ *Id.* at § 709(b)(4) (“No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids . . . through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under this subsection.”)

³² See text accompanying notes 39 - 44, *infra*.

³³ See, e.g., FTC Workshop, Testimony of Frank Lin, p. 107; Testimony of Ian Windmill, p. 109.

³⁴ PCAST 2015, *supra* note 4, at 3.

³⁵ FDARA Section 709(b)(1)-(2).

³⁶ *Id.*

³⁷ *Id.* at Section 709(b)(4).

³⁸ *Id.*

³⁹ Frank R. Lin, et al., *Hearing Loss Prevalence in the United States*, 20 ARCHIVES INTERNAL MED. 171 (2011), doi:10.1001/archinternmed.2011.506 (analyzing national examination survey data and audiometry exams of study participants and estimating 30 million in US with bilateral hearing loss and 48.1 million with unilateral hearing loss).

⁴⁰ See CDC Vital Signs, *supra* note 4; see also Maddens, Weeks, & Elgaddal, *supra* note 4; Frank R. Lin, et al., *supra* note 39; NASEM, *supra* note 3; PCAST 2016, *supra* note 4.

⁴¹ The National Academies Report notes considerable empirical evidence that hearing loss is “associated with diminished physical and psychosocial well-being and overall quality of life, depression, anxiety, low self-esteem, social isolation, stress, mental fatigue, cognitive decline and dementia, reduced mobility, falls, and mortality.” NASEM, *supra* note 3, at 273; see also, e.g., Frank R. Lin, et al., *Hearing Loss and Cognitive Decline in Older Adults*, 173(4) JAMA INTERN. MED. 293 (2013) (hearing loss independently associated with accelerated cognitive decline and incident cognitive impairment in community-dwelling older adults); Frank R. Lin and Luigi Ferrucci, *Hearing Loss and Falls Among Older Adults in the United States*, 172(4) ARCH. INTERN. MED. 369 (2012) (magnitude of the association of hearing loss with falls is clinically significant).

⁴² See, e.g., Larry E. Humes, et al., Effects of Service Delivery Model and Price on Hearing Aid Outcomes, 26 Am. J. Audiology 53 (2017); Robyn M. Cox, Jani A. Johnson, & Jingjing Xu, *Impact of Advanced Hearing Aid Technology on Speech Understanding for Older Listeners with Mild to Moderate, Adult-Onset, Sensorineural Hearing Loss*, 60 GERONTOLOGY 557 (2014).

⁴³ Hearing loss has been associated with diverse effects, ranging from other health conditions, see *supra* note 41, to worker productivity. The National Academies Report notes varied estimates of economic impact based on association of hearing loss with, e.g., reduced productivity and earnings, acknowledging both substantial suggested impact and difficulties associated with establishing causation based on available data. *Id.* at 62-63.

⁴⁴ “Estimates of hearing aid use are that 67 to 86 percent of adults who may benefit from hearing aids do not use them.” NASEM, *supra* note 3, at 1; Wade Chien & Frank R. Lin, *Prevalence of Hearing Aid Use Among Older Adults in the United States*, 172 ARCH. INTERN. MED. 292 (2012) (estimating 22.9 million older Americans with audiometric hearing loss who do not use hearing aids).

⁴⁵ NASEM, *supra* note 3; PCAST 2016, *supra* note 4,

⁴⁶ Alison Gwinn, AARP, 8 Ways to Save Money on Hearing Aids: Don't Let Cost Keep You from Getting the Help You Need (updated Dec. 16, 2021), <https://www.aarp.org/health/conditions-treatments/info-2021/saving-on-hearing-aids.html?intcmp=AE-HEALTH-HEARING-HEARBETTER-SPOT1>

<https://www.aarp.org/health/conditions-treatments/info-2021/saving-on-hearing-aids.html?intcmp=AE->
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[HEALTH-HEARING-HEARBETTER-SPOT1](#); The 2016 National Academies Report observed that the average retail price of a pair of hearing aids in 2013 was \$4,700 (in 2013 dollars). NASEM, *supra* note at 11. Similarly, the 2015 PCAST Letter Report citing a 2014 survey of hearing aid dispensers, notes an average price of \$2,363 per single hearing aid and higher prices for premium models. PCAST 2015 at 1 (citing Karl E. Strom, HR 2013 Hearing Aid Dispenser Survey: Dispensing in the Age of Internet and Big Box Retailers, 21 Hearing Rev. 22 (2014), <https://hearingreview.com/hearing-products/hearing-aids/ite/hr-2013-hearing-aid-dispenser-survey-dispensing-age-internet-big-box-retailers-comparison-present-past-key-business-indicators-dispensing-offices>).

⁴⁷ FTC Workshop, Testimony of Scott Davis, p. 63.

⁴⁸ NASEM, *supra* note 3, at 208 (citing report from VA Office of the Inspector General, 2014).

⁴⁹ FTC Workshop, Testimony of Kim Cavitt, p. 74 (“while I would love to pay what Dr. Beck [VA] and what Mr. Swearingen [Costco] pay for a hearing aid, that is unrealistic in the private sector. We are not offered aids at that price.”)

⁵⁰ Staff have seen no indication that larger buyers obtain hearing aids at below-cost pricing. As the NPRM explains, the proposed rule aims to increase access by reducing barriers to more efficient channels of distribution faced by many consumers, in addition to facilitating entry of new devices.

⁵¹ *Id.*, Testimony of Scott Davis, p. 63.

⁵² The 2015 PCAST Report cites a 2013 survey indicating that over 80% of audiologists use bundled pricing. PCAST 2015, at 3 (citing Karl E. Strom, 2013 Hearing Aid Dispenser Survey: Dispensing in the Age of Internet and Big Box Retailers, 21 HEARING REV. 22 (2014); see also NASEM, *supra* note 3, at 206 (citing Letter to staff for the Committee on Accessible and Affordable Hearing Health Care for Adults, from Kim Cavitt, President, Academy of Doctors of Audiology, Judith Page, President, American Speech-Language-Hearing Association, and Larry Eng, President, American Academy of Audiology. Received August 27, 2015, which suggests slightly more than two thirds use bundled pricing.)

⁵³ See, e.g., NASEM, *supra* note 3, at 209, table 5-1 (comparing retail prices of hearing aids at different outlets, including lower average prices at Costco and Walmart); FTC Workshop, Testimony of Gary Swearingen, pp. 65-6 (regarding Costco pricing and delivery model); Testimony of Scott Davis, p. 73.

⁵⁴ “The prevalence of hearing loss rises steeply with age.” NASEM, *supra* note 3, at 1 (“estimated 45 percent among the 70- to 74-year age group and more than 80 percent in the 85-years-and-older age group.”)

⁵⁵ NASEM, *supra* note 3, at 183; PCAST 2015, *supra* note 4, at 3; FTC Workshop, Testimony of Frank Lin, p. 110; Testimony of Ian Windmill, p. 109.

⁵⁶ *Id.* For example, California law stipulates that a dispensing audiology license is required to sell hearing aids, in addition to state licensure as an audiologist. Cal. Bus. & Prof. Code § 2539.1. It permits selling hearing aids by mail, but only if those hearing aids are sold by California-licensed hearing aid dispensers, only if there is no fitting, adaptation, or selection of the hearing aids, or advice given with respect to fitting, adaptation, or selection, and only upon the seller’s receipt of a signed statement by a California-licensed physician, audiologist, or hearing-aid dispenser. Cal. Bus. & Prof. Code § 2538.23. Under Connecticut law, “No person may engage in the practice of fitting or selling hearing aids, or display a sign or in any other way advertise or claim to be a person who sells or engages in the practice of fitting or selling hearing aids unless such person has obtained a license under this chapter or as an audiologist.” Ct. Gen. Stat § 20-398 (2020). For a listing of various state and local hearing aid requirements exempted from federal preemption, see 21 CFR Part 808(c). The 2015 PCAST Report notes that 14 states prohibit sales by mail. PCAST 2015, *supra* note 4, at 4 (citing American Speech-Language-Hearing-Association. Hearing Aid Dispensing).

⁵⁷ VA Audiology, Enterprise Remote Tuning of Hearing Instruments (ERTHI), <https://www.rehab.va.gov/audiology/>.

⁵⁸ AARP, National Hearing Test, https://www.nationalhearingtest.org/wordpress/?page_id=2730.

⁵⁹ As contemplated in the Proposed Rule, medical care or other ancillary services may be recommended for some hearing health indications; and they may be required for certain higher-risk devices or other interventions, instead of the low-risk Class-I type technologies that would be available as OTC hearing aids.

⁶⁰ PCAST 2015, *supra* note 3, at 3. Workshop participants also noted that consumers may purchase “locked” devices, unaware that they will be restricted in their ability to seek follow-up services. FTC Workshop, Testimony of Barbara Kelly, p. 142; Testimony of Stephanie Czuhajewski, pp. 142-143. Staff do not allege any particular violations of the antitrust laws. Still, we note the potential for anticompetitive effects with certain bundling or “tying” arrangements. See generally, e.g., *U.S. v Microsoft Corp.*, 253 F.3d 34 (D. D.C. 2001) (discussing possible violations under Section 1 and Section 2 of the Sherman Act with regard to the bundling of a computer operating system and a browser).

⁶¹ FTC Workshop, Testimony of Kim Cavitt, p. 62.

⁶² FTC Workshop, Testimony of Lisa McGiffert, p. 141.

⁶³ PCAST 2015 (citing Consumerreports.com, How to Buy a Hearing Aid, CONSUMER REPORTS MAGAZINE (July 2009)).

⁶⁴ NASEM, *supra* note 3, at 219-221 (noting limited price transparency and limited transparency with regard to nature of product/service bundles, as well as literature suggesting benefits to greater transparency); PCAST 2015, *supra* note 4, at 3, FTC Workshop Testimony of Kim Cavitt, p. 62; Testimony of Scott Davis, p. 74; Testimony of Stephanie Czuhajewski, p. 141.

⁶⁵ *Id.*

⁶⁶ Catherine Roberts, Consumer Reports, It's Confusing and Difficult to Shop for Hearing Aids. Here's How to Figure It Out (updated Nov. 16, 2021), <https://www.consumerreports.org/hearing-aids/how-to-shop-for-hearing-aids-a3418587720/>.

⁶⁷ Alison Gwinn, AARP, 8 Ways to Save Money on Hearing Aids: Don't Let Cost Keep You from Getting the Help You Need (updated Dec. 16, 2021), <https://www.aarp.org/health/conditions-treatments/info-2021/saving-on-hearing-aids.html> <https://www.aarp.org/health/conditions-treatments/info-2021/saving-on-hearing-aids.html>.

⁶⁸ See notes 55 - 58, *supra*, and accompanying text; FTC Workshop, Testimony of Frank Lin, p. 107.

⁶⁹ NASEM, *supra* note 3, at 153, 207; see also FTC Workshop, Testimony of Rupa Balachandran, p. 71; Testimony of Scott Davis, p. 72 (noting advantages to specialization as well as limitations). The 2015 PCAST report cites survey evidence finding that 20 percent of retailers carry only one brand, and that, even when multiple brands are available, vendors represent a single brand to 75-80 of their patients. PCAST 2015, *supra* note 4, at 3 (citing Strom, *supra* note 44; Earl E. Johnson, *Survey Explores How Dispensers Use and Choose Their Preferred Hearing Aid Brands*, 60 HEARING JOURNAL 23 (2007)).

⁷⁰ R. M. Cox, et al., *Impact of Advanced Hearing Aid Technology on Speech Understanding for Older Listeners with Mild to Moderate, Adult-onset, Sensorineural Hearing Loss*, 60 GERONTOLOGY 557 (2014); Humes, et al., *supra* note 42, at 77.

⁷¹ NPRM at 58157.

⁷² *Id.* at § 709(b)(2)(d).

⁷³ See, e.g., Frank Fitzpatrick, How FDA's OTC Ruling Will Fuel the Hearables Revolution, Forbes (Oct. 5, 2021), <https://www.forbes.com/sites/frankfitzpatrick/2021/10/25/how-fdas-otc-ruling-will-fuel-the-hearables-revolution/?sh=2e45de0f6a7a> (estimating large potential for “hearables” and OTC Hearing Aids, and noting inroads by audio firms such as Bose and Sennheiser, and by tech firms such as Apple); PCAST 2015, at 7. Some manufacturers have already entered with direct sales, where permitted under state law. See, e.g., Bose Sound Control Hearing Aids (advertisement), https://www.bose.com/en_us/products/headphones/earbuds/soundcontrol-hearing-aids.html?mc=25_PS_SN_BO_00_GO_&gclid=CjwKCAiA5t-OBhByEiwAhR-hm5tjVRyCtKwSPokqjCrmsmOtCv8ePft0hMwqxvvaoyuSvowgCkRuyBoCWIAQAvD_BwE&gclsrc=aw.ds%22%20\l%20%22v=soundcontrol_hearing_aids_gray#v=soundcontrol_hearing_aids_gray.

⁷⁴ FTC Workshop, Testimony of Dianne VanTasell, pp. 21-24; Testimony of KR Liu, p. 149; Testimony of Lucille Beck, p. 70.

⁷⁵ FTC Workshop, Testimony of Dianne VanTasell, p. 24.

⁷⁶ Compare Julia Calderone, *Can PSAPs Help Your Hearing*, Consumer Reports (Feb. 2, 2017), <https://www.consumerreports.org/hearing-ear-care/can-psaps-help-your-hearing/> (some PSAPs can help with mild to moderate hearing loss, although effectiveness can vary across products); Lisa Brody, et al., *A Comparison of Personal Sound Amplification Products and Hearing Aids in Ecologically Relevant Test Environments*, 27 *Am. J. Audiology* 581 (2018) (tested hearing aids outperformed tested PSAPs, but all PSAPs included in study improved speech recognition and listening effort compared to unaided testing); with Adam Voss, et al., *How Do Today's PSAPs Stack Up In Comparison with Traditional Hearing Aids?* *Hearing Rev.* (2018) (testing certain basic and premium hearing aids as well as certain PSAPs and finding comparable results for basic and premium hearing aids, that PSAP performance was "mixed," with some performing well for mild hearing loss but most failing to meet performance targets with more severe hearing loss).

⁷⁷ See *supra* note 57, and accompanying text; see also FTC Workshop, Testimony of Lucille Beck, pp. 70-71, 75-76 (describing the VA's provision of hearing aids and other hearing health care).

⁷⁸ See, e.g., FTC Workshop, Testimony of Kim Cavitt, pp. 72-73 (regarding some emerging practices of unbundling).

⁷⁹ Workshop participants discussed various potential costs and benefits to bundled pricing of hearing aids and services. See, e.g., FTC Workshop, Testimony of Kim Cavitt, pp. 61-63; Testimony of Rupa Balachandran, p. 69.

⁸⁰ 21 CFR § 801.421(a)(1)-(2).

⁸¹ § 801.421(d)).

⁸² NPRM at 51855 (citing NASEM, *supra* note 3, at 98).

⁸³ *Id.* at 51856.

⁸⁴ See *supra* note 31.

⁸⁵ *Id.* at 51854-56.

⁸⁶ *Id.* at 58160.

⁸⁷ *Id.*