

EXECUTIVE OFFICE OF THE PRESIDENT
PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY
WASHINGTON, D.C. 20502

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Dear Mr. President,

Untreated hearing loss, especially in older Americans, is a substantial national problem. Only a fraction of consumers who need assistance with hearing obtain and use hearing aids, in large part because of high cost, complex dispensing procedures, social stigma, and performance shortfalls. While the contributing factors are complex, your President's Council of Advisors on Science and Technology (PCAST) believes that a few simple actions by the Federal Government could dramatically enhance the pace of innovation and level of competition in this domain, leading to rapid decrease in cost and improvement in capability, convenience, and use of assistive hearing devices. We expand on these ideas in this letter report.

We focus here only on devices to assist the tens of millions of Americans with age-related, progressive, mild-to-moderate hearing loss. PCAST recognizes that many Americans have severe hearing impairment or deafness from congenital or illness/injury causes, but we do not address these categories of need here.^a

I. Age-related hearing loss is a substantial national problem.

Age-related hearing loss affects many Americans, with older adults particularly at risk—a quarter of adults between 60 and 69 years, over half in the range 70-79 years, and almost 80 percent of those older than age 80 have difficulty hearing.¹ The absolute number of those affected, already almost 30 million,² is expected to grow as the population ages.

Untreated hearing loss is statistically associated with higher risks of social isolation; depression; dementia; falls with injury; and inability to work, travel, or be physically active.^{3,4,5,6,7,8,9} While the National Institutes of Health is planning a large randomized trial to supplement these correlational findings, the volume of studies, the number of correlations, and their clinical plausibility are indicative of the types of problems that may be avoided with improved hearing. Recognizing the importance of good hearing health, *Healthy People 2020* has set a national goal to increase the use of hearing aids and other assistive devices for hearing.¹⁰

While untreated hearing loss likely impairs physical and cognitive health, only a minority of Americans with hearing loss (perhaps 15-30 percent) seek out and use assistive hearing technologies.^{11,12,13,14,15} Adoption rates are even smaller for people with lower income and for racial and ethnic minorities.^{16,17}

II. The market for hearing aids is characterized by high cost and low innovation.

PCAST believes that cost is the largest barrier to hearing-technology adoption. A 2014 survey found that the average price of one hearing aid was \$2,363, with premium models costing \$2,898.¹⁸ Many, if not most, individuals need two hearing aids, one in each ear, doubling the cost. High costs are a major obstacle

^a The National Academy of Medicine (NAM) is engaged in a much broader study on hearing health care, which is likely to be completed by mid 2016. It is supported by the Food and Drug Administration, Centers for Disease Control and Prevention, Hearing Loss Association of America, National Institute on Aging, National Institute on Deafness and Other Communication Disorders, Department of Defense, and Veterans Affairs. It will aim to address topics including the full range of hearing loss in adults at all ages; third-party payment systems; new delivery models; innovative approaches such as telehealth, mobile health, and team-based care; and specific challenges for select populations.

for many people. One survey found that 64 percent of people with the most serious hearing loss reported that they could not afford a hearing aid, and over 75 percent identified financial factors as a barrier.¹⁹

Most people pay for hearing aids completely out of pocket since traditional Medicare and most private insurance plans do not cover the cost of hearing aids or their fitting. The lack of Medicare coverage is widely cited as a major barrier to access, with one survey finding 50 percent of consumers identifying lack of insurance coverage as a barrier to their acquiring a hearing aid.²⁰ That failure dates from the original 1966 Medicare amendments to the Social Security Act, which bar Medicare from covering hearing aids. Congressional action is required to change this policy, and legislation to do just that has been introduced multiple times by members from both parties. When legislation has been introduced to change this policy, the changes are typically found to be prohibitively costly due to the combination of high cost and large number of consumers in need of hearing aids. This analysis is based on the current high average prices of hearing aids. If market forces were to lower costs, the analysis and potential for Congressional action would change.

Hearing aids have not experienced the dramatic reductions in price and increases in features that have been routinely seen across consumer electronics. When compared in complexity to today's smartphones costing a few hundred dollars each, even premium-model hearing aids are simple devices but can cost several thousand dollars. A 2010 study suggested that a hearing aid's components then cost less than \$100; the number today is likely less.²¹ Innovations in premium models, while real, have been remarkably expensive for the consumer.²²

Compared with other kinds of consumer electronics, the innovation cycle for hearing aids is slow. Features such as Bluetooth and WiFi connectivity or a smartphone app interface, routine in other consumer electronics, command price differentials of as much as \$500-\$1,000 in premium hearing aids. Interestingly, studies suggest that premium and basic hearing aids offer comparable levels of hearing improvement.²³

Beyond today's models, PCAST sees many opportunities for both incremental and disruptive improvements in assistive hearing technologies, none of which should be intrinsically expensive in a competitive market. In the near future, people could check their hearing using automated hearing tests available online or through common smart devices.²⁴ Interfaces between smart devices and users could allow adaptive self-fitting by devices in response to user needs.²⁵ Custom earbuds and configurations could be made routinely by 3D printing.²⁶ Wirelessly integrated with smartphones and other wearable electronics, hearing aids could merge with "hearables" (wearable audio technology discussed below), extending devices such as today's Bluetooth earpieces to become general interfaces to the cyber world. Assistive devices could correspondingly tap into much more computational power, enabling advances such as noise-source identification and cancellation, speech localization and recognition, and auditory (or visual closed-caption) reconstruction.²⁷ Conversations in noisy environments or at a distance across crowded rooms—impossible today even for people with normal hearing—could become convenient and routine. Hearables, as interfaces to cyber-assistance generally, could offer forgotten names (via face recognition), health alerts (Fitbit equivalents), navigational information (indoor and outdoor GPS), and much more.

The hearing-aid industry is highly concentrated and lacks a steady influx of new innovative companies. Following a wave of acquisitions, just six hearing-aid manufacturing companies (mostly based outside of the United States) have been dominant for the past 15 years. In 2012, these six companies accounted for 98 percent of the global market.²⁸ There is considerable evidence that hearing aids can be profitably sold for a fraction of today's end-user cost. The Veterans Health Administration, which accounts for approximately 20 percent of all hearing aids dispensed in the United States, purchases hearing aids from the major manufacturers at a cost of about \$400 per unit.²⁹ Costco now accounts for about 10 percent of all hearing

aids sold, and it sells its house brand (reportedly manufactured by one of the big six manufacturers) for about one-third of the typical retail price, including the cost of fitting.^{30,31} Some Medicare Advantage insurers provide partial hearing-aid coverage; United Health notably uses its own hearing aid manufacturing and dispensing networks, reportedly at costs a small fraction of retail prices.

Cost is not the only barrier to more widespread use of hearing technology. Even in European countries where hearing aids are supplied free or at low cost, adoption rates are not what they should be.^{32,33,34} Social stigma—the association of hearing aids with old age or infirmity—is a barrier. Public education can play a role in expanding use, and the arrival of the Baby Boomers as new seniors with different attitudes, including greater familiarity with wearable electronics and greater use, may shift attitudes toward social acceptance. But, robust technology innovation could also be a potent force for wider use – with the introduction of devices that are simpler, better, and more fashionable.

III. Current distribution channels create barriers to access.

Consumers find it difficult to shop for the best value. Bundling is a common practice in hearing aids, where patients pay a single fee for the professional evaluation, the hearing-aid devices, and follow-up and adjustments of the device after it is fitted and worn for an initial period. In 2014, more than 80 percent of hearing-care professionals used the practice of bundling.³⁵ A *Consumer Reports* analysis found an average markup of 120 percent from the wholesale device price, so that the technology accounts for less than half of the bundled price. Surveys suggest that many people do not use the services included in the bundle, with approximately one-quarter of people never using a follow-up appointment.³⁶ Moreover, with bundling, patients are often locked into the services of one professional and cannot easily shop around or change location.

Complex State regulations restrict the distribution channels for hearing aids. Most States require that hearing aids be sold only by licensed “credentialed dispensers,” typically audiologists; ear, nose, and throat physicians; and licensed hearing-aid specialists. Audiologists and hearing-aid dispensers typically offer a limited selection of brands and models. About 20 percent sell only one brand,³⁷ and surveys find that—even when multiple brands are available—dispensers recommend a single brand to 75-80 percent of their patients.³⁸ In recent years, the big six manufacturers have expanded into retail by purchasing chains of audiologist and dispenser practices,³⁹ while independent dispensers are frequently offered contracts and incentives that favor a single brand.⁴⁰

Vertical integration practices such as these mean that hearing-aid dispensers have a disincentive to selling hearing aids from a wide range of manufacturers. This has inhibited new device designers and manufacturers from releasing competitive devices because they must establish their own dedicated dispensing channels or only sell on-line in States that allow it. As a result of such vertical integration, a person wanting to try out different kinds of hearing aids sees fewer differentiated, innovative devices in the marketplace and must visit multiple hearing-aid dispensers in-person and on-line to sample what is available. The difficulty in obtaining clear information can be a significant burden for a person seeking to buy a hearing aid.

Studies of dispensers have found that average dispensing rates of various hearing-aid features do not follow evidence-based practice (EBP) guidelines, and that dispenser preference has a bigger influence on the brand recommended than the needs of the patient population served by that dispenser.⁴¹ A different study of hearing-aid dispensers found that they did not heavily use peer-reviewed research in recommending a particular brand of hearing aid, relying instead on information from manufacturers (and presumably distribution agreements).⁴² Findings like these suggest that vertical integration reduces consumer choice.

In addition to regulating the professions that may dispense hearing aids, some States prohibit mail and Internet orders outright or allow them only after a prior in-person sale.⁴³ There are limited statistics on the percentage of hearing aids distributed by mail or online, but the most recent statistics available (from 2008) suggest that less than five percent are distributed by mail.⁴⁴ A recent analysis suggests that approximately 14 States have some type of restrictions on mail order or Internet sales.⁴⁵ These State legal restrictions further limit consumer choice and the ability to comparison shop. We note that some of the State regulations on hearing aids may be pre-empted by regulations of the Food and Drug Administration (FDA). A Federal appellate court has recently overturned one State's law for this reason.⁴⁶

In addition to consumers not being able to find the best value, it is unclear how well these distribution arrangements are helping consumers find hearing aids that improve their hearing. For example, as many as 12 to 18 percent of the 3 million hearing aids sold in the United States each year may end up not being used,⁴⁷ and a *Consumer Reports* study in 2009 suggested that two-thirds of hearing aids were misfit.⁴⁸ There are many reasons for these poor experiences, including that current hearing aids may require practice and time in use to achieve maximum effectiveness; the devices often do not restore normal hearing as fully as people expect; or there are physical challenges managing the devices for those with arthritis or limited dexterity.⁴⁹ Because there are many ways to help consumers adapt, and innovation can drive greater usability, PCAST finds that today's distribution and dispensing models are inadequate, especially to meet future needs.

IV. Modest changes in FDA regulation could dramatically increase accessibility and innovation for tens of millions of Americans, without compromising patient safety.

FDA's current regulatory framework involves two fundamental types of devices, which are differentiated by their intended use (see the appendix for more information):

The FDA defines a Personal Sound Amplification Product (PSAP) as a wearable consumer electronic product that is intended for non-hearing-impaired consumers to amplify sounds in certain environments "such as for recreational activities." A PSAP must not be "intended to compensate for impaired hearing"—that describes a hearing aid. Because PSAPs are "not intended to treat, cure, or mitigate disease and do not alter the structure or function of the body," the FDA forbears from asserting any regulatory authority over them, except incidentally under the Radiation Control for Health and Safety Act of 1968 (which applies to all sound amplification equipment and, among other things, seeks to ensure that there are volume limits to prevent ear damage).^{50,51}

The FDA defines a hearing aid as "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing." (21 CFR 801.420) All hearing aids must comply with specific requirements regarding patient and professional labeling identified in 21 CFR 801.420.... Additionally, all hearing aids must comply with the required conditions for sale, as stated in 21 CFR 801.421." Current FDA regulations for hearing aids impose requirements on both consumers and manufacturers, as follows.

(A) FDA requires that consumers undergo a medical evaluation before they can purchase any type of hearing aid.

With the evaluation requirement instituted in the 1970s, FDA regulations sought to have users evaluated by a physician to ensure the hearing aid would treat the underlying causes of the hearing loss, although it allowed consumers to waive the requirement of a medical evaluation by simply signing a form. Today a majority of people waive that requirement; several sources suggesting that between 60 and 85 percent of patients now forgo the medical evaluation.⁵² While encouraging patients to seek medical evaluation is a

laudable goal, it is important to weigh the benefit of such a requirement in terms of the frequency and severity of the conditions that are likely to be detected against the risks and costs that result from greater barriers to obtaining assistance for mild-to-moderate hearing loss among tens of millions of aging Americans.

FDA, for example, has noted that hearing loss in some patients might be caused by acoustic neuroma, a benign tumor arising from the lining of the vestibular nerve. However, this cause is extremely rare. Acoustic neuroma has an incidence of only 1 in 90,000 individuals⁵³ and is associated with unilateral, rather than bilateral, hearing loss, as well as other symptoms such as dizziness and headache. By contrast, the incidence of glaucoma in North America is 3.54 percent,⁵⁴ but this has not prevented reading glasses from being sold over the counter.

Ear wax is another often-cited issue. A consumer might mistakenly purchase a hearing aid when simple ear-wax removal at a clinic or local drugstore might be all that is needed.^{55,56,57} A comparison to vision is again useful. Over 35 percent of adults age 70-74 age have cataracts that will not be mitigated by eye-glasses. Even so, older adults are not prevented from “mistakenly” purchasing over-the-counter reading glasses. Individuals are expected to check with an eye professional when they suspect vision loss from another cause.

More generally, concern has been expressed that sudden or unilateral onset of hearing loss could indicate other problems for which patients might seek medical evaluation. While there are anecdotal reports of rare, serious conditions being found during the required medical evaluation or examination by a hearing aid professional, such reports do not address the question of whether the affected patients would have instead sought treatment anyway through conventional medical channels, nor are these reports statistically adequate for estimating the actual frequency of such rare cases. Carrying through with the vision analogy, there are frequent occurrences of sudden or unilateral visual impairment due to retinal tears, retinal vein or artery occlusion, or ocular tumors, but those incidences have not prevented the marketing of easy to access over-the-counter (OTC) or commercial vision enhancement for people who need it. Patients are trusted to seek emergency medical help in the case of sudden and unusual visual events.

PCAST concludes that Americans would be better served if non-surgical air-conduction devices intended to address bilateral, gradual-onset, mild-to-moderate age-related hearing loss (referred to here as “basic” hearing aids) were available over-the-counter. Such devices meet the criteria for OTC sale, which is appropriate when consumers are able to self-diagnose, self-treat, and self-manage a disease or condition. For such devices, the requirement for a medical examination (or a written waiver of such examination) provides little patient benefit, while acting as a barrier to access for the millions of Americans needing hearing assistance. FDA could require such devices to carry a warning about “red flag” symptoms of conditions for which medical attention should be sought, while continuing to require medical examination for hearing aids that do not qualify as “basic.” Simple hearing tests to aid consumers in purchasing such OTC hearing aids should also be available OTC, including on-line and in stores.

FDA’s regulation of “basic” hearing aids, then, should be similar to FDA’s regulation of reading glasses, which are also classified as “medical devices.” In making some hearing aids and tests available as OTC products, FDA should preempt State requirements that the OTC devices be sold by credentialed dispensers. While this approach would lead to changes in the business models of many audiologists and hearing-aid dispensers, PCAST believes that the net benefit to the public would be large and positive. The analogy with vision is again useful. While complex eye cases require prescription medical devices and professional dispensing, people are able to treat a wide array of uncomplicated conditions with OTC technology. In

these cases, consumers can judge whether the device meets their need, and, if it does not, they can visit a professional to obtain a more advanced device, as well as comparison shop.

With respect to hearing aids not deemed appropriate for OTC sales, PCAST believes that new actions by the Federal Trade Commission (FTC) are needed to increase consumer choice, promoting competition that benefits both price and innovation. The Federal Trade Commission's "Eyeglass Rule" (16 CFR Par 456), dating from 1978, ended bundling practices by ophthalmologists and opticians, requiring them to give consumers a portable copy of their refraction prescriptions. By the Fairness to Contact Lens Consumers Act (PL 108-164), Congress gave FTC authority to ensure that contact lenses could readily be purchased by mail, phone, or (today) the Internet, independent of State regulations that restricted who was allowed to dispense. Analogous actions, which may also benefit from new legislative authority, are needed for assistive hearing devices.

(B) FDA also places requirements on manufacturers of air-conduction hearing aids.

Air-conduction hearing aids are classified as Class I medical devices (FDA's least-regulated category). Class I medical devices are exempt from any requirement for premarket notification to FDA and do not require FDA clearance before marketing. Their manufacturers are required, however, to maintain an annual registration with FDA (at a cost of several thousand dollars) and to register their devices at the time that they are first marketed. More importantly, air-conduction hearing aids are *not* exempted from FDA's Quality System Regulation (QSR), nor from its record-keeping and complaint-process regulations.

While this regulatory framework is appropriate for a wide range of medical products under FDA's regulatory authority, there are narrow cases when even such apparently light regulation turns out to have large negative unintended consequences. Most air-conduction hearing aids represent such a case.

FDA's QSR (often referred to as "good manufacturing practices" or GMP), even at its least cumbersome form (Inspection Level 1, Abbreviated), mandates a system of documentation of production and process controls (P&PC) and corrective and preventive actions (CAPA) by manufacturers.⁵⁸ QSR seeks to assure product quality by assuring that controllable design and manufacturing processes exist and are followed. This makes sense for things like pharmaceuticals and medical devices, for which a design or manufacturing failure can lead to patient harm. In other areas (including some kinds of software apps for smartphones), such regulation may not be burdensome.

For hearing aids needed for age-related hearing loss, however, an inherent failure of the product to perform does not provide an increased health risk to the user. Furthermore, the QSR/GPM fundamentally conflicts with the nature of the consumer-electronics industry. The consumer-electronics industry's fast innovation cycles for both design and manufacturing processes can lead rapidly to increased performance and lower cost. Volume production and open consumer preference are strong feedback mechanisms to drive product performance and manufacturing quality. In short, the consumer electronics industry focuses on product rather than process.

PCAST's assessment is that QSR and related regulatory requirements on documentation are more stringent than necessary. Instead, FDA could foster innovation by using quality standards appropriate to the nature of the devices and compatible with broadly accepted industry approaches towards quality management in the consumer electronics industry. Such standards could be developed in conjunction with the Consumer Electronics Association (CEA), which is currently developing standards and performance measurements according to features and quality for PSAPs.

It is important to emphasize that PCAST does not favor weakening FDA's overall regulatory framework for medical devices. Indeed, each device area needs to be considered in the context of the relative risks

and benefits to consumers. Our concerns here are focused on the special circumstances concerning non-surgical air-conduction devices intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss – where regulations have been largely unchanged since 1976; where dramatic advances in consumer electronics have transformed audio products; where the medical risks are extremely low; and where the needs of tens of millions of Americans are not being adequately met by the existing market.

V. Personal Sound Amplification Devices illustrate the negative consequences of the barriers to competition in the hearing aid market and its current regulatory regime.

The FDA, as described above, largely forbears from asserting regulatory authority over PSAPs. But the distinction between a PSAP and a hearing aid (which is based on “intended use” rather than actual performance) is not clear, and there are many people with mild hearing impairment who can benefit from amplification by headphones and other devices, including PSAPs. PSAPs are improving and can be helpful to people with hearing loss, something that has been noted by several experts and organizations.⁵⁹ The regulatory distinction between PSAPs and hearing aids has led to an unproductive and escalating exchange between PSAP vendors and the FDA over the wording of product labels and advertisements for PSAPs. The sometimes tortured legalisms that result have the effect of confusing the consumer, who deserves access to accurate information.

The artificial distinction between PSAPs and hearing aids has also led to a natural experiment that shows what could be possible with a more open market: more innovation, at lower cost, is occurring in the less-regulated PSAP market. Companies ranging from established consumer electronics manufacturers to small startups are today developing innovative new PSAPs. “Hearables” can combine multiple functions (from listening to music to accessing calendar appointments), coordinate with other technologies (such as smartphones), and record health information and vital signs. Using technology similar, if not identical, to that in hearing aids, PSAPs can improve the clarity of sound, for example in situations with a lot of environmental noise. Some PSAPs are fashionably designed as “bling” in bright or metallic colors, a far cry from beige plastic hearing aids. At the same time, PSAPs are marketed at much lower price points than hearing aids. A *Consumer Reports* analysis found that behind-the-ear PSAP models range from \$25-\$500, while in-ear PSAP models may cost in the range of \$400.⁶⁰ In some cases, companies have marketed similar devices as a PSAP (under one model name) and as a hearing aid (under another model name and at a higher price).

Since the publication of the 1977 FDA rules, there have been several appeals to FDA (most notably in 1993 and 2000) by innovative technology developers and consumer groups to take actions that would open the market to more competition. No significant changes have been made.

On the contrary, the FDA’s recent draft regulatory guidance on PSAPs moves in the wrong direction. In 2013, FDA greatly extended its 2009 regulatory guidance by issuing draft guidance that, if finalized, would have the effect of forbidding PSAPs from making truthful claims about capabilities like providing assistance in “situations in which environmental noise might interfere with speech intelligibility” or “difficulty understanding conversations in crowded rooms.” The 2013 draft guidance defines the mention of such capabilities in advertising or labeling as evidence that the PSAP is actually a hearing aid. Under such a definition, innovative products addressing such scenarios could not be marketed *even to people with normal hearing, which is clearly allowed under the 2009 guidance*. The situations described in the 2013 draft guidance do not refer to medical conditions, but rather to issues related to normal human perception. PSAPs should be broadly defined as devices for discretionary consumer use that are intended to augment,

improve, or extend the sense of hearing in individuals. FDA should continue its current practice of forbearing from regulating PSAPs, except incidentally (as under the Radiation Control for Health and Safety Act of 1968).

PCAST finds the 2013 draft guidance on PSAPs is unsupportable by the facts and should be withdrawn. After presentations by a number of potential market innovators, PCAST assesses that the existence of this guidance *even in draft* has created concerns over the scope of FDA's regulatory authority and the future of the PSAP business model.

VI. PCAST's Recommendations

Hearing loss is a substantial national problem. Cost is the largest barrier to hearing technology adoption by more people who need it, but technological shortfalls are also a significant barrier. Consumers are limited in their ability to shop for the best value, due to bundling and State restrictions on who is licensed to sell hearing aids.

The Federal Government has immediate opportunities to open up the hearing technology market to lower cost and increased innovation. The FDA is a critical actor as it tries to balance its important responsibility to protect the public from unsafe drugs and medical devices with the rapidly changing world of consumer electronics, such as wearables and biometrics, that are empowering consumers to find the solutions to their needs in the innovative technology market. The FTC also has an important role to play. We believe the following actions would greatly serve the public interest.

PCAST makes the following recommendations:

Open up the market for innovative hearing technologies

Recommendation 1. FDA should designate as a distinct category ("basic" hearing aids) non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss and adopt distinct rules for such devices.

(a) FDA should approve this 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. Such hearing treatments and tests meet the FDA requirements for OTC products, which are that consumers should be able to self-diagnose, self-treat, and self-monitor the condition.

(b) FDA should exempt this class of hearing aids from QSR regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer-electronics industry, developed by an appropriate third-party organization and approved by FDA. Similar actions should be taken with respect to diagnostic hearing tests used to dispense and fit Class I hearing aids.

Recommendation 2. FDA should withdraw its draft guidance of November 7, 2013 on Personal Sound Amplification Products (PSAPs). PSAPs should be broadly defined as devices for discretionary consumer use that are intended to augment, improve, or extend the sense of hearing in individuals. PSAP manufacturers should continue to be able to make truthful claims about their use in normal settings. FDA should not require language in PSAP labeling or advertising that excludes their use by individuals with age-related hearing loss no worse than mild-to-moderate.

Increase opportunities for consumer choice

Recommendation 3. Analogously to its “Eyeglass Rule,” FTC should require audiologists and hearing-aid dispensers who perform standard diagnostic hearing tests and hearing aid fittings to provide the customer with a copy of their audiogram and the programmable audio profile for a hearing aid at no additional cost and in a form that can be used by other dispensers and by hearing-aid vendors. Also analogously, the availability of a hearing test and fitting must not be conditioned on any agreement to purchase goods or additional services from the provider of the test.

Recommendation 4. Similarly in effect to its “Contact Lens Rule,” FTC should define a process by which patients may authorize hearing-aid vendors (in-state or out-of-state) to obtain a copy of their hearing test results and programmable audio profile from any audiologist or hearing-aid dispenser who performs such a test, and it should require that the testers furnish such results at no additional cost. While FTC has the authority to issue new regulations of this sort, action can be accelerated and strengthened by legislative direction. We urge the Administration to work with Congress to initiate bipartisan legislation that would instruct FTC to issue a rule for hearing aids and PSAPs similar to the eyeglass and contact lens rules.

In summary, PCAST finds that the costs and risks of inaction with respect to untreated hearing loss in the aging U.S. population are large. PCAST finds that the unnecessarily high price of hearing aids for individuals and the conspicuously slow pace of innovation by their manufacturers compared with other consumer electronics are consequences of a concentrated and increasingly vertically integrated incumbent industry, operating in the context of longstanding Federal and State regulations that appear to discourage potential new entrants. PCAST recommends specific actions by FDA and FTC that would have the effect of opening up the market for innovative hearing technologies and increasing opportunities for consumer choice.

Sincerely,

The President’s Council of Advisors on Science and Technology

APPENDIX

Excerpt from FDA's *Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products* (2009) relevant to Class I air-conduction hearing aids and PSAPs.⁴⁷

1. Introduction

...Hearing aids and [personal sound amplification products] (PSAPs) both affect our ability to hear sound, but the products have different intended uses, and are therefore subject to different regulatory controls.

A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. A PSAP is a wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in the environment for a number of reasons, such as for recreational activities. While some of the technology and function of hearing aids and PSAPs may be similar, the intended use of each article determines whether it is a device or an electronic product. The intended use may be established by labeling materials. Promotional materials that make claims or suggest the use of a PSAP for hearing impaired consumers, such as in the description of the types and severity of hearing loss, establish an intended use that causes the product to be a device and therefore subject to the regulatory requirements for a hearing aid device, as described in this guidance...

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited...

2. Hearing Aids

The regulations define a hearing aid as "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing." (21 CFR 801.420)... All hearing aids must comply with specific requirements regarding patient and professional labeling identified in 21 CFR 801.420.... Additionally, all hearing aids must comply with the required conditions for sale, as stated in 21 CFR 801.421.... Finally, the hearing aid dispenser must retain records of all medical evaluation statements and waivers for a period of three years after dispensing of the hearing aid. These regulatory conditions for sale were established to encourage prospective users to receive proper medical evaluation and treatment for treatable causes of hearing loss...

3. Personal Sound Amplification Products (PSAPs)

PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. They are not intended to compensate for hearing impairment. Examples of situations in which PSAPs typically are used include hunting (listening for prey), bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations, performances). Because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not devices as defined in the Food, Drug and Cosmetic Act. As such, there is no regulatory classification, product code, or definition for these products. Furthermore, there are no requirements for registration of manufacturers and listing of these products with FDA...

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