most, individuals need two hearing aids, one in each ear, doubling the cost. High costs are a major obstacle 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

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 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 manufac-

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 betwe

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

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

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