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Aging America & Hearing Loss: Imperative of Improved Hearing Technologies



October 2015

PCAST Hearing Study Scope

- Part of broader PCAST examination of aging and technology
- PCAST recognized timely opportunity to support older adults with mild to moderate hearing loss
- Children, adults with severe hearing loss, and those with red flag conditions were outside the scope of this study



PCAST Aging and Technology Study Full Working Group

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Hearing Loss: Major Problem for Older Adults

- Major health and social problem
 - 30 million have difficulty hearing now
 - Hearing loss associated with social isolation, inability to get around safely, dementia, falls, depression, and other issues
- Growing importance with aging population
 - Nearly half of people over age 60 have hearing loss
 - Number of older Americans will rise from 46 to 82 million between 2014 and 2040
- Few adults with hearing loss use hearing aids
 - Only ~15-30% of older adults with hearing loss use hearing aids



Cost Major Barrier to Use of Hearing Technologies

- High cost (~\$2400 per hearing aid)
- Most people pay out of pocket
 - Medicare and many insurers do not cover it
- Innovation has not reduced cost



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Other Barriers to Wider Use of Hearing Technologies

- Difficult for consumers to shop for best value
 - Challenges include bundling, complex state regulations, limited distribution agreements, and restrictions on online shopping
- Social stigma
- Lack of engagement by health providers



PCAST Study Scope

- Technology solutions for a major public health problem
- Administrative actions that could accelerate improvement in access, innovation and outcomes



Conclusion: Problem Ripe for Change

- Focus on mild to moderate, age related, bilateral hearing loss in adults
- New technology advancing rapidly
- PCAST believes a few key Federal actions now could give momentum to needed changes



Conclusions

- Untreated hearing loss of tens of millions of Americans is a greater challenge than small risk of unusual medical conditions
 - Current regulations do not identify those problems or stimulate demand for medical screening.
- Now an opportunity to increase access to better, cheaper technology for mild to moderate hearing loss, like reading glasses
 - And bring more people into the hearing health system



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PCAST Goals for Recommendations

- Reduce cost to consumers
- Increase the number of people who use hearing technology
- Stimulate innovation and technology development



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PCAST Study Recommendations



PCAST Recommendations

Open the Market

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.



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PCAST Recommendations

Open the Market

Recommendation 2. FDA should withdraw its draft guidance of November 7, 2013 on Personal Sound Amplification Devices (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.



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PCAST Recommendations

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 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.



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PCAST Recommendations

Consumer Choice

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.



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Summary

- Untreated hearing loss is a major health and social problem
- Consumers have difficulty accessing hearing technologies because of hearing aid costs and limited ability to shop for best value
- PCAST analysis finds a few key changes in Federal regulations could accelerate consumer access without increasing risk



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