

## **EOP: October 23<sup>rd</sup> PCAST Call**

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### **SPEAKERS**

Dr. John Holdren  
Dr. Eric Lander  
Dr. Chris Cassel

### **PRESENTATION**

Moderator: Ladies and gentlemen, thank you for standing by and welcome to the October 23<sup>rd</sup> PCAST Call. At this time all lines are in a listen-only mode. (Operator instructions.) And as a reminder, today's conference call is being recorded.

I would now like to turn the conference over to John Holdren. Please go ahead.

John Holdren: Thank you very much. This is John Holdren, Assistant to the President for Science and Technology and Co-Chair of the President's Council of Advisors on Science and Technology. I want to welcome everybody to this conference call meeting of PCAST, which will be focused on the PCAST study entitled "Aging America and Hearing Loss: Imperative for Improved Hearing Technologies." And with that, I am going to turn the floor over to my PCAST Co-chair Dr. Eric Lander. Eric?

Eric Lander: Yes, thank you very much, John. I want to thank the members of PCAST, the members of the public who have joined us for this telephonic meeting of PCAST today. We're going to begin our meeting with the opportunity for public comment. One individual has signed up for public comment, and it is our practice to encourage the public to make comments and to provide two minutes to make those comments. I'll let you know when we've reached the 90-second point and there's 30 second left.

We have with us today Mr. Alex Crowley from the National Hearing Test in Bloomington, Indiana. Can we confirm that Mr. Crowley is on the line?

Moderator: And yes, he is on the line, and Mr. Crowley, your line is open.

Eric Lander: Please go ahead, Mr. Crowley.

Alex Crowley: My name is Alex Crowley, speaking on behalf of Charles Watson, Professor Emeritus at Indiana University and principal investigator with the National Hearing Test. People delay an average of eight to ten years before seeking help for their hearing. It's called denial, and it's part why nearly 20 million Americans with hearing loss have never been tested, especially seniors, people in rural communities, and people in lower economic brackets. An NIH working group recognized that what is needed is a convenient, inexpensive or free self administered trustworthy screening test. A telephone administered screening test was developed in the Netherlands and accomplished this goal 11 years ago.

Versions of that test are now available without charge in nearly every western industrialized country, except the US. The US version of the Dutch test, the National Hearing Test, was developed in 2011 with funding from the NIH and validated in studies at Indiana University and at three hearing centers operated by the Veterans Administration. During a one-month trial in 2014 with minimal promotion, more than 30,000 people took the National Hearing Test, and 81% had significant loss in at least one ear. These were not curiosity seekers.

The strong appeal of the test appears to depend on its being convenient, valid, without commercial ties, and its results are entirely confidential. Follow-up studies have shown that those who fail a screening test are more likely to seek services. The question now is how the test can be made freely and widely available in the US. The price tag is approximately \$1 million.

Eric Lander: Thirty second remaining.

Alex Crowley: Depending on usage. The annual economic impact of untreated hearing loss is said to be between \$50 billion and \$100 billion nationally. The

scope of the National Hearing Test's benefit to the country and return on investment make it a worthwhile program for government to support. This is not a problem in need of a research solution. It is a problem that research has solved, and the solution can be delivered across ubiquitous technology. This test could for a very small cost lead to improved quality of life for millions of US citizens.

Eric Lander: Thank you very much. We really appreciate you're joining us and providing that comment.

Very good. So, in fact, very much related to this topic, the next order of business on this PCAST meeting call is the report on technology and hearing that PCAST has been engaged in for some time. At our last PCAST meeting and public session, we discussed the progress on that report and received a description from PCAST member Chris Cassel about where that study was. The preliminary conclusions were shared, and we're now at the point, I understand, where Chris and her working group have a report that they wish to present for approval to PCAST, and we would on this call have Chris now present about the report. We'll turn to PCAST members for questions, and then we will be in a position to vote to approve this report if PCAST so decides.

So, I'm going to turn it over to my colleague, Chris Cassel, to lead us through.

Chris Cassel: Thank you, Eric, and the PCAST members will be familiar with most of this, so I think we can go through it fairly quickly. For the public members who are dialing in, the slides are available on the PCAST website.

So, the scope of this study I want to point out is part of a larger study that PCAST is doing on ways that technology can help us all function better and be healthier as we age, but we recognize the timely opportunity to look specifically at the hearing issue, and that's what this letter report is aimed to do. People need to be clear that this is intended to address the problem of age-related mild to moderate bilateral hearing loss, the most common cause of hearing problems in the country and does not include the hearing loss that occurs in children or adults with very severe hearing

loss or with red flag conditions such as unilateral or other symptoms that go along with it.

I want to turn to the slide that shows my coach here, Ed Penhoet, and thank Ed, who's on the call for his support and participation and leadership throughout the process. And you can see there a number of PCAST members who are part of the technology group and also the wonderful staff of PCAST, but I particularly want to recognize Ashley Predith, who has put in an enormous amount of wonderful work and support into this report.

So, moving on. The background, as actually we just heard from our public comment is that hearing loss is a major problem for older people in the United States. Somewhere around 30 million people have difficulty hearing now, and it's associated with social isolation, with worsening dementia, with falls, with depression. And increasingly as people are healthier as they age and they can and want to or need to continue working, it's a major barrier for people staying active in the workforce as well, so there's a whole lot of reasons why there's huge both social and health-related impact to hearing loss.

In people over the age of 60, nearly half of people have some kind of hearing loss, and that number as we all are looking forward to living long, the number of people who suffer from this problem is only going to grow to between 46 million and 82 million people between 2014 and 2040. And right now very, very few people even seek help or get help for their hearing loss, roughly 15% to 30% depending on what numbers you use, and even that's hard to tell because it is so widely underreported.

So, the next slide is what are the major barriers? Why aren't people seeking help for this condition? There are number of them. The major one that PCAST found though is the high cost, and we hear this all the time that if the average cost is \$2,400 per hearing aid, most people need two, and that's average, so many of them cost much, much more and Medicare and most insurance companies don't cover this fully. Medicare doesn't cover it at all, so most people pay out of pocket. And innovation, unlike other areas of electronics and scientific progress in electronics, innovation has not driven the cost down.

Other barriers, if you go to the next slide, include that it's complicated; it's difficult for consumers to shop for the best value that you have to go to a special dispensary to link in to one kind of hearing aid or another kind of hearing aid. It's not easy or even possible sometimes to do it online, and there's not a sort of an easy access that's private and simple to just ask a basic question do I need a hearing aid or not.

And that adds to the fact that there still is unfortunately social stigma about this problem and therefore limited consumer awareness. People just don't want to think about it, and similarly, health providers aren't engaged. Even primary care physicians who care for elderly patients, it's not usually part of the routine wellness exam for elders, in part because it's off in this sequestered area unto itself.

So, if you look to our conclusions from this, we've concluded that this is a problem that is really ripe for change. There are actually, there are lots of advances in technology that ought to be able to drive the cost down and make these devices more adaptable and more available. And we believe that just a few key federal actions could really give momentum to the needed changes. We want to acknowledge that the regulatory approach that FDA has been using, which dates for about 40 years ago, is focused on identifying unusual causes of hearing loss that might have serious consequences and that need to see a doctor and be treatable other ways. And we acknowledge that those things do exist, but they are so relatively uncommon and their presentation is usually very different than this gradual onset kind of mild hearing loss that is the norm in age-related hearing loss that we think consumers could easily tell the difference and could be able to self-identify when they need to see a doctor.

So, we think that this is a perfect opportunity as in many other areas of consumer health products to increase access to better, cheaper technology much like people do with reading glasses. If they just need a reading connection as they age and they need reading glasses, as long as it's a mild impairment, you can go to the local drug store and try out glasses and get one that works for you.

So, if you turn then to the recommendations, think about our goals for these recommendation. First is to reduce cost. The second is the increase the number of people who use this technology. The third is stimulate and [audio disruption]. So, turning then to the first recommendation in the category of opening the market, we are recommending that FDA should create a new, distinct category for basic hearing aids that would be able to be sold over the counter.

These would be non-surgical air conduction hearing aids intended to address bilateral gradual onset, mild to moderate age-related hearing loss. This over the counter class of hearing aids would not require consultation with a credentialed dispenser, and consumers would also be able to get both in stores and online tests that are appropriate to the self [audio disruption] adjustment. I would remind PCAST that the criteria that FDA uses for over-the-counter products are that consumers should be able to self-diagnose, self-treat, and self-monitor the condition, and we believe that this condition fills all three of those.

The second part of that is that FDA should exempt this class of hearing aids from the quality systems with new regulation in its present form that it uses for medical devices and substitute instead compliance with standards that are appropriate to the consumer electronics industry, which has a very different sort of manufacturing process and allow appropriate third-party organizations to develop standards that would be approved by the FDA. And again, similar actions could be taken with respect to the diagnostic hearing test.

If we go to recommendation two, recommendation two has to do with PSAPs, personal sound amplification products. This one category of devices that might be made available in this over-the-counter mode, and we're recommending that PCAST should withdraw a draft guidance that was issued in November of 2013 about PSAPs and instead broadly define PSAPs as devices for discretionary consumer use that are intended to augment, improve, and extend the sense of hearing in individuals.

Basically PSAPs are personal amplification devices that are used in a range of situations, and the PSAP manufacturers should be able to label and market their products to say that people who need mild amplification

might be helped by this and make those available to people who are willing to try them out. All of them have policies where you can return it if it doesn't work, people can try it out at home, etc.

If you turn to recommendation number three, we now turn to the consumer choice portion of the recommendations. The first one of these recommendation number three is again with the analogy of eye glasses. FTC, in parallel to the eye glass rule, should require audiologists and hearing aid dispensers who perform these standard diagnostic hearing tests and fittings to provide the customer with a copy of their audiogram programmable audio profile at no additional cost after they've had the exam, so then they can shop around and go to whatever vendor they want and get the best product for them.

And then recommendation number four is also a parallel for the Federal Trade Commission contact lens rule, and basically we think that FTC should define a process by which patients can authorize the hearing aid vendors, and this is important, either in state or out of state to obtain a copy of their hearing test results, so that when you're going to another vendor or another provider that person can access the results and be able to provide in a cost effective way the services that you need.

I do want to point out that FTC has the authority to issue regulations like this, but of course that would also be very much helped and accelerated by legislative direction should the Congress want to make such a recommendation as well.

So, in summary, we think that the risks of continuing down the road we're on of having so many millions of people who do not or cannot get hearing aids is just unacceptable to having a vibrant and active aging population. The major barriers, we believe, are cost and the limited ability to shop for best value, so these few changes which are within the federal capability we think could go a long way towards addressing this problem.

So, Eric, I'm going to turn this back over to you.

Eric Lander:

Chris, thank you so much for that very clear presentation, and thank you and your colleagues for the leadership of this group and all the members

of the group. So, at this time, we've gotten to hear from Chris. The slides that you have notionally shown by making available on the web or just show them on the phone call here, are available to everyone.

I'm going to open the floor to questions from PCAST. Our usual pattern is for people to raise their flags around the table, but that's going to be inconvenient, so I'm just going to suggest that PCAST members jump in and ask to be recognized.

Michael McQuade: Hi, Eric. It's Michael.

Eric Lander: Go right ahead, Mike.

Michael McQuade: Sure, Michael McWade. Chris, a question for you, can you just say a few more words about how quickly the FTC could move to implement or what other guidance or approvals they might want from a legislative point of view?

Chris Cassel: FTC has the authority, Michael, to do this. We've talked with them, and actually that's how—but they don't in this day and age generally unless there's a strong pressure from Congress or some constituent group, they generally don't initiate that action, so I think some message from Congress would definitely be helpful in accelerating this process. And this is definitely a [audio disruption] issue and one that comes up often because so many elected representatives do have constituents who struggle with this problem.

Michael McQuade: Okay, thank you.

Eric Lander: Other questions? Anyone else from PCAST? That's fine. Can I just ask just for a clarifying question? I think it's clear from what you said, but my understanding is that this category of basic hearing aid is not for everyone. It's useful for a very large number of people, but there are people for whom this isn't the solution, and so you're not saying that all hearing aids should be over the counter.

Chris Cassel: That's right, Eric, any more than we think all eye glasses should be over the counter. If you have a either very severe hearing loss or just a sudden

onset, there's a kind of a list of red flag conditions that could be posted in every place where these devices are manufactured. FDA has done a very nice job of pulling those together. If you have a headache, if you have dizziness, if it's just on one side, if it's happened very suddenly, then those are the red flag conditions, and then you should definitely see your doctor. So, it's for people who just have this insidious slow onset very mild hearing loss. And, you know, the products are such that if they don't work for you, then you can always seek professional help.

Eric Lander: Right. Look, that's great. Are there any other questions? I'm not surprised there are not, because, of course, we've discussed this extensively including most recently in our most recent public session, so I feel comfortable in calling the question. I'm going to ask all PCAST members, we know who's on the line, so just all PCAST members, when I ask for yay votes to just indicate, and then I'll ask if there are any opposed.

All PCAST members in favor of approving this report?

All Aye.

Eric Lander: Are there any opposed? Are there any abstentions? Hearing none, the report is unanimously approved. Our next step is to make sure that it is carefully reviewed for typos and other things. It goes through some copy editing, but I am optimistic that the text of the report should be available for release next week.

So, with that, I want to thank everyone on PCAST who's worked on this, those who have joined for the public meeting today by phone, members of the public who have joined listening, and this is of course recorded and available later, and our public commenter, Mr. Crowley.

I don't believe there's any other business, and so, John, unless you have anything you'd like to add, I would like to declare us adjourned.

John Holdren: I can only add my thanks to everybody and particularly to Chris and Ed who led this study, but also to all who contributed.

Eric Lander: We are adjourned.

John Holdren: We are adjourned.

Eric Lander: Thank you.

Moderator: Thank you. Ladies and gentlemen, that does conclude your conference call for today. Thank you for your participation and for using AT&T Executive TeleConference Service. You may now disconnect.