PANEL 4: INFORMING CONSUMER CHOICE IN HEARING HEALTH CARE

Panelists:

- **Stephanie Czuhajewski, Executive Director, Academy of Doctors of Audiology**
- **Barbara Kelley, Executive Director, Hearing Loss Association of America**
- **K.R. Liu, Director, Accessibility & Advocacy, Doppler Labs**
- **Lisa McGiffert, Director, Safe Patient Project, Consumers Union**
- **Carole Rogin, President, Hearing Industries Association & Better Hearing Institute**

Moderators:

- **Gerald Stein, Bureau of Competition, New York Regional Office, Federal Trade Commission**
- **Daniel H. Wood, Bureau of Economics, Federal Trade Commission**

DANIEL WOOD: Hello, I'm Daniel Wood, and I'm pleased to introduce my co-moderator Gerald Stein.

In this panel, we're going to focus on the consumer decision making in hearing health care. So, what the consumers know or learn as they engage in the process of purchasing a hearing aid and having it fit, what the consumers need to know in order to make appropriate decisions.

We're hoping there will be a lively discussion between our knowledgeable panelists about these issues. Gerald is going to introduce them.

GERALD STEIN: Since last panel was all men, we figured we would have all women. And I'm pleased to introduce our panel. Our panel is also going to be slightly different than the other ones. Like the prior panel, we're not doing the little intros, but we're also not directing questions. We're going to have just a free for all. We'll introduce topics, and our panelists will engage in conversation about them.

So I'd like to introduce our panelists.

Sitting next to Dan is Stephanie Czuhajewski. I knew I was going to screw that up. Stephanie Czuhajewski. Stephanie is the executive director of the Academy of Doctors of Audiology, ADA, a leading national association representing autonomous audiologists who are committed to best business and clinical practices. Ms. Czuhajewski has two

decades of nonprofit leadership experience, with a focus on outreach and stakeholder relations.

Next is Barbara Kelley. Barbara is the executive director of the Hearing Loss Association of America, otherwise known as HLAA, a consumer organization whose mission is to open the world of communication to people with hearing loss through information, education, advocacy, and support. Their national headquarters is in Bethesda, Maryland, and they have state organizations and local chapters across the country.

Next is Kristen "KR" Liu. She's the Director of Advocacy and Accessibility at Doppler Labs. KR leads the advocacy and accessibility at Doppler Labs. She has been a technology executive for over two decades. Diagnosed with severe hearing loss at the age of three, KR has made it her life's work to be a strong advocate and voice championing new products that enhance the way we hear the world.

Next is Lisa McGiffert. Lisa directs Consumer Reports' Safe Patient Project, which works on state and federal policies to end medical harm, including medical device safety. Consumer Reports recently updated its hearing and buying guide and included, for the first time, tests of several PSAPs available to consumers over the counter.

Last, but not least, is Carole Rogin. Carole is the president of the Hearing Industries Association and its consumer information and education arm, the Better Hearing Institute. The members of her association are the 17 hearing aid and components manufacturing companies that produce over 90% of the hearing aids dispensed in the United States on an annual basis and support MarkeTrak, the highly referenced longitudinal survey of people with hearing impairments in the United States.

And without further ado, I'll turn it back to Dan.

DANIEL WOOD: OK. Well, this morning in the delivery panel, Kim Cavitt said something like, the road to hearing evaluation is treacherous. Lisa, could you start us off by explaining some of the difficulties at sort of the beginning of this road?

LISA MCGIFFERT: Yes, thank you. So I feel like we need to talk about a few things related to how people pay. You know, it's all tied up with pay. So insurance often determines how people enter into this market, and a lot of people just go to their primary care doctor, which we've heard about. Some people have access to specialists.

But generally—we did a survey and I'm going to be talking a lot about a survey that Consumer Reports did of our subscribers. Our subscribers are generally higher income, higher educated. It's not a randomly selected group, representative group. But we did this survey of a significant number of people, I think 130,000 people, and about 20,000 of them had bought hearing aids. So I'm going to be talking about this.

About 60% of those that we surveyed that had hearing aids said nothing was covered. Their aids were not covered by the insurance coverage. I don't think we parsed that out separately, but I think that this is definitely an issue that has been raised over and over about how people access the diagnosis and where they go to get care.

And I might say that we looked at what reasons—there were a significant number of people who had hearing loss, reported hearing loss, who had not gotten a hearing aid, and we asked that group why they didn't. And we found that the highest reasons for those with hearing problems that didn't get an aid were, my hearing loss was not severe enough, that was 57%, and 34% said, I only have trouble hearing in certain situations. So cost was not at the top of the list.

So I think there is sort of an issue with people determining whether they do have significant hearing loss or not. Some others might want to weigh in on that.

GERALD STEIN: Carole?

CAROLE ROGIN: I'd like to just reinforce the information that Lisa just provided from her survey, and also put our survey, MarkeTrak, on the table.

I think most of you here know that we have been conducting a demographically balanced, highly projectable survey of the beliefs, attitudes, and behaviors of people with hearing loss in America, for over 35 years. We tend to do the survey every four to

five years. And one of the things that has not changed over that time is exactly what Lisa just said.

Where I don't mean to diminish cost as a consideration in people's acquisition of hearing health care, the two primary reasons that people with hearing loss tell us that they have not yet tried hearing aids are because they believe—for their lives, their hearing loss is not severe enough yet. And they don't have problems in a sufficient number of situations.

So I think this afternoon, if we can close our discussion today, which I think has been very, very valuable, with a consideration of the kinds of information and the delivery channels for that information that consumers need, we will do a real service to ourselves—all of us who are committed to what my organizations have been committed to, which is first and foremost, raising the importance of hearing in the hierarchy of health concerns in the United States, and secondly, increasing the numbers of people with hearing loss in America who benefit from hearing aid use.

GERALD STEIN: Steph? Did you want to—

STEPHANIE CZUHAJEWSKI: Sure. Thank you.

In addition to that statement, I know that there have also been significant studies done around stigma. And I think we have to recognize that stigma is really a formidable adversary.

Cost is certainly a factor. Stigma is also a huge factor. I believe Dr. Weinstein and Dr. Blustein conducted—They wrote an article in 2016 where they cited data that showed that half of people who would benefit from a hearing aid and don't have one, don't have one because of stigma.

GERALD STEIN: And Barbara, do you want to add to that?

BARBARA KELLEY: Yes, and thank you for inviting me, because I feel like I represent the boots on the ground consumer. We've heard some great speakers today, but I feel it's all come from a very paternalistic point of view, maybe.

So we have to hear what the consumers think. And it might be anecdotal evidence, but I've been with HLAA for 29 years, and since day one, we at least have two inquiries, phone calls, emails a day, and we've had up to eight, consistently of people saying, I can't afford hearing aids. I need some help.

It might be a little piece of plastic and it might be a device, but the majority of people can't afford it. And, you know, why can't we have a competitive marketplace for hearing aids? And I think we here in Washington DC, we forget that even the Costco price, which is lower and wonderful, it's a very non-threatening environment—$1600 is still not a line item in most people's budget.

Cost is a factor, and I just think there are no two ways around it. And people aren't getting help because of cost. And also when they think of buying a hearing aid, they might be thinking of a traditional type of hearing aid.

And I've talked with some people in a certain age group who are talking about, I don't need a hearing aid, but at a certain price point, I sure might like some hearing enhancement from time to time. So I think that plays into stigma. And I also addressed the cost.

[APPLAUSE]

LISA MCGIFFERT: I want to follow up on the cost issue, because 25% did say cost—of the big group—I can't afford it, afraid that I'm going to be pressured to pay a lot of money for a product. But when we looked at the people who did buy hearing aids, and we asked them some questions, 70% waited two years or more before they got a hearing aid, and half of those waited five years, and among that group, the most common reason for waiting was cost.

So I really didn't want to diminish the cost factor, because it is a great one when consumers get to the point where they really know they need something, they may not move forward if there's not an affordable product for them to choose.

GERALD STEIN: We have a question from the audience regarding insurance reimbursement and how that works, and whether or not—and we're going to get to OTC later—but whether if hearing aids are available over-the-counter, how that might change or how might that complicate, if at all, the situation?

LISA MCGIFFERT: Well, I don't think—I think that it might complicate it for a small minority, but most people don't have insurance coverage for the full array of services, whether it be to buy the hearing aid or to get an audiologist test or to even see a specialist, if they decide to do that. So, you know, those are real barriers without insurance coverage, and these are pretty costly. I have a really good insurance plan with my organization, and they paid a small amount of my hearing aid cost. So the rest of it is out of pocket, and I know most people don't have that kind of coverage.

STEPHANIE CZUHAJEWSKI: And if I could just jump in here. Cost is an absolutely irrefutable barrier to care, both in terms of insurance coverage and also just, with or without it, the cost of the device itself, but also the services to be provided. So what we're seeing is—you've seen at least seven federal agencies over the past couple of years taking steps to address this. We've also had significant numbers of legislation and bills in Congress trying to address this, both from the device standpoint, but also from the service side of the equation.

As we sit here today, Medicare Part B does not cover audiological rehabilitative services when they're provided by an audiologist. As we sit here today, for a patient to have Medicare Part B coverage, the audiologist and the patient has to get an order from a physician in order to go to the audiologist. In this day and age, where the FDA has now come out and said—and there's been a lot of agreement around the fact that there is no clinical benefit to the medical evaluation prior to seeking treatment directly from the audiologist, there is no reason why this should continue going forward.

So in as much as the cost of the device is an issue, so too are the costs of the services. We've done a fantastic job. The research areas—medicine, everybody's done a great job in early intervention in children, and we have seen the outcomes from that

based on how they've improved in their functionality. We must do the same thing for adults.

GERALD STEIN: And one of the other topics we wanted to talk about, and I think this provides a natural movement to that, is the role of audiologists and dispensers and what role they play, as well as other hearing care professionals, if you can comment on that.

STEPHANIE CZUHAJEWSKI: Sure. So audiologists and hearing aid dispensers are responsible for dispensing of about 90% of all hearing aids in the United States currently. They both play a very important role in those services, but their role is very different. So hearing aid dispensers are focused really around the device itself, evaluation of hearing for the purpose of fitting a device, device fitting, helping for the selection of the device, efficacy of the device, and so on.

The audiologist really has a longer role on that continuum, if you will, in that they are responsible for all of the diagnostic evaluations, communication needs assessment, all of the rehabilitative services that come after the device is fitted. So the best way that I can describe the differences, maybe, is that along that ideological continuum, the audiologist plays a role the entire way, where the hearing aid dispenser is on certain points in that continuum around the fitting of a hearing aid and that construct there.

What we have seen is that there are a lot of consumers who are extremely confused about the differences between audiologists and hearing aid dispensers. And some of that, frankly, is the industry's terminology around hearing health professional, which while it may be a convenient catchall for us to use, it really does sort of help form some of that confusion within the consumer community as they're attempting to try to select one provider or another.

What does that really mean? Is it a dispenser? Is it an audiologist? Is it an otolaryngologist? It really depends on the context when we use that term as to who we might be talking about. And then additionally there have been sort of some

unscrupulous practices for hearing dispensing that will sometimes use the word audiology in the name of their practice. And so the consumers become confused about, well, is that provider an audiologist or not? This has happened so frequently that there is now a term called "fraudiology" or "fraudiologists" that is sometimes used to describe people who will intentionally attempt to fool the public by tricking them into believing that they have an audiologist on staff when they don't.

GERALD STEIN: Barbara did you want to—

BARBARA KELLEY: Lucille Beck was talking about patient-centered care, and the whole trend today is a very well informed person coming to make choices on behalf of herself about her health care. There is so much confusion for the consumer about how to enter into the hearing health care system. Their primary doctors don't even know how to deal with it. They're often told, oh, you have hearing loss. It's part of aging. Learn to live with it. Because they really don't have an answer.

So there's no way for the person to even take control of their health care. They are very much at the mercy of the gatekeepers along the way. And it's incredibly confusing. The terminology is confusing. Dr. Windmill was talking about the words "mild-to-moderate" hearing loss. That means nothing to the consumer. All they know is I'm having trouble hearing around the dinner table, or something like that. So I don't know how we can have people take charge of their own hearing health care if we don't clear up this mess and offer some choices.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: I would just add that we also found a lot of confusion about the professionals, and most people were very satisfied with the audiologist or dispenser. And we had 87% of our surveyed people who went to seek care, said they visited an audiologist, but when we looked at who they visited, they were mostly vendors that don't hire audiologists, so that indicated a great deal of confusion.

We also, in 2009, we followed some people who bought hearing aids, and we had a separate audiologist check them for quality of fit. And there were 48 hearing aids

involved, and of those, two-thirds of them were a misfit, when looked at by a second audiologist expert. And they were either amplified too great or too little.

And so we did really find some concerns about the quality of the care, even though most people were very happy and satisfied with their audiologist, and the information from the audiologist was one of the highest influences on which hearing aid they selected.

DANIEL WOOD: Carole?

CAROLE ROGIN: Let me just comment on a few of the observations here. First of all, Stephanie's observation that we are confusing people by calling professionals "hearing care professionals." I want to share with everyone the fact that the users in MarkeTrak who talk about their satisfaction with their hearing aids, are above 80% of our users. In fact, 81% of the hearing aid users in MarkeTrak say that they are satisfied or highly satisfied with their hearing aids.

And, in fact, for those users who had hearing aids that were one-year-old or newer, that satisfaction rate jumps up above 90%, which I think, sitting here at the FTC, we have to agree even if we aren't reaching enough people with hearing loss, those that we are reaching, we are reaching very well. And there are other factors in satisfaction and the way that we're delivering hearing health care right now, that work for people who can get into the system.

So I just want to make sure that as we solve the problem, the very real problem, of not reaching enough people, we don't damage what's working really well for consumers. Our research indicates that people search for their hearing care professional in exactly the same way that they search for other hearing—or other health care professionals. They ask friends. They ask family. They do ask their family physician, because they know that their ears are attached to their bodies, and they view it as a medical condition.

And in a lot of qualitative work with physicians in the '90s, we learned that unfortunately general practice physicians know the same thing that most consumers

know about hearing health care. They know it from the same sources, and it is unfortunately very little.

So I think that when we're looking at this, we really need to make sure that the information that we want to change is the information that consumers need us to change and that we do it in a way that provides greater simplicity and clarity, rather than more and different terms that people need to learn.

GERALD STEIN: So you referenced MarkeTrak a couple times, and I've gotten a couple of questions. Is that study available?

CAROLE ROGIN: Yes.

GERALD STEIN: I've gotten a couple questions as to whether it's publicly available and people can access it.

CAROLE ROGIN: It absolutely is. All of the historical MarkeTraks dating back to an initial survey in 1981 are available at betterhearing.org, BHI's website. And the review of the MarkeTrak IX findings—they are the most extensive review of those findings, is also available.

GERALD STEIN: OK. Thank you.

DANIEL WOOD: Carole, you said that people tend to find their health care professional by word of mouth. Are there other sources people use? Is the web now used extensively?

CAROLE ROGIN: It's interesting. We looked in MarkeTrak IX at what people do before they make that first visit to a hearing care professional. And we found that, interestingly enough, although people go to that first visit to learn—they go to learn and get tested—is what MarkeTrak tells us—they don't do a lot of investigation before that first visit. Only 35% of our survey respondents with hearing loss who don't own hearing aids say that they did any investigation before they had their first appointment. But of those 35%, 66% of them told us that they went first to the Internet.

So just for fun the other day, I've been kind of tracking it, and about two days ago, if you Google "hearing aids," there were close to 12 million entries on the Internet. I think that anyone who is looking for information uses that as a sign to be a little more discrete in what they're looking for. But I think that there is a lot of information out there for people to at least get started learning. And consumers, as Barbara said, are taking a wonderful, an increased responsibility for all of their health care. People know how to evaluate information. And I think that the more we can put out there, the more people are going to be looking.

If I can just provide a little bit of insight into consumer behavior from our statistics at betterhearing.org. We had in just this past year a 50% increase in the visitors to our site. Additionally, the time that they spent on this site increased almost 50%, and very importantly, the numbers of those visitors who used the BHI hearing check to see if they perhaps ought to get a professional evaluation also increased 50%, and what I would say is that the efforts of the National Academy of Sciences, NIDCD, FDA, today FTC, over the past three years, and all of the organizations who are in this room, have shed a very bright light on hearing health care that I think has been very beneficial to consumers.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: Yeah I would just add that when people go on the Internet, we need to look at the kind of information that's available. And there really isn't much out there that compares products, that gives them information about what kind of situation this product would be better than another, or quality of the products.

And when we know that most people are choosing that product based on their audiologist's recommendation—and audiologists, like Carole said, you know, they get information, just like the rest of the health care system—they get it from the manufacturers, you know, just like drug companies give doctors information about drugs. The manufacturers of hearing aids are probably the major source for providers in getting their information.

So it's not exactly unbiased, and we really need a more unbiased evaluation system of these products that people can use when they make their choices.

GERALD STEIN: Stephanie?

STEPHANIE CZUHAJEWSKI: I agree with that wholeheartedly. When looking for comparative analysis on the Internet for products and services, it's very difficult to find information that is not manufacturer driven or in some way biased. Hearing Tracker is a site that I know a lot of consumers do use, and we have found it to be reputable. It's managed by an audiologist.

I believe that he's got a policy where the provider and the manufacturer cannot basically buy their way into ratings on that particular list. I know there are probably others out there, but they are very difficult to find. And a lot of times the names of the sites are a little bit tricky. There are some that look a lot like Consumer Reports, that in fact are being—driving people to a particular segment of either the provider community or a particular type of hearing aid.

BARBARA KELLEY: We get that question all the time. They need help finding an audiologist. We often point them to Hearing Tracker, or we point them to one of our local chapters so they can talk to people in the chapter to find out who they've used. Some audiologists are listed on Yelp. But there really is no clear information on comparing features. We also get the question, what's the best hearing aid? And years ago, I tried to dig into that and do a real comparison of different hearing aids, and at the end I was really still confused with no clear answer, as well as created more consumer confusion.

GERALD STEIN: Well, I'm glad you said that because I'm an antitrust guy, and when I started looking at this industry, the one thing that piqued my curiosity is how do consumers compare for quality, and how do consumers compare based on price. It seems to me, from the outside—I mean, two months ago I knew nothing about this industry. But when I started looking at it, it seemed the only way that people or consumers could do this is to actually go to the audiologist, sit through an exam, be

given the choices, and either take those choices, or go through an entire new exam with someone else.

I was wondering if you guys can talk about that process? How do consumers choose? How do they make informed decisions? What do they do? Anyone? Carole ?

CAROLE ROGIN: They do exactly what they do, as I said before, with other medical conditions. I mean, if you need a hip replacement, how do you compare and contrast? You visit a couple of orthopedic surgeons. Our data indicates that people who purchase hearing aids visit at least two hearing care professionals before they make that purchase. You listen to the professionals that you go to. You ask them what brand of hip replacement they use. You look that up on the Internet. And I think that people with hearing loss who are looking for a comparative experience, have the opportunity, and in fact, do the same thing.

GERALD STEIN: But I guess a big difference in my mind would be the hip replacement might be covered under some insurance. And so if you're going in-network versus out-of-network, you can make that choice as a consumer, whereas you don't have that option for hearing aids.

CAROLE ROGIN: Absolutely. You know the cost issue is different, although influenced by—or influences the decision making. But I think when we're talking about the decision making, how do you decide which professional to visit, what kind of technology to explore, we have to recognize that, at least at the current time, this is a medical device addressing a medical condition.

And in fact, I think Stephanie mentioned this before, maybe Barbara as well, when we look at satisfaction rates for hearing aid owners and ask them what feeds into that, the single most important element of their satisfaction is their hearing care professional.

GERALD STEIN: KR, Did you want to jump in?

KR LIU: Yeah, I think recommendations also come from consumers talking to each other who are experiencing a similar issue, and their satisfaction with the product that they would recommend. Then they usually ask for a recommendation of their audiologist, and then get an opinion.

But I actually think more feedback comes from consumers themselves in talking to one another about what their experience has been with certain hearing aids, and if they're happy with it. And if it's providing them what their needs are.

So I think that's really important, that it is word of mouth network. We do all talk to each other, as far as what product we think might be beneficial when compared to the other.

GERALD STEIN: Steph?

STEPHANIE CZUHAJEWSKI: I think I would just add that finding good pricing comparisons is very difficult for consumers, and it's also very difficult for independent audiologists. So they struggle a great deal in trying to determine if they can negotiate basically a fair price from the manufacturing community.

And that has resulted actually in a lot of them joining various buying groups. And through the buying groups, some have had more success than others in being able to at least negotiate or look across some of the various brands in a more holistic way.

But it is very much a challenge. And it's something that I think will continue to be, unless or until we're able to sort of, maybe bring more competition in a marketplace that's transparent.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: I would just say that when we looked, when we asked for consumer satisfaction in our survey, we didn't find any significant difference between the brands, the makers of the hearing aids. But we did find some differences in the retailers.

And most of that difference was connected to the evaluations that the retailers provided, the discussions and options, the staff. And very much the service. That service part was what set a couple of the higher rated retailers apart from the rest of them.

DANIEL WOOD: Barbara?

BARBARA KELLEY: The service is critical, because you don't necessarily get information from the manufacturers about some very practical things, like telecoil use in large area systems. Everything is to Bluetooth, which is great, but there is some latency if you use that with speech reading and your residual hearing at the same time.

The other thing is you might not get a hearing aid compatible rating, because cell phones have to be hearing aid compatible. If I buy a hearing aid, I want to know if it's going to work with my cell phone.

But I do agree, I think that people who have the good care of a hearing health care professional, whether it's an audiologist, or a dispenser, or a hearing instrument specialist, and they get really good needs assessment, they are satisfied.

But they have to be able to afford that hearing aid in the first place. And there are so many more people who can't afford that good care. And they deserve it.

DANIEL WOOD: We've heard about high prices. Just to turn it around a little bit, in certain markets, if you pay more for something, it actually provides better quality. If I pay $50,000 for a car, I know I'm getting a different experience than if I paid $10,000. To what extent is price a useful signal of quality in hearing aid hardware?

STEPHANIE CZUHAJEWSKI: I would say that Dr. Johnson's presentation this morning did a really good job in covering some of that. So what we have found is that there is not necessarily a correlation in terms of high price and outcomes. And there is more and more data that's being made available at this point that does allow researchers at least to compare across, although that data is still limited.

DANIEL WOOD: How about pricing for audiological services?

STEPHANIE CZUHAJEWSKI: I think, again, there's a limited amount of data, but one can expect that in going to an audiologist that they—actually HLAA has a fantastic resource that consumers can download that gives them the information, minimally, that they should expect through that process. And it has some really good prompts about questions that they can ask along the way to ensure that they're sort of—that that service is meeting the expectations of the consumer community.

But there should be the expectation by the consumer that the more intense the services are, and the more complex the needs are, that those prices would be higher. I know there has been some recent work done by Dr. Brian Taylor, and I think Dr. Windmill did some work as well, in looking at how to segment consumer needs by complex cases versus simple cases and being able to price those accordingly.

I think as we look at the future and the potential of over-the-counter devices—and really, we're kind of late to the table even talking about over-the-counter, because probably you're going to be able to bring your own hardware potentially, and you're going to have some sort of a subscription. Or your hearing aid may just be ubiquitous basically. So at that point it's going to come all down to the provision of the high quality services. And I think we'll have to look at different mechanisms and different models than what we're using today to sort of put people into the appropriate categories for care.

DANIEL WOOD: Barbara?

BARBARA KELLEY: The higher end, more expensive hearing aids, probably do provide more features, but it comes down to then the care. Does a person really need all those features? And are they going to use them? And I think Dr. Lin wrote an article that talked about those premium features have been around for a long time in hearing aids, yet the cost hasn't come down. And I'm sorry if I misattributed him, but I think that's who wrote it.

So there hasn't been any price decrease like there has been in cell phones and other technologies that have disrupted the market. And really there's no way for a

consumer to really compare prices, because the manufacturer's customer is the audiologist and the hearing aid specialists, and then that person has bundled prices within there. So it's just really confusing to compare apples to apples.

DANIEL WOOD: OK. Well, shall we turn to bundling?

GERALD STEIN: Well, I just want to address a question that we got from the audience. And we touched earlier on the notion that basically the only way a consumer can comparison shop based on price is to go to an exam, get fitted, get a quote. And then go to another exam, get fitted, and get a quote.

The question here is, does the restocking fee, for those instances where a consumer might have to pay a restocking fee, is that going to inhibit the ability for consumers to comparison shop? So, in other words, it's going to cost now, in addition to time, it's going to cost out of pocket money for a consumer to go from one to another. Do you guys have any views on that?

STEPHANIE CZUHAJEWSKI: I think that that is potentially an issue. Certainly that varies by state. And not to throw HLAA out there too much again, but they have another fantastic resource that consumers can download that actually outlines state by state what those basically return fees are, if that should happen, and how much money the consumer can expect to get back in different states. So at least they have that going in.

But it can be a challenge if you have to go from provider to provider. There are some mechanisms online to get a ballpark. I think most audiologists, if you went in and could start talking about the range before you're ever fitted with a hearing aid, they're going to be able to provide you with some of that information so that you have a decent understanding of where you are before you would be in a position to have to pay that fitting fee or restocking fee.

DANIEL WOOD: So we've heard about this issue of bundling and al a carte prices, itemized prices versus bundled prices, in the delivery panel and other panels this morning. To what extent do you think consumers understand the pricing model and know what they're paying for when they purchase a hearing aid?

BARBARA KELLEY: I think very few consumers understand it. I think if you're really astute and know what questions to ask—but I think it's very confusing.

Some people like a bundled model. That's great. They don't want to ever think about paying another dime, and they want to go back as many times as they can for adjustments. But I think other people would like a situation for pay-as-you-go and have a choice in how they want to deal with their own hearing loss. But I think it's confusing.

LISA MCGIFFERT: Our survey showed that most people didn't go back for more than two visits. So it wasn't like they kept going back and going back. I think in the bundling situation, it probably does help the person who is really needy and needs to have a lot of adjustments and has problems adjusting.

But for most people, it's probably not. They probably don't get the full value of the bundle.

GERALD STEIN: Related to that question from the audience, is there a correlation between lower-cost hearing aids and an increased amount of having to go back for service? In other words, is the—lower end hearing aid, does it require more visits to get tuned? Is there any correlation between visits and the quality of the hearing aid?

CAROLE ROGIN: There is no correlation.

GERALD STEIN: We all agree on that? Wow, we have agreement.

LISA MCGIFFERT: So one of the issues that we're not really talking about is value. And you can't really get to value, unless you have price and quality. And the fact is that this market doesn't have much out there for quality.

And also there's not much diversity in the market in terms of quality and consumer satisfaction. So we really do need to have more competition to get to determining different values of these products.

DANIEL WOOD: So pricing is often, sometimes problematic. What other business practices are consumers confused by in this industry?

STEPHANIE CZUHAJEWSKI: I can speak from ADA's perspective, from the audiology perspective. To us it's all about transparency. So if the consumer is not aware that the practice is owned by a manufacturer and the employees there are employed by the manufacturer. If there are manufacturer loans perhaps, or agreements where the dispenser is going to buy a certain number of units from a manufacturer, and the consumer is not aware of that, and it may somehow lead to bias in terms of what products are recommended for a patient, that's problematic.

We've looked at things like commissions for audiologists. I mean, we're dispensing medical devices here. And so is it ethical to pay on commission for somebody who is dispensing a medical device like that? So things around sort of the incentivization, if you will, that might lead somebody to choose one product over a different product based on money that they may be getting.

DANIEL WOOD: Barbara?

BARBARA KELLEY: I think there are also some issues, I think, sometimes you might get a copy of your audiogram and sometimes you might not. Or if you buy your hearing aid in one state and you move to Florida, that program for adjusting your hearing aid might be locked with that certain manufacturer. So you'll either go to a new person to get it adjusted and they can't do it, or it's going to cost a lot, or you have to start with new hearing aids. That's a problem.

DANIEL WOOD: And consumers are not informed of this, this locking before, when they buy this device originally?

BARBARA KELLEY: I don't know. Stephanie?

STEPHANIE CZUHAJEWSKI: Very seldom does that happen. A lot of times it may be a franchise or a particular brand. At the point where they're dispensed the consumer is not notified that the device is locked in some way and then if they try to seek another provider, they can have some significant challenges.

GERALD STEIN: Even a provider that services this same brand hearing aid?

STEPHANIE CZUHAJEWSKI: Not typically, no. It really depends a lot of times, as I said, if it's a franchise type arrangement, they can go from provider to provider within a franchise, and they'd be able to do that. But oftentimes they are not informed at the point of purchase.

So again, it's about transparency. If the consumer knows going in that that's the expectation, and that's the way it will be, great. If they're not informed, that's really where the problems come in.

GERALD STEIN: So, is it a best practice of an audiologist when they're getting to know the patient and saying, well, how are you going to live in your daily life? Is it to ask an elderly person, well, do you spend six months in Florida and six months in New York? Is that a question they should ask?

STEPHANIE CZUHAJEWSKI: Audiologists conduct a comprehensive needs assessment most of the time. You know, if they're doing it the right way, they're doing this for every single patient. And yes, as part of that they are talking to them extensively about their lifestyle, their family support, things like their dexterity, cognitive abilities. What settings are they going to be using the hearing aid in? I mean, it's a very lengthy process actually, and yes, as part of that, the expectation would be that they would ask.

Oftentimes we get on our Listserv requests from audiologists for other audiologists in another state. So I have a patient that's in Florida six months out of a year, can you recommend an audiologist so that we can have a cohesive care plan for this patient.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: I'd like to interject some age issues here. Because I think—my experience getting a hearing aid before I was 50, was that everything was kind of targeted towards older people who were much older than I was. And I think a lot of the advertising, a lot of the drawing in of patients, a lot of paying attention to what people are experiencing, there is this layer of, oh, this is a product for elders.

And I think that one of the things that we found that I thought was pretty interesting, and I'm trying to find the stat—well, I'll find it—but a good number of the people we surveyed who said they had hearing loss were under the age of 39, so there are—And we all know, this is our environment, our world. there are a lot of young people who have lost hearing. This market—what I hear all the time is it's a small market, and the market's not very big. Well, that's because the market doesn't fit the needs of the people. And I think that that is a real problem that we're facing here and that needs to be addressed. I'll let KR talk about that.

KR LIU: Yes I would love to talk about that, Lisa. I agree with her. A lot of advertising that you see out there shows people who are older or retired, right? It doesn't resonate with the younger demographic. The younger demographic in their 20s and 30s now are experiencing hearing loss and are being more vocal about it.

They're also the ones that are helping their parents and their grandparents make the decision as to what hearing aids they should get, because they're the ones telling them, you can't hear me as well as you used to. You should do something about that. So we have a lot of influence in that decision making process.

We also are looking for products that speak to our generation, that fit our lifestyle. And we're a very large demographic. I consider our generation the iPod generation, where we're wearing earbuds in our ears that are 144Db for six hours a day, every day.

We're losing our hearing even sooner than we used to. And that's a large, large demographic. And the World Health Organization released a report that said 1.1 billion young adults are at risk of hearing loss. And I believe this generation wants to do something about it. But there's no marketing, no petitioning, and no part of that speaking to us, to have us address that issue, so we're just not. And I think that's a big issue and that's something that needs to change.

LISA MCGIFFERT: So 39% of our surveyed population were between the ages of 18 and 29 that reported having hearing loss. A lot.

DANIEL WOOD: I don't think we would be the FTC if we didn't ask at least a little bit about advertising. So in many markets, advertising does provide information. What sort of advertising goes on in this, in hearing health care, and who are the ads targeted to, and are they useful? Entertaining? Barbara?

BARBARA KELLEY: Well, we've seen ads that use scare tactics, especially where there are concentrations of older people. Because they'll take the link with cognitive and dementia with untreated hearing loss and they'll put it together. And they'll say things like, prevent dementia. Get a hearing aid. And using scare tactics like that. A tactic that I recently was very surprised at, is—I personally like WebMD. I use it as my medical go-to very often, before I go to the doctor.

And they had something on hearing loss and they made you go through a hearing test. Of course, I took it because I wanted to see what happened. And then at the end of the hearing test—I purposely failed it—I wanted to see what they would tell me to do. And it immediately went to a manufacturer of hearing aids. No choice, no nothing. It was one of the big six manufacturers.

DANIEL WOOD: KR?

KR LIU: Yes, I'd also like to say that the advertising and positioning is not very diverse either. It doesn't speak to many different cultural demographics. It seems to speak to an older, white demographic, which I think is really alarming, right? You have people in many different backgrounds that are looking for hearing assistance and there's no marketing or advertising or information speaking to that group. So that's something that we really need to change.

GERALD STEIN: There was an audience question related somewhat to that, that I wanted to address. And the question is, has anyone surveyed reasons why people in lower income brackets don't use hearing aids? I imagine one reason might be cost.

KR LIU: Cost, and also again, back to the diversity issue. I don't think it speaks to many different cultural backgrounds or lifestyle backgrounds and their positioning. So, it doesn't speak to them.

DANIEL WOOD: Barbara? And then I think will move on to—

BARBARA KELLEY: And I think the system is intimidating, to get into the health care system. And we saw a panel at the American Academy of Audiology that talked about taking PSAPs and pocket talkers into inner city Baltimore, into the poor African-American neighborhoods, and taking those devices in there, and the responses that they got from that. Very interesting.

GERALD STEIN: So let's switch gears a little bit, and there's been talk on several panels today regarding over-the-counter, OTC, hearing aids. Putting aside the merits of whether we think that's a good idea or a bad idea, let's just assume it's here, what we want to ask you guys is, what information do you feel should be available to consumers who purchase hearing devices over-the-counter? Carole, do you want to start?

CAROLE ROGIN: Sure. I think we had a good introduction to that from Dr. Mann earlier, who went through the two aspects of current regulation. I think everyone here knows that FDA regulation is about two things, safety and efficacy.

I think that the regulatory scheme has worked extremely well for people with hearing loss, for manufacturers who make the product, and for professionals who serve people with hearing loss, because compliance with those regulations that Dr. Mann outlined earlier, have led to virtually no reportable incidents of injury or damage to people from hearing aids. If Dr. Mann is still here, I'd ask him to confirm that.

But there are not problems. And I think that as we talk about a new category of hearing aids, over-the-counter hearing aids, we will best serve consumers if we regulate those products in the same way for safety and effectiveness that current hearing aids are regulated. I think, again, going back to my guidance to us that we simplify, not make more complex, any decision making that has to be had.

FDA regulation, even if consumers don't know what it is, provides a level of assurance of safety to people. And I think that any consumer communications that we start about over-the-counter hearing aids need to give people the assurance that

regulations are in place for both the safety and the effectiveness of any hearing aids that they buy.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: Consumer Reports tested some PSAPs, and we looked at five different products. Unfortunately, two of them were off the market by the time we went to print. And that's another story probably. But we did see some differences demonstrated in this market.

We looked at two very cheap products that over amplified sharp noises like sirens, and we didn't really recommend them. These were typically worse—these were less than $50. When we looked at them, we said, this can cause more harm.

We also looked at two others that we felt were worth trying, and they were each very different. One was able to—it was pretty good at watching TV and came right out of the box without adjustments.

And the other one had a more sophisticated model, with tweaking the settings and customizing with a smartphone.

I think the thing that we really learned was that there needs to be more comparative information when these products go on the market, and that information needs to come from unbiased sources. And I think that having that will be important in the future if this moves forward.

We also support having some standards for these products, so that people can see some distinguishing issues among the ones that may meet certain standards and those that don't.

DANIEL WOOD: Barbara?

BARBARA KELLEY: I echo the standards like Bill Belt was talking about, with the voluntary standards for PSAPs. Also we need very clear language at health literacy levels that—where everybody can understand. I mean, not written to the level that people in

this room can understand, but everybody can understand, and clear expectations and ways to compare products. And choice, ways to compare your choices.

GERALD STEIN: Steph?

STEPHANIE CZUHAJEWSKI: I will just disclose the ADA has been very supportive of the efforts to go forward with an OTC product. We do have a caveat with that. One of our caveats is that they be very specifically labeled. We'd like to see that label include a strong recommendation that the consumer seek an audiologic evaluation. We also want to make sure that the consumer has information about the technical aspects of the device and the amount of gain, the expectations for how it will function, things of that nature.

DANIEL WOOD: Before we move on from over-the-counter, just to refocus the question a little bit, does anybody else want to tell us what consumers might need to know to purchase over-the-counter devices that will suit them well? Stephanie?

STEPHANIE CZUHAJEWSKI: I do have one additional comment. State by state laws vary widely about return policies as it relates to hearing aids today. This is going to be something that could be particularly problematic in the delivery process for these types of devices going forward. So it's going to be important that consumers have a good understanding on the front end of what their rights and responsibilities are as they take these products and in terms of returns. And it may be something down the line that we look at standardizing.

GERALD STEIN: So we touched a little bit during this panel and others about technology and stigma. And we wanted to just explore that a little more. And what we want to understand from your guys' perspective is, what are the views towards hearing aids? Have they changed over time? KR mentioned the iPod generation. And it's funny because I was walking around—I got turned around. I got lost and I wanted to ask people direction. I had to wait till like four people passed, because everyone had the earbuds in. It's amazing how many people walk around with things in their ears.

So has this stigma changed? Or do you see anything that can be done to destigmatize hearing aids?

KR LIU: Great question. As someone whose worn hearing aids for over 35 years, no. I would say the stigma has not changed. I can tell you from experience, in talking to many people who don't really identify with having hearing loss, but know they have hearing issues—just the stigma is still a really big barrier to entry and addressing their hearing issues. And I think that's partially because the technology perpetuates that. Invisibility is not the answer to solving stigma issues, whatsoever. People should be—

GERALD STEIN: So in other words, making a cooler looking hearing aid is not—

KR LIU: Making something that's more visible, more socially acceptable, more affordable—and with technology companies wanting to explore this area, companies like Apple and Panasonic and Bose, and others, there is a brand affinity and social acceptance with those brands. So I really believe that hearing technology and the hearing industry and consumer electronics companies can live hand-in-hand.

And they've already started doing that over the last few years, especially when you look at made for iPhone hearing aids. Apple partnering with other hearing aid manufacturers. People see Apple, and they trust that brand and they think that's cool, and it gets them looking into that type of technology.

But I think this whole issue is as much a social innovation issue as it is a technology and innovation issue. We have to change the conversation and what it means to have hearing issues. And I think more options to the consumer, more awareness on the issue, is going to change that conversation, which gets more people addressing the issue sooner. And I think that's really important here.

Not many people talk about stigma today, but that is one of the biggest reasons people don't get help, that they don't want to admit that they have an issue—makes them think they're getting older, makes them think they're not fitting in in certain social situations, so they isolate themselves and they just don't address it until it becomes a really big problem. And that's not just older people, that's younger people as well.

And cost also is a barrier to entry. So I think that's something that we really need to think about here, is that we have to give more options to consumers that not only are affordable, but are socially accepted, so that we start changing the conversation around hearing loss.

GERALD STEIN: Steph?

STEPHANIE CZUHAJEWSKI: I think, with that, as well, we have to give the consumer more ownership of hearing, not hearing loss, but prevention of hearing loss. I think we've done a fantastic job with optometry and dentistry and a lot of other health care fields, but not a very good job in audiology, in giving the patient ownership from the beginning, of optimizing their hearing over a lifetime.

And with that comes regular visits to your audiologist. With that comes the notion that you're going to pay for the services that the audiologist provides to you and that those are going to be decoupled from the device. So that there isn't this perception that it's this one-size-fits-all model. The one-size-fits-all model has been fitting exactly 25% of the population, leaving 75% out.

DANIEL WOOD: Lisa?

LISA MCGIFFERT: Yeah, I totally agree with that. And I think that we need more public service type advertising or announcements about how hearing is degraded, and the things that people do that cause a problem, to sort of promote good hearing practices.

And it needs to be targeted at a younger population and not an older population. And it needs to be worked into our culture. I live in Austin, Texas, so I go to listen to a lot of music. And sometimes it's so loud that I have to leave. It's physically affecting me. And there are lots of young people up front, and a lot of them aren't protecting their ears.

And I think that there needs to be—we need to create a stigma for that. You know, we need to create that as unnecessary. And really help people understand what it is, how this is going to play out in the not too distant future for those consumers.

GERALD STEIN: Barbara?

BARBARA KELLEY: There are also times when people might not always need a hearing aid, but they have a hearing loss. And they might want—I talked about this earlier—some enhanced hearing. And you walk around that consumer electronics show, and you're faced with intelligent earbuds buds, where you have an app and you decrease the background noise and raise the volume.

And I know people who have a hearing loss, but they don't necessarily want to be treated with the traditional hearing aid, but they would go for this type of product when they need it. So I think there are all those kind of people that could be reached as well, and then probably would end up at the audiologist eventually with a traditional high tech hearing aid with telecoils and Bluetooth, and all of that.

GERALD STEIN: KR?

KR LIU: Yeah, I agree with what Barbara said. There are a lot of people who have trouble hearing in restaurants, or they work in an open office. It's very situational based. Where if they had technology that was available over the counter for those situations, to see if they helped them, that also might make them realize that they need to take that next step as to, wow, this is helping me in this situation, maybe I need to address it even more so and go see an audiologist. It's actually a tool to get them to address the issue.

Because not everyone needs it in every situation. Sometimes it's just in certain loud situations where they're trying to have a conversation. There is technology that could really benefit them.

STEPHANIE CZUHAJEWSKI: And the audiologist should be at the forefront of delivering this technology to the consumer. The audiologist, by and large, advances as

the technology advances, so changing that paradigm of what the services and products that you deliver to your patients are, so, in such a way, that you would have OTC devices. You would have all of these assisted listening devices in your practice that the consumer can come in, sample, and then when it's time for that care to be advanced to a different level, they know exactly where to go.

GERALD STEIN: Is there a relationship between—In selecting a hearing device, will a patient forego a better device for a less visible device? How does it work as far as when it comes time for the patient to select the device? Are they looking for something that they can't be seen or something that works best, if those things are mutually exclusive? KR?

KR LIU: I think it depends on who's making it, to be very honest. The consumers, everyone has an emotional attachment to brands and how things reflect who they are. I think it's really important on thinking about who is that product for and does it fit them? I think it's the consumer that will drive that decision.

So the more options that are out there and available, more mainstream brands that consumers resonate with, absolutely they would wear something more visible as opposed to hidden.

DANIEL WOOD: Carole?

CAROLE ROGIN: It's interesting to note that in about the past 10 years the style of hearing aids that consumers select has absolutely reversed itself. When in the late 1970s we were first able to make comfortable, attractive, in-the-ear hearing aids, it was a time at which visibility was an issue. And people flocked to in-the-ear hearing aids. They, at that point in time, although it's different now, did not have the same power as behind-the-ear hearing aids, but there was a desire to have what was viewed as a cosmetically desirable hearing aid.

Then President Reagan actually made that point to America. And if we could bring somebody back who encouraged people to get hearing aids to the degree that he did, we'd be having a very different conversation today.

But with the creation of what we call receiver in the canal instruments, which are behind-the-ear instruments where the microphone and receiver are down in the ear canal and provide a whole array of benefits, starting with technological benefits and reduction of things like wind noise and a whole host of things to comfort factors. We have seen a complete reversal from in the late '80s, early '90s, 80% of the hearing aids that people purchased in the United States being in-the-ear hearing aids, to today where 80% of the hearing aids that people purchase are behind-the-ear hearing aids. So I think people—consumers are smart. They're thoughtful. I think they are getting excellent professional services today that enable them to try out technology, to learn about it from their hearing care professionals. And I think that they are making the decision obviously more on the basis of performance than style.

DANIEL WOOD: KR?

KR LIU: As someone who has worn hearing aids for 35 years and wore hearing aids in the '80s and was bullied and picked on for many years, of course hearing aids will get more and more visible to hopefully help that problem. And technology has come so far and is so innovative that it's something that people are OK with wearing visibly, like Apple AirPods for example, who don't mind that because it's socially acceptable. And invisibility is not socially acceptable, it's just hiding the problem, right?

So over the years, "hearing aid", unfortunately has a very high stigma to the word, even. So to fix that problem they went to making invisible, instead of changing the aesthetic or partnering with brands that have more social acceptance and innovating that way. We're now seeing that now.

So I think that that's a little misleading. Yes, it's gotten more invisible and more technology savvy, but that's not the answer.

DANIEL WOOD: Should we go to the CTAs then?

GERALD STEIN: Sure. So with the remaining time, the prior panel had discussed the CTA standards for PSAPs, and we thought we would just ask from the consumer's

perspective, do the CTA standards provide information about PSAP quality that may help consumers obtain useful information?

KR LIU: So the Consumer Technology Association formed the PSAP quality standards committee to provide consumers with what would be called like a Good Housekeeping Seal of Approval for personal sound amplifiers that would meet the requirements of the standards. So it would give consumers trust in what they're buying is a good high quality product, much like when you go and buy a product that has a made for iPhone or a made for iPod logo on it, you're trusting that Apple has put their seal of approval on that product, and they think it's a good product.

So I think that standard would enable consumers to trust the seal of what they're buying and identify good products.

GERALD STEIN: OK. Steph?

STEPHANIE CZUHAJEWSKI: ADA has not had the opportunity to review the standards, so we don't have a comment. I just wanted to make it clear why we were not commenting.

GERALD STEIN: Lisa?

LISA MCGIFFERT: I have not reviewed the standards either but agree that standards do provide something for consumers to connect with. And I've followed the FDA for a long time, and it often takes a long time for the FDA to come up with standards. So I think what I've heard today is that this market is moving forward pretty quickly, and it might take a while for the regulators to catch up. So having some kind of standard out there to look at is probably a good idea, at least to get started.

CAROLE ROGIN: I would just observe that the FDA does have an excellent set of standards out there, and rather than, as CTA has done, relying on the manufacturers to regulate themselves, I think that we would be serving people with hearing loss well if we relied on the standards that the FDA has developed with scientists and engineers and

that have been proven over the years to provide safe and effective hearing aids to people with hearing loss.

GERALD STEIN: Barbara, you get the final word.

BARBARA KELLEY: Oh, thank you. I'd just like to go back to the National Academy of Sciences' engineering and medicine report, that says hearing loss is a primary health concern. And 85% of people who could benefit from hearing aids don't wear them. And hearing loss has been linked with co-morbidities, and that's the group that we have to worry about.

Those people need treatment. And I know that Mr. Cleland from the FTC said that it's really a nightmare regulating 500 devices and whatever, but from the consumer, I really don't care. I just want more. I want more choice for people, affordable choice. And people have to get treated for hearing loss.

Getting hearing aids just should not be for wealthy people. It should be for everybody. We all deserve to hear well.

GERALD STEIN: OK. Thank you very much.

[APPLAUSE]

CLOSING REMARKS

- **Daniel J. Gilman, Attorney Advisor, Office of Policy Planning, Federal Trade Commission**

DANIEL GILMAN: I want to thank the panel and all the panelists throughout the day, and the speakers, and participants. I have a couple of brief remarks—I promise they'll be brief—at the end of the day.

First, I'm asked to cover some administrative details. Number one, those of you who have telecoil headsets, please be sure to drop them back on the table where you got them.

Number two, those visiting the Commission, if you received a lanyard with a plastic FTC event security badge, please drop your lanyards with the guards at the front.

And, number three, if you could please take all the trash that you might have with you and throw it in the bins outside the auditorium, that would be great.

Also, a couple of thanks—I want to start with just three. We say there are too many people to name, but the three people I want to single out who have not been up here at the lectern or at the table who've been key—Liz Callison, from our Bureau of Economics has been part of the team planning this event, doing the research behind the scenes—very valuable; Chris Bryan, also from OPP, has been a terrific asset; and Jonathan Aid, a paralegal assisting us from the Bureau of Consumer Protection, has been very helpful. I did at least want to mention them.

Also—just all the staff who have been involved here. This has been a great collaboration between our Office, OPP, and the Bureau of Economics, and then, of course, having Gerald here come help us from our Northeast Regional office in New York has been terrific on a Bureau of Competition perspective.

I want to return to, very briefly, to a point Tara made at the beginning. This is an ongoing inquiry. And, in particular, we are receiving public comments through the website, through May 18th—a month from now.

So, we're going to review the transcript, input from participants, input from the public, and we hope that you'll share more information with us as we continue to think about these issues.

Thanks very much to all of you for sticking with us throughout the day, and again to our participants for their input. Thank you.

[APPLAUSE]

[END OF WORKSHOP]