

Hearing Aids and Personal Sound Amplification Products
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Moderator: Elias Mallis

Elias Mallis: Greetings, everyone. And thanks for joining us for today's CDRH webinar. I'm Elias Mallis, Director of the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. And I'll be your moderator for today's program.

Today's topic will cover the proposed rule for over-the-counter hearing aids, as well as the related draft guidance on the regulatory requirements for hearing aid devices and personal sound amplification products. These proposed regulatory actions are currently available for public comment. So we're holding this webinar to provide you with an opportunity to learn more about the efforts and to answer your questions as you consider providing us with your feedback.

It's my pleasure to introduce you to our presenters for today's program: Dr. Eric Mann, Chief Medical Officer in CDRH's Office of Product Evaluation and Quality, Office of Health Technology One. Now this is OHT1 for short or the Office of Ophthalmic, Anesthesia, Respiratory, Ear, Nose, and Throat and Dental Devices. Also from OHT1 are Dr. Srinivas Nandu Nandkumar, Director of the Division of Dental and ENT Devices, and Dr. Vasant Dasika, Biomedical Engineer. And finally, we have Ian Ostermiller, Policy Advisor in the Office of Policy.

We'll kick off today's program with a presentation from our panelists and then come back around for a discussion and field your questions about the topic. Dr. Mann will get us started. Thank you Eric.

Eric Mann: Thank you Elias, and good afternoon, everyone and welcome to this FDA webinar. Today we will be providing you with an overview of the proposed rule for over-the-counter hearing aids as well as an overview of the draft guidance document on regulatory requirements for hearing aids and personal sound amplification products. And both of these documents published on October of this year.

And following the presentation, we look forward to answering any clarifying questions from our online audience. We recognize that many of the people in the audience today will likely have hearing loss, or are relatives or caregivers of people with a hearing loss, or you may be hearing health care professionals or even members of the hearing aid industry. We know that there's been a great deal of anticipation regarding the proposed rule and we're very pleased to be sharing this information with you today.

So I will remind everyone in our audience that we do have links on our FDA website to the proposed rule and draft guidance document, which are shown here. And you can access these documents during today's webinar, if you like. And just to make sure that everybody follows us during the presentation, we're frequently going to be using the term OTC as shorthand for Over the Counter, and we will also use the term PSAP as an abbreviation for Personal Sound Amplification Product.

Our learning objectives for today's webinar are listed here. By the end of the webinar, we hope that participants will be able to describe the current landscape of hearing aid regulations, be able to summarize the proposed rule for OTC hearing aids, be able to summarize the distinction between hearing aids and PSAPs, as outlined in the draft guidance, and very importantly, we would like for you to be able to know where and how to provide comments on the proposed rule and draft guidance, since we very much want to hear your feedback on these documents.

So let's begin with the first learning objective regarding the current status of hearing aid regulation. And we'll start with some brief background on hearing aid use that led up to the proposed OTC hearing aid rule. By one estimate, close to 30 million US adults have a hearing loss that could benefit from hearing aid use. But despite this finding, the rate of hearing aid usage is strikingly low, with less than a third of adults aged 70 or older who could benefit from a hearing aid ever having used one. And that drops even further to about 16% overall for adults less than 70 years of age.

The reasons for this are varied, but stigma may play a role, with some people not wanting to be perceived as old or disabled. And certainly the high cost of hearing aids has been an issue for many people, with a pair of professionally-fit hearing aids easily costing several thousand dollars. And finally, we've learned from external stakeholders, including from a 2016 report from the National Academy of Sciences, Engineering, and Medicine, that certain federal and state regulations may be posing a barrier for hearing-impaired Americans.

We believe that the proposed rule we are discussing today will address some of these barriers, will promote the use of safe and effective devices, and will promote choices and innovation in hearing aid technology.

So this slide shows that FDA regulates several major device types to aid hearing loss. At the top we have conventional hearing aids, which are the devices most commonly used to compensate for hearing loss, that can range all the way from mild to severe. And of these devices, air-conduction hearing aids, which deliver amplified sound into the ear canal, are by far the most common type in use. Much of adult-onset hearing loss tends to be of the mild to moderate severity, and thus there is a large public health need for access to affordable, good quality air conduction hearing aids.

Air-conduction hearing aids come in a variety of styles shown here, such as behind the ear or in the ear-wearable devices. Less commonly used than air-conduction hearing aids are bone-conduction hearing aids, which transmit sound through vibration of the skull. And we also have implantable hearing aids and cochlear implants for greater degrees of hearing loss. However, for the purposes of the proposed rule today, we will only be considering air-conduction hearing aids as being suitable for OTC use, as specified by Congress in the OTC Hearing Aid Act.

So narrowing our focus to air-conduction hearing aids, we have 3 device regulations using this technology that are potentially suitable for OTC use. The standard air-conduction hearing aids, which we sometimes refer to as legacy hearing aids, amplify sound and deliver it to the ear canal and they are oftentimes programmable to meet the hearing loss needs of an individual patient.

We also have a separate regulation for air-conduction hearing aids that incorporate wireless technology that enables the devices to be programmed wirelessly, or adjusted or controlled by user remote or a cell phone app. And finally, we have a relatively recently added regulation for self-fitting air-conduction hearing aids. These devices allow the user to program the device to aid their individual hearing loss without the assistance of an audiologist or hearing health care provider. And we anticipate that many of the devices pursuing OTC status will actually fall under this regulation.

So an important point to understand, though, is that the vast majority of all of these air-conduction hearing aid devices are currently not prescription devices, but they are subject to certain federal restrictions.

And these restrictions would include requirements for labeling, such as what needs to be in a user instructional brochure. And this would include things like instructions for use of the device, or certain warnings about conditions that would require a medical evaluation, and so forth.

But really the restriction that has been perceived more as the significant regulatory barrier to prospective hearing aid users is the conditions for sale regulation in the second bullet here. And this requires that a medical evaluation by a licensed physician be performed within six months of dispensing of the hearing aid, although it does allow for a waiver of this requirement for users 18 years of age and older.

But since 2016, FDA has been exercising what we call enforcement discretion and has not been actively enforcing this requirement for a medical evaluation or waiver. And this is based in part on recommendations in the report of the National Academy of Sciences and is outlined in our immediately in effect guidance document that is cited here. So really even before the proposed rule, we did take steps from a federal government standpoint to reduce regulatory barriers.

But in addition to these federal restrictions, some states have enacted additional laws or regulations which may further restrict access to hearing aids. And this may include additional requirements for audiological testing, or medical evaluation, or additional restrictions on internet or mail order sales, or specific licensure requirements for hearing aid dispensers.

So taken together, the current federal and state regulations may be creating a barrier to the uptake and use of hearing aids. And the proposed rule aims to address these perceived regulatory barriers. So now I'd like to introduce Ian Ostermiller, Policy Advisor in the Office of Policy within CDRH, who will provide an overview of the proposed rule.

Ian Ostermiller: Thanks Eric. Again, I'm Ian Ostermiller, a policy advisor in CDRH's Office of Policy. And I'll provide an overview of the proposed rule for over-the-counter hearing aids. In describing our proposals, I'll occasionally refer to FDARA. That's the acronym for the FDA Reauthorization Act of 2017, which is the law that established FDA's authority to regulate OTC hearing aids in this way. I'll also occasionally refer to the FD&C Act, which is an abbreviation for the Federal Food Drug and Cosmetic Act.

As you can see, we had a few primary overarching goals when we developed our proposal. But ultimately, the proposed rule is focused on devices that compensate for the kind of hearing loss typically associated with aging. Or in the law's terms, perceived mild to moderate hearing loss.

Hearing loss from other etiologies, like a disease process, or more profound hearing loss, should still be monitored by a licensed professional. And in that case, the audiologist or the licensed fitter, for example, would select the most appropriate device and fit it to the individual. And then that hearing aid would just be one part of a more comprehensive hearing rehabilitation regimen.

From FDA's point of view, most hearing aids can already be sold directly to consumers. Most are not prescription devices. And for that matter, most air-conduction hearing aids are already exempt from premarket notification requirements, or also known as 510(k)s. That means that much of the current gatekeeping for the sales is done by states, especially the more populous ones.

Thus from our perspective, one of the most significant changes from Section 709 of FDARA is to establish strong federal preemption specific to hearing products. This means that FDA takes on more of that gatekeeper role for the sale of hearing aids, specifically OTC hearing aids.

Given this strong preemption, as well as the detailed requirements laid out under FDARA Section 709, we're proposing to establish a comprehensive set of regulatory requirements for OTC devices. And as we do that, we're also proposing to update various other regulations that apply to hearing aids to make them consistent with the new OTC rules. We're also proposing to repeal some existing regulations, perhaps most significantly, the current conditions for sale for hearing aids. This means that prescription hearing aids would be regulated in the same way as other prescription devices.

As I mentioned before, FDARA is relatively prescriptive about the kinds of requirements that FDA must establish for over-the-counter hearing aids. This is in part because one of the main tenets of selling hearing aids over the counter is the removal of any licensed person from the process.

Nonetheless, each of these proposals, which we'll discuss in more detail, still fits within our usual standard of reasonable assurance of safety and effectiveness. And moreover, given high stakeholder interest, we've received a wealth of input on these topics, even before the enactment of FDARA. And we're not done yet. If you want to provide feedback, we encourage you to submit your comments to the docket so we can consider those when we develop the final rule.

And we talked about this a little bit earlier. One of the other things that FDARA does is it directs FDA to update and finalize a guidance on distinguishing PSAPs from hearing aids. We currently have a final guidance in effect. It's been in effect since '09. And we issued a new draft guidance in 2013.

However, in order to fulfill FDARA requirements, we decided to reissue the draft guidance. And we've taken into account comments that we've already received on that 2013 draft. And then once we go to finalize the OTC rules, will also finalize this PSAP draft guidance as directed by FDARA.

When you think about hearing aid regulation, you might think of it in terms of two kinds of regulations. Now, what I'm about to say is an informal way of thinking. This isn't a formal distinction that FDA makes. I'm just hoping to help you understand the strategy that we used in developing our proposals. So in this informal way of thinking, one kind of regulation is a classification regulation. This is the regulation that specifies the identification of the different device types, the device class, in other words, whether it's a class I or class II device, as well as any applicable special controls.

Eric touched on these a little when you talked about the different kinds of air-conduction hearing aids that FDA has classified. But another kind of regulation in this informal way of thinking is the kind that applies regardless of the device type. So for hearing aids, a good example might be a rule like the current labeling requirements. So it doesn't matter whether a hearing aid is a class I exempt device or a class II self-fitting device. The same labeling requirements apply from 801.420.

I mention all of this because a key thing to understand about the rules that we propose for OTC hearing aids is that we're not creating a new device classification, and we're not clearing or approving a new kind of hearing aid technology to fulfill FDARA's requirements. In other words, we're not making one of those first kinds of regulations. We're making one of the second kinds of regulations, something that's more like a rule of the road.

So for example, a manufacturer could take a class I device and using this metaphor, he could drive that class I device down either the prescription or the OTC lane and that would still be a class I device. Likewise, a 510(k) exempt hearing aid would still be 510(k) exempt, regardless of whether it was driving down the prescription lane or the OTC lane.

We did propose to realign the classification regulations - that first kind - according to sound conduction technology but that's just a rearrangement of the existing regulations. It's not the creation of a new device type. It's not the approval of a new device. It's not a change in a device class. So this all means, in fact, that a manufacturer could potentially market their existing devices as OTC if they comply with the rule's final requirements.

One important caveat is we think that most manufacturers will have to update their device's labeling. Although that would be the case, regardless of whether it was intended to be an OTC or prescription device, since we're proposing amendments for both categories. And the eventual OTC device would, of course, have to follow the other requirements that we finalize, including, for example, the appropriate output limit.

For some manufacturers, making these changes might just mean documenting the changes to file. For other manufacturers, that might mean submitting a 510(k), depending on the specifics. In particular, whether the manufacturer's device is 510(k) exempt and if so, whether the change exceeds the limitations of exemption. But in any case, determining the need to submit a 510(k) should still follow our usual policies. We're not proposing anything unique or peculiar for OTC hearing aids.

Of course, in all cases, applicable general controls would remain in effect too. So for example, a manufacturer that wishes to market their current non-medical device as a medical device would need to register their establishment if they haven't already. And they would need to list the device, as well as follow other requirements for example, establishing an appropriate quality system that complies with Part 820.

Hopefully this slide helps you visualize the changes that FDA is proposing. On the left are the requirements that would allow people to drive in the OTC lane, and on the right are the kinds of requirements that would allow people to drive in the prescription lane.

One thing to note, Vasant will talk shortly about the more technological requirements of the proposal. But we've also included some legal requirements dealing with the effect that FDARA has on certain state and local requirements. And the reason we're doing this is simply to codify them in the regulations. FDARA did not amend the FD&C Act to state these requirements. So if you were to peruse the FD&C Act, you wouldn't actually run across them and read them. They're still in effect because FDARA put them into effect. But you wouldn't find them in the FD&C and so we've included them in the regulations.

So as I said, Vasant will now go through the more technological aspects of our proposal.

Vasant Dasika: Thank you for the introduction. In the next three slides, I will summarize some highlights of the proposed technical and performance specifications for OTC hearing aids.

FDA is proposing a maximum acoustic output limit requirement for an OTC hearing aid to balance patient safety and device performance. Too high a limit allows excessive sound levels, posing a safety

risk. However, too low limit unnecessarily limits the signal, reducing audio fidelity of the amplified sound.

The maximum output limit FDA proposes is 115 Decibel Sound Pressure Level, dB SPL. And for hearing aids with both input-controlled compression and a volume control, the maximum output limit is 120 dB SPL.

These limits are proposed in consideration of several sources, including the American National Standards Institute and Consumer Technology Association, ANSI CTA 2051 standard, National Institute for Occupational Safety and Health, NIOSH, 1998 noise exposure guidelines, National Academy of Science, Engineering and Medicine, NASM, 2017 public workshop and report, and an FDA 2016 public workshop on hearing aids.

The ANSI CTA 2051 standard is a PSAP standard that we believe has relevant aspects for OTC hearing aids because hearing aids, like PSAPs, provide sound amplification. ANSI CTA 2051 specifies a 120 dB SPL limit, stating exposure at this level would be acceptable for up to about 30 seconds of cumulative time per day, per NIOSH '98 guidelines. The rationale is that a user can recognize and mitigate the exposure within a shorter time frame.

In consideration of other stakeholder input, including the NASM 2017 workshop, a somewhat lower output limit was considered by FDA to increase the safety margin while still providing audio fidelity. Therefore a 115 dB SPL maximum output limit is proposed by FDA, which allows for approximately 90 seconds exposure per NIOSH '98.

FDA believes a user will have sufficient time to mitigate such exposures by removing or turning off the device, adjusting the environment or their proximity to sound sources, or lowering the hearing aid volume if a volume control is present.

For devices that include both input-controlled compression and a volume control, FDA proposes a higher maximum output limit of 120 dB SPL. This is because each of these features reduce the likelihood of output at or near the device's limit at any given moment.

Another aspect we considered was gain. Gain is the amount of amplification provided by a hearing aid for a given input sound level. Gain limits are not proposed to allow for flexibility in the technology and for the goal of maximizing innovation. In terms of best practices, we encourage OTC hearing aid designs to incorporate reasonable gain limits for the intended population and the specific device designed to optimize safety and effectiveness.

However, we believe the output limit requirement alone may be sufficient to address safety. We recognize that finding the right balance for an appropriate output limit is challenging. We welcome comments on this issue.

Electroacoustic performance requirements for OTC hearing aids are proposed so that amplified sound is of sufficient fidelity for the user to accurately perceive social and environmental sounds. We propose certain requirements of ANSI CTA 2051. ANSI CTA 2051 is, to FDA's knowledge, the first voluntary consensus standard to specify performance characteristics for hearing amplifiers. This is separate from the standardized measurement test methods and tolerance requirements specified in the ANSI Acoustical Society of America standard as 3.22.

Potential applicability of certain ANSI CTA 2051 electroacoustic requirements were discussed during both the FDA 2016 workshop and the 2017 NASM workshop, with general support for the following proposed requirements. Total harmonic distortion plus noise shall not exceed 5%. Self-generated noise shall not exceed 32 dB SPL. Latency shall not exceed 15 milliseconds.

For frequency response, bandwidth, and smoothness, the lower cutoff frequency shall extend to 250 Hertz or lower, and the upper cutoff frequency shall extend to at least 5 kilohertz. And no single frequency band response shall excessively exceed the average levels of neighboring frequency bands.

FDA also proposes the following design requirements for an OTC hearing aid insertion. Insertion depth. The design of an OTC hearing aid shall limit the insertion depth of the ear tip to the bony cartilaginous junction of the external auditory canal and no deeper. We believe this is a practical way to describe the depth limit. However, we welcome comments to simultaneously limit the insertion depth, prevent injury, and promote device effectiveness.

Atraumatic materials. The ear tip material of an OTC hearing aid shall be atraumatic to mitigate the risk of trauma or damage to the ear canal by the user. Physical fit. The OTC hearing aid shall be designed to enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear.

Tools, test, or software. The OTC hearing aid shall, through tools tests or software, permit the user to control the device and customize it to their hearing needs. Examples of tools, tests, or software include: a user adjustable volume or tone control, or a way to manually change pre-set listening programs.

Alternatively, interactive software for self-selecting and fitting a device. Or a switch to enable or disable settings, such as noise cancellation or acoustic environmental sensing. An OTC hearing aid needs to include some combination of tools, tests or software to customize the device to the user's hearing needs.

And next, Dr. Srinivas Nandu Nandkumar, Division Director, OHT1, will discuss the updated draft PSAP guidance.

Srinivas Nandkumar: Thank you Vasant for the introduction. I will now present the next slides on our proposed draft guidance that outlines the distinctions between hearing aids and PSAPs.

The draft guidance describes hearing aids, PSAPs, their respective intended uses, and the regulatory requirements which apply to both types of products. First, a hearing aid is defined by regulation as a wearable device designed for and intended for aiding persons with impaired hearing or compensating for impaired hearing.

Hearing aids meet the definition of a medical device per 201(h) of the FD&C Act, which states that medical devices are products that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and are intended to affect the structure or any function of the body. Thus hearing aids are medical devices and subject to FDA's medical device regulations.

PSAPs are considered as products for non-hearing-impaired consumers to amplify sounds in certain environments, such as for hunting or other recreational activities, and are not intended to aid persons

with impaired hearing. Therefore, they do not meet the definition of a medical device per 201(h) of the FD&C Act.

The updated draft guidance clarifies that both hearing aids and PSAPs are electronic products with some similarities, such as emitting amplified sound. They're regulated by Radiation Control and Safety Act of 1968. The difference is that while hearing aids are regulated as medical devices, PSAPs are not regulated as medical devices. PSAP manufacturers do have some responsibilities under the Radiation Control Act, such as reporting defects and repair and replace requirements.

The draft guidance provides examples of situations in which PSAPs typically are used. These include the following: during hunting, that is using amplified sounds to listen for prey, listening to sounds while bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult even for non-hearing-impaired persons to hear, for example, listening to conversations from a distance.

FDA is aware of confusion in the marketplace over what is regulated as a hearing aid that is a medical device and what it considers a PSAP and therefore not a medical device. Some of this confusion arises due to similarities in the technologies and certain statements made in the labeling of PSAPs. The draft guidance clarifies that FDA considers intended use to distinguish between hearing aids and PSAPs. FDA may also consider, among other things, any written or oral claims or statements in any label, labeling, advertising, and/or promotion of a product, by or on behalf of a manufacturer in determining whether a product is a hearing aid or a PSAP.

The updated draft guidance provides examples of explicit or implicit claims or statements that we believe would cause a PSAP to meet the medical device definition, in which case the product would be subject to the regulatory requirements as hearing aids. For example, if a product states that it is for users with certain types of severity of hearing loss or impaired hearing, it is a hearing aid.

If a product is suggested for use in situations typically where hearing loss is to be compensated for, it is a hearing aid. If a product is suggested as an alternative to, or a substitute for, a hearing aid for persons with hearing loss, then it's not a PSAP but a hearing aid. If a product has information conveyed to the user to optimize the product to their hearing loss or to their impaired hearing profile, for example, through use of software or other features, then the product is not a PSAP, but a hearing aid.

In the next couple of slides, I would like to add some notes about providing comments on the proposed OTC rule and the hearing aid versus PSAP draft guidance. First, regarding guidance documents, you can comment on any FDA guidance at any time. However, to ensure that the FDA considers your comment on a draft guidance before we begin to work on the final version of the guidance, please submit your comments on the draft guidance before the close date, which is January 18, 2022.

Next, the comments should be submitted to the dockets on [regulations.gov](https://www.regulations.gov). The proposed over-the-counter hearing aid rule and the draft hearing aids versus PSAPs guidance each have a separate docket and the comments should be submitted separately to each docket. Comments can be submitted via an online form or by mail. The web links to the Federal Register notices are available on this slide where you can access each online form to submit the comments.

In summary hearing aids have an extensive history of federal and state regulations. There is a widely acknowledged need to expand hearing aid access to users with hearing loss in a safe and effective manner. In 2017, the FDA Reauthorization Act, or FDARA, directed FDA to establish the category of over-

the-counter hearing aids through rule-making and mandated requirements for safe and effective use of these devices. FDARA also directed FDA to update and finalize the draft Hearing Aids and PSAP regulatory requirements guidance issued in 2013.

FDA's proposed rule creates requirements to ensure a reasonable assurance of providing safe and effective over-the-counter hearing aids to users with perceived mild to moderate hearing loss. The proposed rule also addresses requirements regarding design and labeling of over-the-counter hearing aids and also on the technical and performance specifications.

The FDA has proposed a draft guidance that helps to guide consumers and stakeholders by providing further clarification regarding regulatory requirements for hearing aids, which are medical devices to treat hearing loss versus PSAPs, which can be used to enhance hearing in some environments, and not intended for use to treat hearing loss, and therefore are not medical devices.

This ends our presentation, and we thank you for your attention.

Elias Mallis: Thank you everyone and thanks to our esteemed panelists for your presentation. Let's now transition to the question and answer segment of our program. But first, I'd like to welcome and introduce Dr. Lindsay DeVries, who's an audiologist in OPEQ's Division of Dental and ENT Devices. Lindsay is going to join us on the panel to answer some of your questions.

So, I'm showing here on the slide on how we're going to handle the Q&A segment here. To ask a question, please click the raise your hand button, which should appear on the bottom of your Zoom screen. I have a screenshot of that here. I'll announce your name one at a time and invite you to ask your question. To do so, you'll need to unmute yourself when called and then you go ahead and ask your question.

A couple of tips about questions. First please try to ask only one question when you're called upon and also keep your questions short as possible. This will allow us to get through as many of your questions as possible during the time we have. And also, please refrain from asking any submission-specific or data-specific questions as well. For those kinds of questions, we ask that you consider submitting a Q-submission or reaching out to the team directly offline.

After you ask your question, please go ahead and unmute yourself again. And if you have more questions you'd like to ask, no worries. Just go ahead and raise your hand one more time and we'll circle back to you if we have some time. So that's how we'll kind of lay out this Q&A segment.

As we await to get some of your questions and hands raised, let's get started with some of the questions that have been coming into the Division of Industry and Consumer Education over the last few weeks since the proposed rule was issued and the guidance published.

So Lindsay, first I want to welcome you to the panel and I'd like to send you this first question. So the question. The proposed rule states that the intended user of an OTC hearing aid is someone with perceived mild to moderate hearing loss. So how would a consumer know if they have this range of hearing loss without actually seeing a hearing health care professional?

Lindsay DeVries: Great. Thank you Elias, that's a great question. So first I want to say that FDA appreciates the role that audiologists play. As an audiologist myself, I absolutely understand how

important our role is in hearing health care. But at the same time, we know that not all potential hearing aid users seek out an audiologist if they're having trouble with their hearing.

So to address your question, we have proposed device packaging that clearly displays information that will aid consumers in determining whether they have a perceived mild to moderate hearing loss. And we have proposed four scenarios that a person may recognize as symptoms of a mild to moderate hearing loss.

So these scenarios currently include difficulty hearing or understanding conversations, particularly in groups or noisy places, or when you can't see who's talking to you, difficulty on the telephone, fatigue or getting tired due to greater listening effort, or needing to turn up the volume of television, radio, or music louder than normal, or loud enough where others around you are starting to complain.

So we've also proposed packaging include red flag conditions so things like ear pain or a history of excessive earwax, a sudden change in your hearing, that might require medical assessment and care.

But what I want to point out is that consumers still have the choice to see an audiologist or a hearing health care provider to get their hearing tested before buying an OTC hearing aid. So nothing in this proposed rule prevents people from seeing a professional about hearing concerns before going out and seeking an OTC device. I want to make that clear. And I hope that this information here I've provided has answered that question.

Elias Mallis: Thank you Lindsay. That was great. Let's get to one more question and then we'll go to our hands. Ian, I'm going to send this one to you. This is probably a very popular question that we'll be getting.

A lot is involved with this proposed rule and the draft guidance. What will happen after the comment period ends?

Ian Ostermiller: Sure. It is a very popular question, actually. So what happens when the comment period ends is we will take the comments from the docket and we'll review them and we'll have several meetings among ourselves to sort through the comments, understand what people are telling FDA, and then formulate our responses. And we'll take all of that input and as we think appropriate, will adjust the final rule based on it.

When we go to publish the final rule, we will provide our responses and we'll provide the reasons for any changes we made or decided not to make. So the public will be able to see the end result of that product. However, the deliberation for the consideration of the comments is a confidential process that isn't open to the public.

Once we've finished drafting the final rule, then it has several clearance steps to go through. A rule with this kind of visibility will almost certainly end up going through OMB review. So the review process itself can take several months. And then once the rule is fully reviewed by all of the appropriate levels, we'll publish the final rule in the Federal Register. And at that point, people will be able to read it for themselves.

After publication of the final rule, there will be a delay until the effective date. For this particular rule, we proposed a 60 day effective date. So 60 days after the publication of the final rule, it will become

effective. As far as the kind of time people will have to adjust, it depends on their device. If it's, for shorthand, I'll just say a new device. If it's a new device, their device will need to be in compliance with the final rule as of the effective date. Again, 60 days after publication of the final rule.

If it's an existing device and they're making modifications, then they'll have an additional 180 days after the publication of the final rule. So a total of 240 days to come into compliance with the final rule.

Elias Mallis: Thank you Ian. There is another part to this question, but I think you already answered it, which was: how much lead time will we have or will the public have in order to comply. So I think you outlined it in response. So thank you for that. Let's go ahead. Oh. Go ahead Ian, if you want to add anything to that.

Ian Ostermiller: No, I think we're all good.

Elias Mallis: OK. Thanks. All right, Andrew, you're going to be our first caller. I'm going to allow you to speak. So you would go ahead and unmute yourself and then tell us your question.

Andrew: Hi. Thank you for hosting the webinar today. Getting right to the question, would you please comment on the distinction between over-the-counter hearing aids and self-fitting hearing aids, specifically what degree or type of customization goes beyond mere control and customization in the OTC hearing aids mission, to its hearing aid programming or fitting by the user, in the case of a self-fitting hearing aid?

Elias Mallis: All right. Thank you. For that question, Lindsay, is that an appropriate question to pass you as our resident audiologist?

Lindsay DeVries: Yes, so I can try to give an answer, and anyone else can jump in if they have any additional thoughts. But if I understand your question correctly, with an OTC hearing aid, kind of a general OTC hearing aid, these hearing aids would have pre-programmed templates or some kind of prescriptive formula that would be loaded onto the hearing aid for the listener, given the assumption that they have a mild to moderate hearing loss.

And in the case of self-fitting hearing aids, there's more of an interactive piece where the listener would use usually something like an app to follow the steps of the app and have a more fine-tuned or individualized proprietary formula applied to their hearing aids. So it would be more interactive and would provide something a little bit more individualized. Not 100% sure if that's what you were asking.

Srinivas Nandkumar: Elias, I can add to this. Is Nandu Nandkumar here. I just wanted to mention that this goes back to what Ian had mentioned in his presentation, which is what you see hearing aids are more can see them as more rules of the road. So whereas self-fitting hearing aid is a classification regulation, so you could have a wireless hearing aid or a self-fitting hearing aid. If they comply with the OTC hearing aid requirements, they could drive on that lane on that lane of that hearing aid highway. If you want to see it that way.

So as Lindsay mentioned, over-the-counter hearing aids would be very simple form of volume control or a simpler interface, which could either fall under a traditional hearing aid or a wireless hearing aid classification. Or they could have a more advanced interface personalized self-fitting interface, which could be under the self-fitting hearing aids.

Elias Mallis: Thank you Nandu. Andrew, do we answer your question there?

Andrew: Yes. I think that one way to phrase that the question is, if a manufacturer is designing a hearing aid, and they'd like to know as early as possible whether they'll be subject to a 510(k) requirement, where is the bright line between knowing that the degree of customization or degree of interactivity may result in a determination that a 510(k) is required? In other words, may result in a self-fitting classification.

Srinivas Nandkumar: So I can take that. I think, again, that goes to a specific device type question. And it's probably very difficult to broadly provide an answer. So I think if you have it, it sounds like what you're saying you're designing a specific type of device and where does that line, which side of the line does it belong to?

So I think some of this, we will have to sort out in Q-submissions, like Elias mentioned, because it pertains to a very specific device type but we will consider as we go along and finalize this rule, perhaps a guidance that might address some of these. But down the road, because this rule is not final yet. So at that point, it may be.

But now, if you are thinking of designing your device now, the best option might be to come in with the submission then talk to us.

Andrew: Thank you.

Elias Mallis: Thank you Nandu and Lindsay, and thank you for that question, Andrew. We'll go to our next caller, Yvonne Petterson. I am going to unmute you now. So please go ahead and unmute yourself and ask the panel your question.

Yvonne Petterson: Several audiologists that I've spoken to believe that they will not be allowed to assist with adjusting or fitting a self-fitting hearing aid or an OTC hearing aid. Is that correct or would they be allowed to assist if a patient came in and asked them to help them with their self-fitting hearing aid? Would they be allowed to do that?

Elias Mallis: Thank you for that question. Nandu, is this also a question to send your way?

Srinivas Nandkumar: I can start, and if someone wants to jump in. We don't have anything in the proposed rule that says that a hearing health care professional cannot help you, if an interface is designed for the user or a consumer to self-program or self-fit their hearing aid. I don't think we have anything in our proposed rule that prohibits the user to take that to a hearing health care professional for help. That's the best way I can answer this. Anybody else, if they want to jump in?

Ian Ostermiller: Hi, this is Ian. Yeah, I can say it a little more definitively. The proposed rule does not say that. An audiologist would certainly be allowed to help a consumer who brings in an OTC hearing aid or potentially even purchases the OTC hearing aid from the audiologist. It's just that when it comes to OTC hearing aids. A state, for example, cannot require that an audiologist be involved in that process. Although they're certainly welcome in that process.

Yvonne Petterson: Excellent. Thank you.

Elias Mallis: Thank you for your question. We'll next go to Mohamed Hamid. I'm going to unmute you now. Please go ahead and unmute yourself and ask the panel your question.

Mohamed Hamid: Can you hear me? Hello?

Elias Mallis: Yes, loud and clear. Go ahead.

Mohamed Hamid: OK. All right. I am a physician, I'm an ear physician. And the point that was raised before, which had the red flags, is very important. Irrespective of the type or the form of over-the-counter hearing, assisted hearing devices I think it should be labeled clearly that if they have a hearing loss in one year only that this would require medical evaluation. That needs to be done either by their primary care physician, or by an ENT or an otologist or certainly an audiologist in the area. And I'm saying this because the slow, shall we say, progression of hearing loss in one ear only may not be recognized early on in the process.

Elias Mallis: Thank you for your feedback. We can respond. Do you have a question for us? Or is this more just providing your recommendation or observation?

Mohamed Hamid: I'm just I'm just making a comment because I know that OTC devices are going to be here with us for a long time.

Elias Mallis: Thank you. We'll have Eric provide a response to your comments.

Eric Mann: Yes. Thank you very much. That was a very important comment that you made. And I will say that FDA has always been very concerned about the prompt diagnosis of any kind of medically treatable causes of hearing loss associated prior to dispensing a hearing aid. And that really was the basis of that conditions for sale regulation that we mentioned in our presentation. That was all the way back in 1977.

And over the years, there's been a number of proposals and citizens petitions to either revise that conditions for sale regulation or even eliminate it. But we really, with all of those kind of proposals, we never had a clinically or scientifically sound justification for why it wouldn't pose undue risks from any kind of delay in diagnosis. And in part, this is probably because nobody really had previously systematically addressed this risk. And there's not a whole lot in the literature.

But FDA, in partnership with a number of other federal agencies, cosponsored a study by the National Academy of Science, Engineering, and Medicine, this was back in 2015, about ways to enhance accessibility and affordability of hearing aids. And they actually published their report in 2016. And they really did kind of focus in on this particular area about the risk of doing away with the conditions for sale with the medical evaluation.

And they really did a very thorough job of looking at the literature, reviewing information from databases from the VA and the DoD, looking at people presenting for a hearing aid and whether or not they had any of these serious conditions that needed diagnosis. And they also got input from stakeholders at a number of meetings. And the conclusion of all of that research was that the incidence of serious causes of hearing loss requiring prompt attention is actually quite low. And in fact, most people are currently opting to sign the waiver, rather than get the evaluation.

So their conclusion was basically that the conditions for sale regulation is acting more as a barrier than it was fulfilling any kind of public health concern. So they really recommended that we approach this more from a labeling perspective and identify the red flag signs and symptoms and lay-friendly language, and that would, in their opinion, likely mitigate the risks to an acceptable level.

So I think Lindsay might have mentioned, we do have these red flags in the labeling actually on the outside of the carton, so that anybody even in the early stages of deciding whether they want this OTC product would see warnings about deformities of the ear or asymmetric hearing loss, like you say, or sudden worsening of hearing loss or drainage, or any other number of things, those red flag signs and symptoms.

So we do have that prominently within the labeling. We believe this would adequately mitigate the risks of delay and diagnosis. But we would very much appreciate any comments we have from our external stakeholders.

Mohamed Hamid: Thank you very much. And I would also suggest adding if they have any ear ringing or vertigo because that can precede the detection of hearing loss. Appreciate your time. This was an excellent presentation for everybody.

Eric Mann: Yes. And we do have, actually, pain and vertigo in the labeling as well.

Mohamed Hamid: Great.

Elias Mallis: Thank you for the question, Mohamed. We have quite a few hands raised and not too much time left, so we'll try to get through as many as we can. Nicole Russell, you are now up next. Please go ahead and unmute yourself and ask your question of our panelists.

Nicole Russell: Hi. Thank you for taking my question. Can you hear me?

Elias Mallis: Yes.

Nicole Russell: Thank you. For OTC hearing aids that will not be self-fitting and therefore will not require a 510(k), how can consumers be assured the device is effective for mild to moderate hearing loss? The output limits address safety, but I'm curious about your views on ensuring or demonstrating effectiveness, especially given that there are a number of lower quality devices on the market today.

Elias Mallis: Thank you for that very excellent question. Vasant, I don't know if you wanted to touch upon the technical specifications as relates to the question?

Vasant Dasika: Yeah, sure. I could talk to that and others can add on if they have input on the FDA side. So, yeah, you mentioned in your question we already have the maximum output limit. And in addition, and like you said, that covers mainly the safety aspect. But for effectiveness we also were trying to look what's out there in the field consensus-wise in this area. And one source that we recognize there was the ANSI CTA 2051 PSAP standard.

So there were a number of, I think they call them category one, two, and three requirements. So we ended up trying to look at that list carefully. And also in consideration of inputs at the National Academy of Science, Engineering, and Medicine public workshop in 2017 to consider both sources as a whole. And

as a result, we proposed there in this proposed rule things like total harmonic distortion plus noise, self-generated noise, sufficiently low device latency and frequency response bandwidth that's sufficient, and frequency response smoothness that's smooth enough.

So those areas should help get to a certain bar of effectiveness or help to ensure that. Does that answer your question?

Nicole Russell: Yes. Thank you. So it sounds like you're really relying on the electroacoustical requirements defined in the regs as the primary driver for effectiveness?

Vasant Dasika: Yes. That's how we're looking at it.

Nicole Russell: Thank you.

Elias Mallis: Thank you, Nicole for the question and Vasant for the response. We have time, I think, for one more question. We'll try to squeeze it out. Virginia Ramachandran, I'm going to unmute you here. Go ahead and ask your question for the panel.

Virginia Ramachandran: Oh, thank you. The proposed regulations, as you stated before, don't explicitly say that hearing health care providers can't be included in the provision of services or selling OTC devices. It does say, however, that a person cannot be compelled to have a hearing test or hearing evaluation, was my understanding of reading it.

There are many state laws that require hearing health care providers to provide a hearing assessment if they are going to sell a hearing aid. Does this mean in many states that hearing, that audiologist or hearing health care providers might not be able to, in fact, sell the devices, OTC devices, in their practices?

Elias Mallis: Thank you for the question. Ian, would you like to provide a response?

Ian Ostermiller: Sure. I can respond and somebody else can add anything I miss. The basic idea is that states will not be able to require any specific action or responsibility when it comes to just selling an OTC hearing aid. So a state cannot compel somebody to go through a fitting test, or can't compel the seller to provide a fitting prior to purchase.

Now if a person comes into an audiologist and wants to buy an OTC hearing aid and also wants a hearing examination or evaluation, that person is free to do so. However, the state cannot make that person jump through those hoops for an OTC device.

Elias Mallis: Thank you, Ian. And with that, will be our last question for the day. I'd like to turn it over to Nandu to give us some final thoughts for our audience today.

Srinivas Nandkumar: Thank you, Elias. Thank you all for your questions and thank you for attending today. As we mentioned in our presentation, FDA's proposed rule, as directed by FDARA, provides consumers with a safe and effective option for an over-the-counter hearing aid. We also expect that this rule, along with the PSAP guidance, will reduce the confusion in the marketplace and provide manufacturers with clear pathways to market their respective products, and clearer options for hearing health care professionals and users to use or help use these products.

So we really would appreciate your comments to the dockets. As we had mentioned earlier in the presentation, the close date for the comments is January 18, 2022. And we will then take those comments and proceed towards finalizing this rule, as Ian mentioned. And again, thank you and appreciate you attending this webinar.

Elias Mallis: All right, thank you, Nandu. Thank you everyone. So this will conclude today's CDRH webinar. I'd like to thank our panelists today, Drs. Eric Mann, Nandu Nandkumar, Vasant Dasika, and Lindsay DeVries, as well as Ian Ostermiller for joining us today for this really important topic, and, of course, of interest to you.

I'd like to also thank Linh Lo, Policy Analyst in OPEQ, who's been instrumental with this effort as well. And finally, I'd like to thank you, our audience, for your participation and questions for our FDA panel today

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We also encourage you to attend a future CDRH webinar. The link on the bottom of the slide provides a listing of all scheduled upcoming webinars. Again, this is Elias Mallis from the Division of Industry and Consumer Education. I'd like to thank you for joining us today. Take care and we'll see you next time.

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