Loud and Clear:

Why Americans Want Effective and Affordable Over-the-Counter Hearing Aids – and How Powerful Special Interests are Trying to Undermine Them

Prepared by the Offices of Sen. Elizabeth Warren and Sen. Chuck Grassley

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Contents

Executive Summary

The *Over-the-Counter Hearing Aid Act*, introduced by Senators Elizabeth Warren and Chuck Grassley, was passed into law in August 2017 and removes outdated regulations that block consumer access to affordable hearing aids.[1] The law allows certain types of hearing aids to be made available over-the-counter (OTC) to Americans with mild to moderate hearing loss, reducing costs and allowing millions of Americans to save hundreds or even thousands of dollars on the hearing aids they need.

The Food and Drug Administration (FDA) is responsible for implementing this law and, in October 2021, issued a proposed rule for "Establishing Over-the-Counter Hearing Aids."[2] The proposed rule contains three key provisions that are designed to ensure that the new OTC hearing aid market is robust and complies with Congress' intent to improve access and reduce consumer costs. First, FDA proposed a "maximum output limit" of 120 decibels (dB) sound pressure level (SPL) for OTC devices.[3] It also did not impose a limit on "gain," which controls how much the device amplifies input.[4] Consistent with the views of leading experts, these two provisions are designed to ensure that OTC hearing aids will amplify sound at levels that will make them effective for consumers with both mild and moderate hearing loss, without compromising consumer safety.[5] The FDA also proposed preempting state and local laws that would artificially restrict the new OTC hearing aid market and unnecessarily limit consumer access to OTC hearing aids.[6] If these provisions are weakened in the final rule, it would make OTC hearing aids much less effective for consumers with mild and moderate hearing loss, diminishing their appeal, and significantly hampering the OTC hearing aid market.

Over the course of a 90-day public comment period, FDA received approximately 1,100 comments on the proposed rule.[7] To understand the nature of the public's response, Senators Warren and Grassley's staff conducted a comprehensive review of these comments. This report contains the results of that review. The comments received by the FDA reveal (1) the significant positive impact that OTC hearing aids could have on Americans across the country, (2) the support of key health care professional groups for the proposed rule, (3) dominant hearing aid manufacturers' strong opposition to critical pieces of the proposed rule, and (4) the wide use of industry-funded "astroturf" campaigns intended to distort the public response to the FDA rule and sway regulators to adopt changes that would benefit the dominant hearing aid manufacturers, reduce competition, and increase costs for consumers. Specifically, the review finds:

- **Americans Believe OTC Hearing Aids Will Have Significant Benefits**

Nearly 38 million Americans experience some degree of hearing loss, and people with hearing loss are more likely to experience feelings of loneliness and isolation.[8] The coronavirus disease 2019 (COVID-19) pandemic has only exacerbated these concerns.[9] In the public comments, Americans shared personal stories about how hearing loss has affected them and their loved ones. As one person explained, "Now I understand why my father didn't want to eat out with us and missed so many wonderful occasions."[10] Others shared their experiences struggling to afford hearing aids: "I do recall my mother struggling with the cost of hearing aids; and I also remember that the hearing aid was the first item to be sacrificed when her budget tightened."[11] On average, hearing aids typically cost around $4,600 a pair and are not generally covered by private health insurance plans or traditional Medicare.[12] Because of these high costs, only one in five people who could benefit from a hearing aid use one.[13] Another commenter shared, "Even with 'good' insurance, I have not yet purchased hearing aids due to the $2000+ out of pocket costs. I know that hearing aids will improve my quality of life, but I need to be able to afford them."[14]

- **Key Health Care Professional Groups Support FDA's Proposed Rule**

Many comments submitted by health care professionals, including the Academy of Doctors of Audiology (ADA), indicated support for the proposed rule and affirmed that it would allow for safe and effective OTC hearing aids. For example, in its comment letter, the ADA wrote that that the organization "enthusiastically supports the Proposed Rule … [and] supports FDA's proposal to allow an output limit for OTC hearing aids … of 120 dB SPL."[15] ADA also asked that FDA "forgo gain limitations for OTC hearing aids," and supported federal preemption.[16] Many comments from other health care professionals also support the FDA proposed rule and grasp the benefit of OTC hearing aids.

- **Dominant Hearing Aid Manufacturers Are Seeking to Weaken FDA's Proposed Rule**

The hearing aid market is highly concentrated, which contributes to the high price of hearing aids. The "Big Five" hearing aid manufacturers – Sonova, WS Audiology, William Demant, GN Store Nord, and Starkey – control more than 90 percent of the market.[17] These giant hearing aid manufacturers benefit from the status quo and have opposed key provisions of the FDA's proposed rule – most notably the 120 dB SPL output limit, the absence of a gain limit, and federal preemption requirements.

- **Dominant Hearing Aid Manufacturers and Aligned Groups Backed Astroturf Campaigns to Weaken FDA's Proposed Rule and Distort Public Perception**

Almost immediately after FDA issued the proposed rule, stakeholders benefitting from the status quo launched letter-writing campaigns that generated over 400 comments which – in whole or in part – appeared to be form letters rather than the independent views of those that sent them. These comment letters were ostensibly written by individuals, but in reality reflect industry talking points. In total, Senators Warren and Grassley's staff identified what appear to be 19 industry-driven form letters, and language from these letters appeared in over 400 comments, accounting for nearly 40 percent of all publicly available comments that FDA received on the proposed rule.

The findings of this investigation are important, revealing a powerful entrenched industry using astroturf lobbying tactics to influence FDA's rulemaking process and weaken the agency's OTC hearing aid rule. If successful, the proposed changes to the FDA rule would result in higher costs and fewer choices for consumers. As FDA reviews the public comments, the agency should not give undue weight to the comments generated by these industry campaigns. Instead, FDA should follow the *Administrative Procedure Act* and finalize a rule that is consistent with the independent recommendations from the scientific community and Congressional intent.[18] In doing so, the final rule should not contain any unnecessary restrictions that hinder access to OTC devices or their utility for Americans with mild to moderate hearing loss. FDA must ensure that OTC hearing aids are effective, accessible, and affordable for all Americans.

Introduction

In 2017, Congress passed the *FDA Reauthorization Act*, which included Senators Warren and Grassley's *Over-the-Counter Hearing Aid Act* requiring the FDA to allow the sales of OTC hearing aids. The law further required FDA to issue implementing regulations no later than August 18, 2020.[19] FDA missed this deadline by over a year. But finally, more than four years after the law passed, the agency released a proposed rule for notice and comment in October 2021.[20]

The *Over-the-Counter Hearing Aid Act* allows hearing aids to be sold over the counter to Americans with mild to moderate hearing loss, increasing competition, and lowering prices in an otherwise highly-concentrated industry. There are

nearly 38 million people in the United States who experience some degree of hearing loss.[21] Older Americans are particularly affected, with nearly half of adults 75 or older reporting difficulty hearing.[22] Americans with hearing loss are at a greater risk of developing Alzheimer's Disease and Alzheimer's Disease Related Dementias,[23] and they are also more likely to experience feelings of loneliness and isolation, which the COVID-19 pandemic has exacerbated.[24]

Despite the prevalence of hearing loss, only one in five people who could benefit from a hearing aid use one, mainly due to high costs.[25] Hearing aids are not generally covered by private health insurance plans or traditional Medicare and can cost thousands of dollars – making them prohibitively expensive for many Americans.[26] The average price for a pair of hearing aids is around $4,600.[27] As a result, a robust OTC hearing aid market could generate as much as $147 million in savings for seniors each year.[28]

The high prices of hearing aids are due, in part, to the degree of market concentration in the hearing aid industry. In 2016, the President's Council of Advisors on Science and Technology (PCAST) described the hearing aid industry as "highly concentrated" and noted that "just six hearing-aid manufacturers (mostly based outside of the United States) have been dominant for the past 15 years."[29] Since then, the "Big Six" hearing aid manufacturers have further consolidated into the "Big Five." Today, Sonova, WS Audiology, William Demant, GN Store Nord, and Starkey control more than 90 percent of the market.[30] The introduction of OTC hearing aids will allow more businesses to enter the hearing aid market, creating more competition and providing consumers with more options at a price they can afford.

Despite objections from the "Big Five" manufacturers and others who benefit from the status quo, FDA's proposed rule contains three key provisions that would ensure that consumers are able to access safe and effective OTC hearing aids. First, the proposed rule establishes a maximum output level of 120 dB SPL,[31] which is consistent with guidance from the American National Standards Institute, National Institute for Occupational Safety and Health, and National Academies of Sciences, Engineering, and Medicine (NASEM).[32] Second, the proposed rule does not include a gain limit for OTC hearing aids, which is also consistent with NASEM's recommendation.[33] Together, these two provisions ensure that OTC hearing aids will provide sufficient output and amplification to help individuals with both mild and moderate hearing loss, making sure that eligible consumers can obtain hearing aids that are both safe and effective.

Third, the proposed rule contains federal preemption provisions on state and local government laws, regulations, orders, or other requirements pertaining to hearing products to prevent restrictions with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids.[34] In 2015, PCAST found that "complex state regulations restrict the distribution channels for hearing aids" and recommended that FDA "preempt State requirements that the OTC devices be sold by credentialed dispensers."[35] They concluded that "the net benefit [of this approach] to the public would be large and positive."[36] NASEM also advised the federal government to "preempt potential future state laws and regulations seeking to limit over-the-counter access."[37] Consistent with these recommendations, the *Over-the-Counter Hearing Aid Act* – which passed 94 to 1 in the Senate and unanimously in the House[38] – established clear lines on federal preemption, which the FDA has implemented in its proposed rule.

After releasing its proposed rule in October 2021, FDA invited public comment on the proposed rule for 90 days. The public comment period closed on January 18, 2022, and approximately 1,100 comments[39] were submitted to the agency by that date.[40] Senators Warren and Grassley's staff analyzed the public comments submitted to the

FDA on the proposed rule, including comments submitted by hearing aid manufacturers, ordinary consumers, audiologists, and other health care professionals. Staff also carefully reviewed comments to determine if they used language that was identical or nearly identical to other comments. This revealed a significant number of form letters, the overwhelming majority of which were driven by stakeholders with a vested interest in weakening the proposed rule.[41] This report contains the results of the staff review.

Findings

- **Finding 1: Americans Believe OTC Hearing Aids Will Have Significant Benefits**

Americans submitted numerous public comments explaining what accessible, affordable, safe, and effective OTC hearing aids would mean to them and their loved ones. Many comments were not technical, but rather clearly focused on the urgent need for effective and affordable OTC hearing aids.

The individuals who submitted these comments shared the impact that hearing loss has had on their lives and how it has changed their ability to communicate with friends and family. Some commenters even mentioned having to watch their parents go through similarly frustrating experiences years before.

- **"Please approve quickly the over-the-counter hearing aids.** This would be such a wonderful way for people with hearing difficulties to get help without spending thousands of dollars. So many times I miss what my grandchildren are saying and have to ask them to repeat it. It takes away the desire to eat out when you can't hear. Now I understand why my father didn't want to eat out with us and missed so many wonderful occasions. This would enrich so many lives. Please hurry with your approval. Thank you."[42] Kathy S.
- **"I am 65 and have mild to moderate hearing loss.** My hearing loss greatly affects my understanding of simple conversation and I am always asking people to repeat what they said while I try to read their lips. Affordable hearing aids would greatly improve my quality of life by allowing me to feel comfortable in social situations."[43] Mark M.

Commenters also shared that the high cost of hearing aids played a significant role in their decision to delay care.

- **"I am 71 years old and have been putting off the purchase of hearing aids for years now because of the high cost.** I do understand what goes into a product such as engineering, product development, marketing [etc.] but my Father had multiple sets of hearing aids 30 some years ago & the prices he paid were also sky high. I thin[k] after all of these years of being out on the market to consumers, most hearing aid manufacturers have more than recouped their own development costs."[44] Robert G.
- **"'Too few manufacturers have a monopoly on the current market and demand very high prices…Even with 'good' insurance, I have not yet purchased hearing aids due to the $2000+ out of pocket costs.** I know that hearing aids will improve my quality of life, but I need to be able to afford them…Please, please move this forward and establish an open market."[45] Dave P.
- **"I do recall my mother struggling with the cost of hearing aids; and I also remember that the hearing aid was the first item to be sacrificed when her budget tightened.** Now, as I am crowding '70', my family is suggesting that I get one [...] I believe that I will benefit from a hearing aid. The prospect of easily obtainable, reasonably priced OTC hearing aids is [a] small consolation in my case. But it is still better than enduring high-cost technology, not covered by insurance, and yet another doctor in my life."[46] Paul G.

It is clear that the time is long overdue for FDA to make affordable and effective OTC hearing aids widely available.

- **Finding 2: Key Health Care Professional Groups Support FDA's Proposed Rule**

Many comments from health care professionals, including the Academy of Doctors of Audiology (ADA), indicated support for the proposed rule and affirmed that it will allow for safe and effective OTC hearing aids. In its comment letter, the ADA wrote that the organization "enthusiastically supports the Proposed Rule overall and supports its goal to increase competition, expand product choices, reduce prices, and remove existing channel restrictions encountered by consumers."[47] The ADA specifically mentioned that it supports "FDA's proposal to allow an output limit for OTC hearing aids equipped with input-controlled compression and user adjustable volume control of 120 dB SPL at any frequency" and to "forgo gain limitations for OTC hearing aids."[48]

Other health care professionals and experts also expressed support for the FDA's proposed rule and grasped the benefit of OTC hearing aids for consumers:

- **"As a physician, I agree with the proposed rule.** There is little risk to patients, and great potential benefit."[49] Robert F.
- **"Please focus on the patient when making this decision…there is a significant disparity in patients due to financial burdens and lack of resources to appropriate personnel which are easily modifiable factors if you were to pass OTC hearing [aids]…I am a practicing PA and as a PA I always feel the need to treat the underserved and this is such a great opportunity to do just that on a much larger scale."**[50] Evan O.
- **"[We support] the current proposed maximum output of 120 dB SPL with a volume control (or 115 dB SPL without volume control)…narrower restrictions would limit the effectiveness of OTC hearing aids, restrict the population of individuals with hearing loss who could benefit from OTC hearing aids, and substantively hinder technological innovation."**[51] Johns Hopkins Cochlear Center for Hearing and Public Health.
- **"[C]laims that federal preemption of state laws in this draft rule will undermine state consumer protection laws are unfounded.** This rule as presently written does not affect current or future state and local laws of general applicability to consumer protections."[52] Former Committee Members of the National Academies Consensus Study on Accessible and Affordable Hearing Care for Adults.

To be sure, not all groups representing audiologists or hearing aid specialists supported the FDA's proposed rule. Indeed, many health care professionals are employed by or enjoy exclusive licensing deals with dominant hearing aid manufacturers, allowing them to benefit from the existing system.[53] But overall, the consensus of independent health care experts appeared to indicate that they support the key provisions of the FDA rule and do not believe that these provisions would pose safety concerns to patients.

- **Finding 3: Dominant Hearing Aid Manufacturers Are Seeking to Weaken FDA's Proposed Rule**

The "Big Five" hearing aid manufacturers and other large manufacturers that benefit from the status quo are working to undermine the effectiveness of OTC hearing aids. These companies are pushing FDA to lower the proposed output level for OTC hearing aids, establish a gain limit, and weaken the federal preemption of state laws that, left standing, would impose serious barriers to accessing OTC devices. In their comments, they indicated:

- **"Starkey believes a reasonable assurance of effectiveness can only be provided for OTC hearing aids by establishing a gain limit of 25 dB and revising the output limit to ensure OTC hearing aids do not provide amplification beyond 110dB."**[54] Starkey, the largest U.S.-based hearing aid manufacturer.[55]
- **"Amplifon urges the FDA to…establish safer product requirements that are more appropriate for users with mild to moderate hearing impairment, including lowering the maximum output (OSPL90) to 110 dB SPL and implementing a gain limit of 25 dB."**[56] Amplifon.
- **"[I]ndividuals who use OTC hearing aids with no gain limit and 120 dB SPL maximum output levels (with or without input compression) as proposed by the draft OTC hearing aid rule are at a significant risk for developing noise-induced hearing loss."**[57] Hearing Industries Association (HIA), a trade group that represents giant manufacturers and distributors including Amplifon, GN Store Nord, Signia, Starkey, and Widex.[58]
- **"In this comment, we…propose the following improvements to the final rule: […] Clarify a narrow scope of preemption that retains state and local protections."**[59] Starkey.
- **"HIA recommends that FDA take a bright-line approach to preemption.** That is, HIA suggests that FDA preempt state requirements pertaining directly to the hearing aid device; states could still retain any licensing requirements that are not specific to the hearing device itself."[60] HIA.

Although couched in concerns about patient safety, the changes sought by these dominant manufacturers and their representatives would actually have the effect of making OTC hearing products less effective, protecting manufacturers' existing market share, and locking in their competitive advantage. The logic is simple: the less effective an OTC hearing aid is, the more likely consumers will be forced to abandon these options and instead opt for more expensive, prescription devices sold by the manufacturers that dominate this line of business. This will be especially true for consumers with moderate hearing loss who will benefit disproportionately from OTC devices with higher output limits.

This also applies to the concerns the dominant manufacturers have raised about federal preemption. Barring a clear, specific, and broad federal preemption, many current state laws and regulations would continue to limit OTC hearing aid access, and steer consumers into manufacturer-owned or affiliated retail clinics by requiring adult consumers to visit a licensed hearing aid dispenser in order to obtain these devices. By preempting these laws, FDA's proposed rule would "lead to changes in the business models of many audiologists and hearing aid dispensers."[61] The potential hit to their bottom lines has prompted dominant hearing aid manufacturer and distributor stakeholders to attempt to weaken FDA's federal preemption standard under the guise of consumer protection, even though "the net benefit to the public [of the proposed federal preemption] would be large and positive."[62]

Efforts to lessen the effectiveness of and access to OTC hearing aids represent a clear attempt to undermine the formation of a competitive OTC hearing aid market – and dominant manufacturers have leaned on these arguments for years. The same groups strongly opposed and lobbied heavily against the *Over-the-Counter Hearing Aid Act* as Congress considered the legislation in 2017.[63] According to reports at the time, dominant manufacturers and some hearing aid specialists were "critical of the legislation from the start."[64] Starkey, HIA, and Amplifon spent tens of thousands of dollars lobbying against OTC hearing aids. Starkey spent "$50,000 lobbying on the issue in the first three months of [2017] – the first time in a decade the company [spent] money

on lobbying."[65] Meanwhile, HIA "spent the same amount" as of May 2017, "as [had] Amplifon, the world's largest hearing aid distributor (which also spent $90,000 on the issue [in 2016])."[66] Moreover, Starkey's President and HIA Board Member Brandon Sawalich fought aggressively to limit eligibility for OTC hearing aids to "only individuals with mild hearing loss," excluding consumers with moderate hearing loss to limit competition and minimize the impact on Starkey's bottom line.[67] Starkey has also accelerated and expanded its contributions to candidate campaigns. Since 2019, Starkey has spent over $2 million in campaign contributions, including more than $1.6 million in the 2020 cycle and another $800,000 so far in the 2022 cycle.[68]

- **Finding 4: Dominant Hearing Aid Manufacturers and Aligned Groups Backed Astroturf Campaigns to Weaken FDA's Proposed Rule and Distort Public Perception**

Senators Warren and Grassley's staff reviewed approximately 1,100 public comments[69] provided to FDA, and found that nearly one in four (439 comments) replicated industry-driven talking points opposing key provisions of the proposed rule. Although written by individuals, many of these letters used identical or nearly-identical language, suggesting that they were sent as part of extensive industry-backed "astroturf" campaigns designed to give the impression of an independent grassroots response.

Staff identified a total of 19 different form letters that either raised concerns with or recommended changes to the maximum output level, gain limit, and federal preemption requirements or any combination of the three. These letters appeared to be part of a coordinated effort to distort the public response.

Senators Warren and Grassley's staff determined that at least three form letters were clearly linked to dominant manufacturers and aligned groups. First, the largest U.S.-based hearing aid manufacturer,[70] Starkey, sponsored a campaign called "Listen Carefully" that encouraged individuals to submit comments using a form letter template, which is shown in Figure A.[71] An example of a public comment employing this template is displayed in Figure B.[72] The substance of the campaign talking points and the letter are identical.

Figure A – Listen Carefully Form Letter

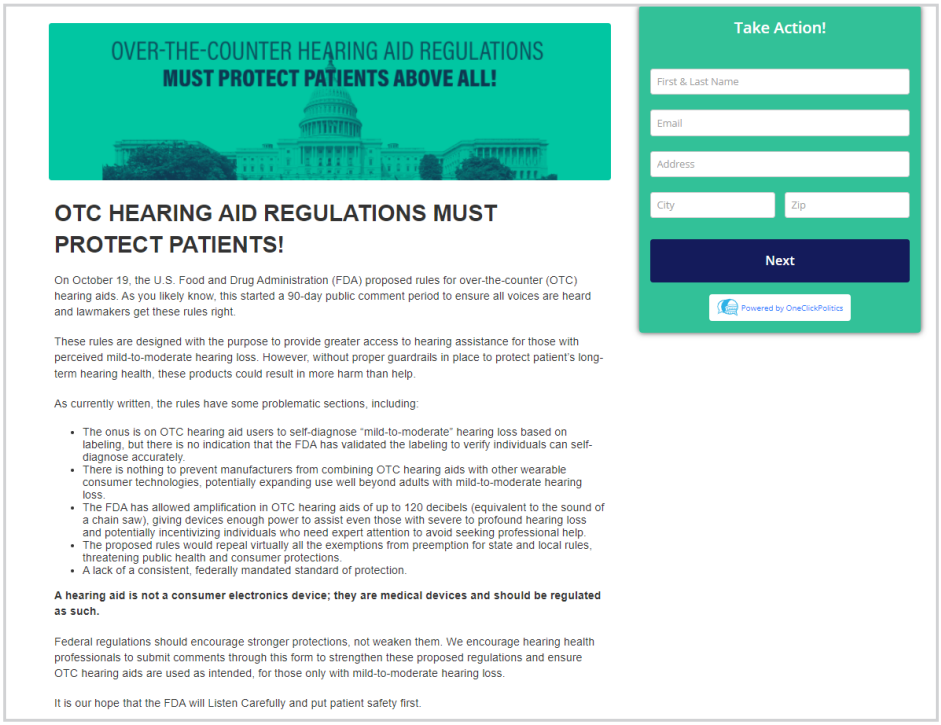


Figure B – Public Comment Generated from Listen Carefully's Template

OTC HEARING AID REGULATIONS MUST PROTECT PATIENTS!

On October 19, the U.S. Food and Drug Administration (FDA) proposed rules for over-the-counter (OTC) hearing aids. As you likely know, this started a 90-day public comment period to ensure all voices are heard and lawmakers get these rules right.

These rules are designed with the purpose to provide greater access to hearing assistance for those with perceived mild-to-moderate hearing loss. However, without proper guardrails in place to protect patient's long-term hearing health, these products could result in more harm than help.

As currently written, the rules have some problematic sections, including:

The onus is on OTC hearing aid users to self-diagnose "mild-to-moderate" hearing loss based on labeling, but there is no indication that the FDA has validated the labeling to verify individuals can self-diagnose accurately.
There is nothing to prevent manufacturers from combining OTC hearing aids with other wearable consumer technologies, potentially expanding use well beyond adults with mild-to-moderate hearing loss.
The FDA has allowed amplification in OTC hearing aids of up to 120 decibels (equivalent to the sound of a chain saw), giving devices enough power to assist even those with severe to profound hearing loss and potentially incentivizing individuals who need expert attention to avoid seeking professional help.
The proposed rules would repeal virtually all the exemptions from preemption for state and local rules, threatening public health and consumer protections.
A lack of a consistent, federally mandated standard of protection.
A hearing aid is not a consumer electronics device; they are medical devices and should be regulated as such.

Federal regulations should encourage stronger protections, not weaken them. We encourage hearing health professionals to submit comments through this form to strengthen these proposed regulations and ensure OTC hearing aids are used as intended, for those only with mild-to-moderate hearing loss.

It is our hope that the FDA will Listen Carefully and put patient safety first.

In another example, the group Hear About Hearing, which does not disclose its funding or membership, launched a letter–writing campaign to oppose the rule.[73] Hear About Hearing provided prospective letter writers with instructions on how to make their comments appear independent, such as stressing the importance of inserting personal experiences between pre-written arguments (as shown in Figure C).[74] A public comment employing this strategy is highlighted in Figure D.[75] The last two paragraphs of the public comment are copied verbatim from the language suggested by Hear About Hearing.

Figure C – Hear About Hearing Form Letter Prompt

Step one:

Go to this site: http://www.hearabouthearing.org/act-now.html

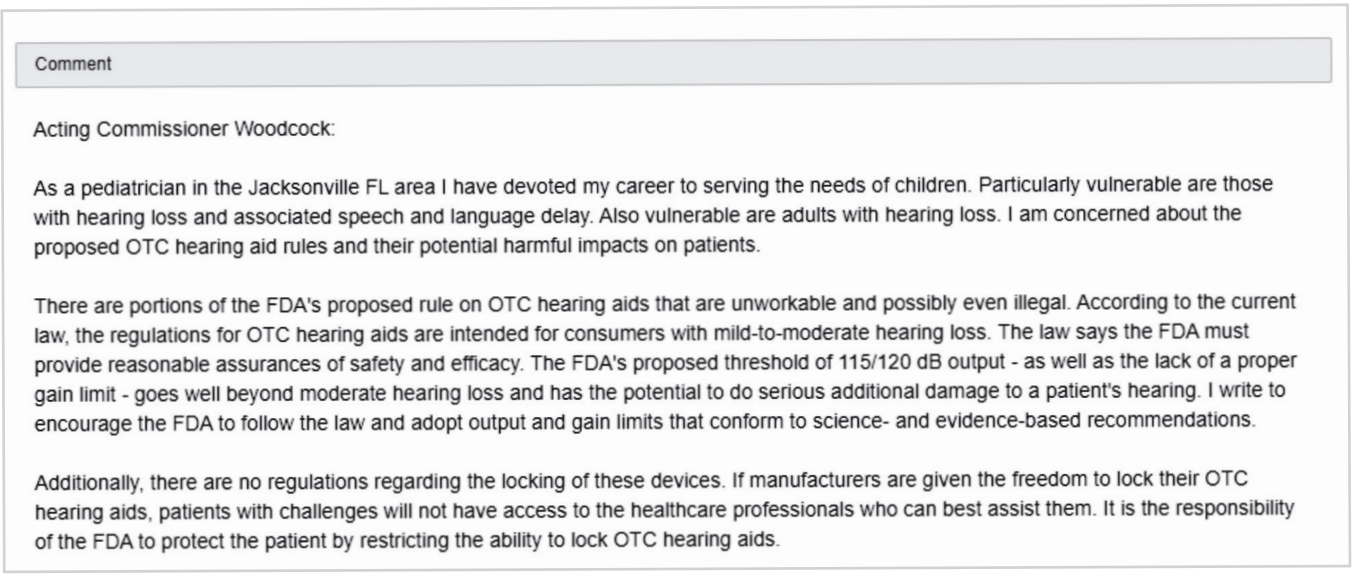
Step two:

Submit your message. You do this on by clicking the link above. You can use the one that is there or the one that we recommended below:

> Subject: Changes Needed to Proposed FDA Regulations
>
> Acting Commissioner Woodcock:
>
> ***[Insert your personal tie, including your journey with hearing loss, your experience with hearing aids, and the audiology services you have received]***
>
> There are portions of the FDA's proposed rule on OTC hearing aids that are unworkable and possibly even illegal. According to the current law, the regulations for OTC hearing aids are intended for consumers with mild-to-moderate hearing loss. The law says the FDA must provide reasonable assurances of safety and efficacy. The FDA's proposed threshold of 115/120 dB output – as well as the lack of a proper gain limit – goes well beyond moderate hearing loss and has the potential to do serious additional damage to a patient's hearing. I write to encourage the FDA to follow the law and adopt output and gain limits that conform to science- and evidence-based recommendations.
>
> Additionally, there are no regulations regarding the locking of these devices. If manufacturers are given the freedom to lock their OTC hearing aids, patients with challenges will not have access to the healthcare professionals who can best assist them. It is the responsibility of the FDA to protect the patient by restricting the ability to lock OTC hearing aids.

More information regarding the proposed regulations can be found at:
http://www.hearabouthearing.org

Figure D – Comment Generated from Hear About Hearing Campaign



Comment

Acting Commissioner Woodcock:

As a pediatrician in the Jacksonville FL area I have devoted my career to serving the needs of children. Particularly vulnerable are those with hearing loss and associated speech and language delay. Also vulnerable are adults with hearing loss. I am concerned about the proposed OTC hearing aid rules and their potential harmful impacts on patients.

There are portions of the FDA's proposed rule on OTC hearing aids that are unworkable and possibly even illegal. According to the current law, the regulations for OTC hearing aids are intended for consumers with mild-to-moderate hearing loss. The law says the FDA must provide reasonable assurances of safety and efficacy. The FDA's proposed threshold of 115/120 dB output - as well as the lack of a proper gain limit - goes well beyond moderate hearing loss and has the potential to do serious additional damage to a patient's hearing. I write to encourage the FDA to follow the law and adopt output and gain limits that conform to science- and evidence-based recommendations.

Additionally, there are no regulations regarding the locking of these devices. If manufacturers are given the freedom to lock their OTC hearing aids, patients with challenges will not have access to the healthcare professionals who can best assist them. It is the responsibility of the FDA to protect the patient by restricting the ability to lock OTC hearing aids.

A third form letter included language that was identical to a social media post that Hear About Hearing shared with its followers. The specific social media post is captured in Figure E[76] and a comment that features the post's language is highlighted in Figure F.[77] In total, 31 comments reflected Hear About Hearing language.

Figure E – Hear About Hearing Tweet

← Tweet

Hear About Hearing
@hear_hearing

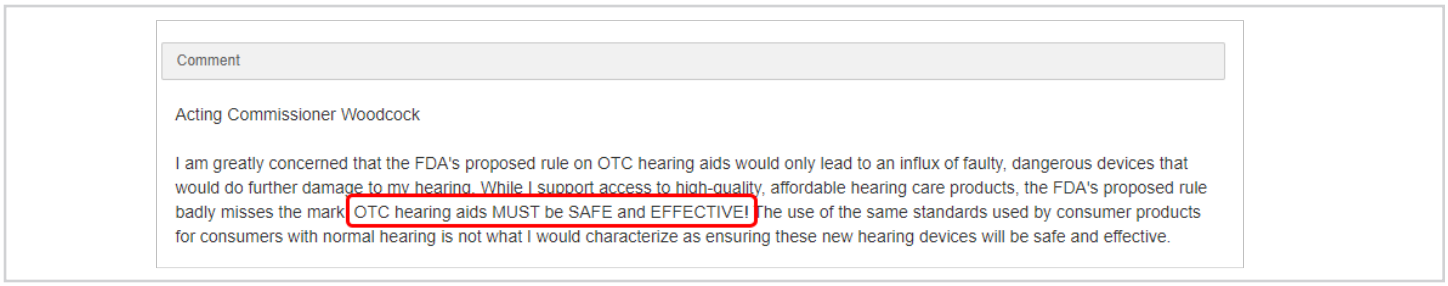
FDA's proposed output threshold for OTC hearing aids is very dangerous for individuals with mild-to-moderate hearing loss.

Tell @US_FDA: OTC #HearingAids MUST be SAFE and EFFECTIVE!

hearabouthearing.org
Tell FDA: Promote Safety and Effectiveness for OTC Hearin...
Submit a comment on the FDA's rulemaking on over-the-counter hearing aids today.

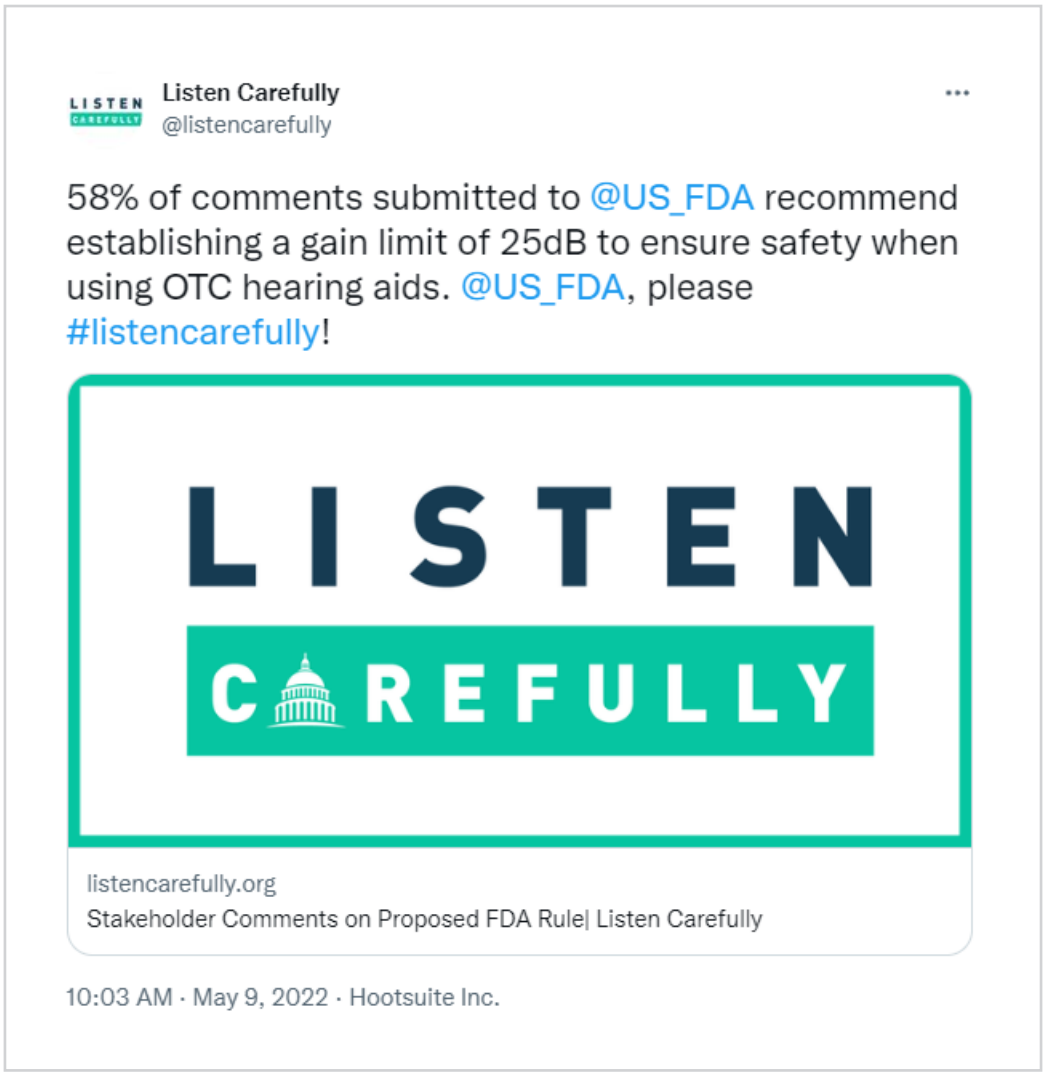
11:02 AM · Nov 16, 2021 · TweetDeck

Figure F – Form Letter with Language from Hear About Hearing's Social Media Post



Stakeholders have used these letters to serve their own interests. For example, Starkey – through Listen Carefully – has cited the public comments generated from these astroturf campaigns in the company's broader efforts to weaken FDA's proposed rule (see Figure G).[78]

Figure G – Listen Carefully Tweet



The other form letters that Senators Warren and Grassley's staff identified, while not conclusively tied to a specific industry group, repeat language and talking points that are similar to those highlighted by Starkey and Hear About Hearing. In some cases, a specific sentence or phrase appeared in dozens of public comments, suggesting the letter may have originated from an astroturf campaign.

For example, the sentence, "OTC hearing aids should have a limit of 110 dB output and 25 dB gain" or a slight variation of it, appeared in 13 of the 19 form letters and in a total of 352 comments.

Similarly, the following sentence or a similar variation about the proposed rule's effect on consumer protections appeared in three form letters and 33 comments: "[t]he proposed section pertaining to state pre-emption, as currently worded, would potentially remove these important consumer protections." Of the 14 comments that contained this exact phrase, all of them were submitted on the same day, suggesting a coordinated effort.

In some cases, the same typo appeared in multiple comments, clearly signaling that they were sent as part of an astroturf campaign. For example, 16 comments omitted the word "limit" from the same sentence, allowing staff to identify these comments as a single form letter (as shown in Table AA under form letter 9). Similarly, a typo in form letter 1 resulted in two different versions of the form letter being submitted to FDA. In 88 of the 97 comments associated with this form letter, the following sentence appeared (the relevant typo has been bolded): "FDA proposes this amplification limit based on the assumption that consumers can determine if a particular level of **sound of if too high** or harmful and then remove the hearing aid, all in less than 30 seconds." In three other comments, the exact same language was submitted, but the typo was corrected (again, in bold): "FDA proposes this amplification limit based on the assumption that consumers can determine if a particular level of **sound is too high** or harmful and then remove the hearing aid, all in less than 30 seconds." A third variation of the letter eliminated the sentence entirely.

Table AA documents the repetitive language used in each of the form letters, which clearly repeat the talking points of dominant hearing aid manufacturers.

Table AA: Excerpts of Repetitive Language in Form Letters Highlighting Industry Talking Points

Form Letter	Repetitive Language	Number of Comments
1	"As such, I recommend that FDA set an output limit of 110 dB and a gain limit of 25 dB"	97
2	"To that end, I recommend that the FDA adopt the recommendations established by the national associations representing hearing care professionals, which call for a maximum output limit of 110 dB SPL and a gain limit of 25 dB"	32
3	"FDA's current output limits of 115/120dB and omission of a gain threshold are unsafe for those with mild-to-moderate hearing loss"	32
4	"While I support access to high-quality, affordable hearing care products, the FDA's proposed rule badly misses the mark"	12
5	"I believe the FDA must lower the proposed output to 110 dB SPL and establish a gain of 25 dB"	35
6	"The FDA's proposed threshold of 115/120 dB output – as well as the lack of a proper gain limit - goes well beyond moderate hearing loss and has the potential to do serious additional damage to a patient's hearing"	19
7	"FDA's proposed threshold of 115/120 dB output cannot be considered safe for individuals with mild-to-moderate hearing loss. It would be my strong recommendation that the FDA adopt an output limit of 110 dB and gain of 25dB"	35
8	"The 110 dB output limit and the 25 dB gain limit were developed through consensus around these two limits based on significant research and experience from audiologists and hearing care specialists who take care of the hearing impaired every day"	26
9	"I strongly urge FDA to fix this rule by lowering the [limit] to 110 dB and establish a gain limit of 25 dB in order to ensure that OTC hearing aids do not harm consumers"	16
10	"OTC hearing aids should have a limit of 110 dB output and 25 dB gain. This is necessary to ensure safety and effectiveness"	30
11	"Appropriate output and gain limits. OTC hearing aids should have a limit of 110 dB output and 25 dB gain"	16
12	"The FDA must adopt output and gain limits of 110 dB/25dB as is recommended by leading hearing care professionals"	15
13	"I strongly recommend that the FDA adopt an output limit of 110 dB and gain limit of 25dB"	12
14	"The proposed 115-120 dB SPL output allows for significantly higher noise exposure than the 110 dB SPL output level recommended by the leading hearing healthcare organizations, which can lead to increased hearing loss. Additionally, the current proposal provides no gain limitations. The 25 dB gain limitations recommended by hearing healthcare professionals will provide access to the necessary amplification for mild to moderate hearing loss without risking further harm"	14
15	"The limits proposed by the FDA are the same as those developed by the consumer technology industry, which is inappropriate and dangerous for those with mild to moderate hearing loss. FDA must adopt output and gain limits of 110 dB/25dB"	10
16	"The FDA has allowed amplification in OTC hearing aids of up to 120 decibels (equivalent to the sound of a chain saw)"	5
17	"Over-the-counter hearing devices offer those suffering from perceived mild-to-moderate hearing loss a glimpse at the benefits hearing aids can bring; however, they can also bring serious issues if not properly regulated. That is why I request you consider and include the below in these crucial rules: • A gain limit of 25 decibel and an overall output limit of 110 decibels. The current proposed regulations would allow dangerous sound pressure levels to be at the user's fingertips endangering users with exposure that may result in discomfort and further hearing loss"	14
18	"The effect of the FDA's proposed threshold of 115/120 dB output – as well as the lack of a proper gain limit - is that serious damage to a patient's hearing could result due to overamplification"	8
19	"FDA's proposed threshold of 115/120 dB output is very dangerous for individuals with mild-to-moderate hearing loss"	11

This analysis provides abundant evidence that dominant hearing aid manufacturers and aligned organizations, whether through overt or disguised astroturf campaigns, coordinated explicit efforts to influence the FDA, weaken its final rule, and limit the threat of OTC hearing aids to their businesses.

Conclusion

Americans want safe, accessible, affordable, and effective OTC hearing aids. Dominant manufacturers have a long history of opposing OTC hearing aids. After their efforts to block passage of the *Over-the-Counter Hearing Aid Act* failed in 2017, these parties have taken the fight directly to FDA and tried to distort the public response to the agency's proposed rule.

FDA must stand firm against pressures to weaken the proposed rule from dominant manufacturers and others who benefit from the status quo. The agency should finalize a rule that protects consumers and promotes competition – and it should do so urgently. Specifically, FDA should maintain the maximum sound pressure level identified in the proposed rule and not introduce any limits on gain. FDA must also maintain requirements to preempt state laws that would restrict the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC products. In doing so, FDA's final rule will ensure consumers can access these devices without interference, as the *Over-the-Counter Hearing Aid Act* intended. Maintaining these provisions will further ensure that the final regulation successfully increases competition, spurs innovation, and brings down prices for consumers, while meeting the high standards of safety, manufacturing protections, and consumer labeling required of all medical devices.

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