

OTC Hearing Aids: Biden Administration Publishes Agenda for FDA Rulemaking; Self-fitting Hearing Aid Regulations Could Provide Template for Over-The-Counter Devices, Likely Increasing FDA Regulation in Addition to Competition

The Food and Drug administration is likely to soon publish a long-delayed notice of proposed rulemaking for Over-The-Counter hearing aid regulations, according to industry sources. Recently, the Biden Administration Office of Information and Regulatory Affairs published a regulatory [agenda](#) that included a timeline for an NPRM, though the rule has missed several similar deadlines in the last few years.

“We are trying to work diligently to put this regulation out there,” Health and Human Services Secretary Xavier Becerra told Senator Chuck Grassley in response to a question about the delay at a recent Senate hearing.

Sara Koblitz, an attorney who advises clients on FDA regulatory processes, told *The Capitol Forum* that the rule has been in legal review for over a year. Proponents of OTC hearing aids are also optimistic that action could finally come, given increased pressure from lawmakers like Grassley and industry groups.

“It is frustrating for many that the FDA has not published the OTC regulation yet,” Kate Carr, President of the Hearing Industries Association told *The Capitol Forum*, “they missed their statutory deadline in August 2020, citing Covid delays as the reason. Given the inclusion in the Spring 2021 Unified Agenda, we hope to see a draft regulation this year.”

Once the FDA publishes the rule, it would trigger an anticipated 60-day comment period, after which the FDA would have 180 days to publish the final rule after taking public comments into consideration.

OTC manufacturers likely to undercut existing price points. Regardless of when the FDA publishes the final rule, the regulations have the potential to seriously disrupt the hearing aid industry by simultaneously make hearing aids cheaper and more accessible for consumers while also placing greater regulations on manufacturers.

By law, OTC hearing aids will not require a visit to an audiologist, who historically have acted as gatekeepers of the industry, writing prescriptions for hearing aids manufactured by companies they have agreements with. These arrangements with hearing aid manufacturers such as Demant (WILYY) and Sonova (SONVY) have kept the price of hearing aids relatively high, with audiologist-prescribed hearing aids costing several thousand dollars.

“There is no reason for these prices except monopoly power,” Matt Stoller, a fellow at the Open Markets Institute, recently [wrote](#), adding, “the requirement that every hearing aid must be a prescription hearing aid redounded to the benefit of audiologists, as well a small cartel of firms who made approved hearing aid devices that cost huge sums of money.”

Tim Wu, a member of President Biden’s National Economic Council, also wrote in a 2017 [article](#) entitled “Antitrust Via Rulemaking: Competition Catalysts” that the FDA’s 2016 effort to open the market in hearing aids was an example of “pro-competitive deregulation.” Wu noted that the hearing aid market “is occupied by an oligopoly of providers, and the prices are high, as compared to the costs of other electronics.” The high price had discouraged the use of hearing aids, according to a report by the Presidential Council of Advisors on Science and Technology referenced in Wu’s article.

“The rulemakings are not yet complete,” Wu wrote, referring to the FDA’s OTC regulations, “but the pro-competitive, deregulatory logic intrinsic to the effort should be obvious.”

As *The Capitol Forum* has previously [reported](#), OTC hearing aids could pose a serious risk to the dominance of incumbent manufacturers, as the product category would make it easier for well-known audio brands like Bose and Samsung to enter the marketplace with cheaper products. Bose, for example, recently debuted \$850 hearing aids that cost a fraction of similar hearing aids.

On a May earnings call with investors, Sonova CEO Arnd Kaldowski discussed Bose’s price point and the effect it could have on the industry, saying that at a minimum, “there is not a transparent price point out in the market... I think we will learn more as other people show their cards after Bose, and we will see whether prices will sit at the end. But it's really hard to say \$850 is high or low. I don't know.”

Bose’s \$850 price point undercuts even the relatively cheap options in the marketplace provided by brands like Costco (COST), which has hearing aid centers at many of its locations where customers can get fitted by trained specialists. Costco markets its Kirkland brand of hearing aids for \$1400 and sells more expensive hearing aids from other manufacturers, capturing roughly 14% of all sales in the country [according](#) to the Hearing Review.

In some cases, the FDA does allow for hearing aid manufacturers to market and sell their devices directly to consumers without an exam, a process that companies like Eargo (EAR) have taken advantage of. Eargo sells its hearing aids for \$2,950, but the FDA requires its customers to sign a medical [waiver](#) informing them that it is not in their health interest to forgo a medical evaluation.

Eargo's direct to consumer product, however, could also be negatively affected by OTC hearing aid regulations if the FDA decides that OTC hearing aids need what is known as 510(k) clearance, a move supported by doctors and industry groups. All air conduction hearing aids are currently exempt from needing 510(k) clearance, which demonstrates the efficacy and safety of devices, because they are generally fitted by audiologists.

The process of getting 510(k) clearance, which can take several months, could cause some companies to remove their products from the market if they wanted to sell their devices as OTC hearing aids. Eargo listed this possibility as a risk factor in their SEC filings, noting that "we could be forced to cease distribution of our products until we obtain regulatory clearance or approval, and we could be subject to additional enforcement action by the FDA."

Eargo and Demant did not respond to a request for comment for this article, and representatives for Costco declined to comment on the FDA's rulemaking. A representative for Sonova said that "we are aware of the new regulatory changes and Spring 2021 Unified Agenda and are monitoring this issue."

Self-fitting regulations could provide template for OTC, requiring 510(k). While the FDA has yet to establish regulations for OTC hearing aids, the FDA has already established regulations for a strikingly similar kind of device, known as self-fitting hearing aids.

In 2018, Bose received a first-of-its-kind [approval](#) for hearing aids, an approval which required the FDA to create a new category for the device. Using a smartphone application, users of Bose's SoundControl hearing aids can make the same kinds of adjustments to the device that an audiologist would make.

Bose currently markets its SoundControl hearing aids for \$849, though without federal OTC regulations, the company is limited to selling the device in a handful of states.

In creating the self-fitting category of hearing aids, the FDA decided that these new devices would require 510(k) clearance in order to show that they are safe for consumers to use without an audiologist. Indeed, unlike the waivers that customers of Eargo have to sign acknowledging that forgoing an audiologist exam is not in their health interest, Bose customers only have to acknowledge "that the assistance of a hearing care professional or a hearing test is not required to purchase this product."

The law directing the FDA to establish OTC hearing aid regulations has several specifications for the new product class that bear similarities to self-fitting hearing aids. For example, the legislation requires that OTC hearing aids allow "the user to control the over-the-counter hearing aid and

customize it to the user's hearing needs" without requiring the involvement of a licensed physician, echoing the capabilities of self-fitting hearing aids. Additionally, OTC hearing aids are to be exempt from requiring any medical waivers, much like self-fitting hearing aids.

Senator Grassley, who wrote the original legislation mandating OTC hearing aids, seemed to say as much in a recent Senate hearing when he conflated Bose's self-fitting hearing aid with the delayed OTC regulations.

"Since 2017 law passed, the FDA has not issued regulations to establish the over-the-counter hearing aid market. Recently, the FDA authorized Bose to sell its over-the-counter hearing aid products, but there is no market for Bose to sell its product. So, my question to you, can you provide a timeline on FDA issuing over-the-counter hearing aid regulations?" Grassley asked Xavier Becerra, the Secretary of Health and Human Services.

"Senator, I know that we are in the works," Becerra replied, "I asked about this myself. I asked because my mother asked me what we were going to deal with this because she is one of those victims of those hearing aid commercials and so forth, and she's fed up with what happened with her. And she's been out some money. But I will tell you this. We are trying to work diligently to put this regulation out there. We know millions of Americans will benefit if we can help them make sure they're good consumers of hearing aids."

Perhaps most importantly, the law also directs Becerra to determine whether OTC hearing aids would require 510(k) clearance for sale. Given that the FDA has already found that self-fitting hearing aids should require 510(k) clearance, it is possible that the Secretary could find that OTC hearing aids should also not be exempt from 510(k) approval.

According to Abram Bailey, audiologist and CEO of [Hearing Tracker](#), "my guess is that they [FDA] may borrow much of the precedent from the Bose de Novo for self-fitting." Bailey believes any hearing aid being sold without real user ear measurements by an audiologist should require 510(k) approval by the FDA.

"There is a certain safety layer between the manufacturers and the consumer currently with audiologists fitting the products in person," Bailey said, "While not required or universal, many audiologists do validate the functionality and adequacy/safety of hearing aids on a daily basis by running test box measurements, real ear measurements, etc. So, if a problematic product were to hit the market, it would not take long for the safety layer to identify the problem and report it."

Medical experts also seem to largely agree that 510(k) approval should be required for all new devices being marketed as OTC hearing products. In a November 2020 editorial in the New

England Journal of Medicine, two Harvard professors advocated for the 510(k) approval requirement.

“This level of regulatory control,” the professors wrote, “could help assure the safety and effectiveness of OTC devices in the absence of traditional postmarket clinical oversight. For example, there are concerns that permitting direct-to-consumer sale of hearing aids could result in patients forgoing necessary care or damaging their hearing as a result of overamplification.”

A [consensus paper](#) endorsed by the American Academy of Audiology, Academy of Doctors of Audiology, American Speech-Language-Hearing Association and International Hearing Society also made a “strong recommendation” for 510(k) approval, saying that “the first OTC hearing device marketed by each manufacturer should be required to undergo the 510(k) processes.”

Given that Bose already has 510(k) approval for its product, a 510(k) requirement for OTC hearing aids could give the company a first mover advantage when selling nationally.

Asked about this, a Bose representative stated that “Bose is hopeful that the 510(k) clearance for self-fit is a large first step to transitioning to over-the-counter, and are eagerly awaiting the draft regulations.”

OTC regulations could envelop other product classes. Should the FDA model OTC regulations off of self-fitting hearing aid regulations, it would force any company that would like to enter the market to get 510(k) approval, and OTC regulations could also extend to other types of direct-to-consumer hearing aids such as those produced by Eargo.

According to Sara Koblitz, the attorney who advises clients on FDA regulations, “from our conversations [in late 2018] with FDA, we have heard that the OTC rules are going to be intended to envelop the DTC Products.”

Indeed, Eargo has labelled this retroactive classification as a risk factor in its SEC filings as well, noting that “our products could in the future be deemed to fall under the definition of a ‘self-fitting air-conduction hearing aid’ or an OTC hearing aid, in which case we could be required to seek 510(k) clearance for our products or otherwise comply with additional regulatory requirements associated with these new pathways.”