

09 Jul 2021 | News

Sweeping Executive Order Puts Hearing Aids Over The Counter; Cracks Down On Internet Providers

by [Brian Bossetta](#)

The Biden administration wants to make hearing aids less expensive and more readily available – and seeks the same for internet service and prescription drugs.

US President Joe Biden signed an executive order today that could make hearing aids less expensive and easier to purchase. The comprehensive action from the White House, which includes 72 initiatives, directs the Department of Health and Human Services (HHS) to issue proposed rules for over-the-counter hearing aids within 120 days.

Momentum to switch hearing aids from prescription to OTC has been growing for some time. In 2017, President Trump signed the Over the Counter Hearing Aid Act authorizing OTC sales of hearing devices and giving the Food and Drug Administration until 2020 to establish guidelines for direct sales of hearing aids. The FDA did not meet that timeline, however, and those regulations were never put forward.

During a Federal Trade Commission summit in April 2017, stakeholders voiced support for switching hearing aids to OTC, though some expressed trepidation. (Also see "[Stakeholders Support OTC Hearing Aids At FTC Summit](#)" - Medtech Insight, 19 Apr, 2017.)

And as far back as 2016, manufacturers of hearing aids opposed the idea of making their devices available over the counter, arguing that hearing aids are more complex than other OTC aids, such as reading glasses, and that professional input is needed for those requiring any type of hearing device. (Also see "[Trade Groups Protest OTC, QSR-Exempt Hearing Aids At FDA Meeting](#)" - Medtech Insight, 25 Apr, 2016.)

Still, others believe the status quo stifles innovation.

“Right now when you need a hearing aid you can’t just walk into a pharmacy and pick one up over the counter, you have to get one from a doctor or a specialist. Not only does that make getting a hearing aid more inconvenient it makes it considerably more expensive.” – President Biden

Now, the renewed focus on hearing aids is part of a larger push from the Biden administration to shake up the marketplace by cracking down on anti-competitive practices in hopes of fostering economic growth. Corporate consolidation, the White House argues, has driven up prices while making it more difficult for American workers to secure higher wages.

For example, a White House [fact sheet](#) said that the four largest hearing aid manufacturers control 84% of the market.

Biden, in speech before signing the order, said “fair competition” is why capitalism has been the world’s greatest force for prosperity and growth, but added “capitalism without competition is not capitalism, it’s exploitation.”

“Right now, when you need a hearing aid you can’t just walk into a pharmacy and pick one up over the counter, you have to get one from a doctor or a specialist. Not only does that make getting a hearing aid more inconvenient it makes it considerably more expensive,” Biden said. “It also makes it harder for new companies to compete, innovate and sell hearing aids at lower prices. As a result, a pair of hearing aids can cost thousands of dollars, which is a big reason why only one in seven Americans with hearing loss use a hearing aid.” Biden added that his order would result in a pair of hearing aids costing hundreds, not thousands, of dollars.

Nearly 29 million American adults could benefit from hearing aids, according to the National Institute of Deafness and Other Communications Disorders (NIDCD). Among adults 70 and older with hearing loss who could benefit from a device, fewer than 30% have ever used a hearing aid, and one in eight people in the US, has hearing loss in both ears.

Peter Borsuk, chair of the Consumer Healthcare Products Association’s (CHPA) consumer medical devices council, and president and CEO of Lansinoh Laboratories, issued a statement in support of Biden’s order and the proposal on hearing aids in particular.

“Approximately 48 million Americans have hearing loss and medical devices such as hearing aids

could help them overcome mild to moderate hearing impairment,” Borsuk said. “However, these devices are currently only available by prescription, and data show that fewer than one-out-of-five people who have hearing loss actually use them.”

Borsuk added that the CHPA and its member encourage the FDA to expedite the prescription to OTC switch for hearing devices as they provide Americans with “accessible, affordable, and trustworthy personal healthcare products which are more important now than ever.”

Biden’s order also pushes harder on getting more reliable internet service to more Americans, especially those in rural areas by addressing issues the White House says limit competition, raise prices and reduce choices for internet service. Broadband has become an essential component of health care, especially for those in remote areas reliant upon medical devices and equipment. (Also see "[Bill Increasing Funding for FDA, Rural Broadband, Passes House Appropriations Committee](#)" - Medtech Insight, 1 Jul, 2021.)

“More than 65 million Americans live in a place with only one high speed internet provider,” Biden said. “Research shows when you have limited internet operation you pay up to five times more on average than families with more choices. That’s what a lack of competition does, it raises the prices you pay.”

The order also bans “exclusivity deals” in which landlords give their tenants only one internet option, while also ending excessive and early termination fees – initiatives the administration says will help consumers, especially low-income Americans, get better rates.

Biden also wants providers to include a “broadband nutrition label,” which would list basic information about their internet service to give consumers more transparency – an idea that began during the Obama administration.

Actual charges for broadband services can be as much as 40% higher than advertised, according to the Federal Communications Commission (FCC).

Biden’s order also asks the FCC to reinstate net neutrality, which was repealed under the previous administration.

Other initiatives in the executive order include lowering prescription costs by having the FDA work with states on importing drugs from Canada and directing the FTC to evaluate hospital mergers the administration argues hurt patients, particularly rural ones.