MEDTECH INSIGHT
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US Regulatory Roundup, July 2021: Presidential Order On OTC Hearing Aids Perks Up Industry Ears

by Shawn M. Schmitt

In a move that undoubtedly left makers of hearing aids unhappy, President Joe Biden last month signed an executive order that will make it easier for people to buy hearing aids without a prescription. News of Biden's EO – and more – topped our list of most-read *Medtech Insight* articles in July.

President Biden Signs EO Targeting Hearing Aids, Internet Providers

In a move that undoubtedly left manufacturers of hearing aids unhappy, US President Joe Biden in early July signed an executive order to make buying hearing aids without a prescription easier. *News of the sweeping EO* – which also takes aim at internet service providers – was of most interest to *Medtech Insight* readers last month.

The president has given the Department of Health and Human Services – the overseer of the Food and Drug Administration – until November to issue proposed rules for over-the-counter hearing aids.

"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," Biden said when signing the EO. "Not only does that make getting a hearing aid more inconvenient, it makes it considerably more expensive."

The National Institute of Deafness and Other Communications Disorders says roughly 29 million American adults could benefit from OTC hearing aids. Among people 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 has hearing loss in both ears.

Hearing aid makers have historically opposed allowing the devices to be offered OTC, arguing that

hearing aids are complex and therefore require the input and expertise of a health care professional. But *stakeholders have been generally supportive* of offering the devices OTC.

Biden's EO also aims to get internet service to more Americans, particularly those in rural areas. Broadband has become an essential component of health care, especially for those in remote areas reliant on medical devices and equipment, as well as telehealth services.

"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."

COVID-19: CDRH's Shuren Talks EUAs, Delta Variant, And More

Meanwhile, the head of the FDA's Center for Devices and Radiological Health (CDRH) said in July's *No. 5 story* that companies that hold Emergency Use Authorizations (EUAs) for their products will have plenty of time to have them approved by the agency so they can stay on the market post-pandemic.

"For most products, the EUA pathway won't end anytime soon and there will be an ample transition period, which we plan to describe in a guidance document that's open for public comments," CDRH director Jeff Shuren said at an FDA small business event. "That said, developers with EUAs shouldn't wait to gather the necessary information and submit an application if they know they want a standard clearance."

> ***"Many of our staff are burned out and we could very well lose talented people as we continue to prioritize COVID-related work." – Jeff Shuren***

Shuren also said he wants to continue the pandemic trend of speedy development of guidance documents after the COVID-19 pandemic wanes: "Early on, guidances were being developed, cleared and published in days or weeks. I would like to see that happen routinely outside the pandemic. That process was a big win for public health."

And in a separate webinar hosted by the Alliance for a Stronger FDA, Shuren acknowledged that the agency is "clearly very concerned about the Delta variant" of COVID-19, but is taking the steps necessary to ensure that coronavirus diagnostics provide accurate results.

He explained in our *No. 8 story* that when the FDA detects a "constellation" of mutations of the SARS-CoV-2 virus, that helps the agency find variants such as Delta within the US population. The FDA then works to determine whether the variant could adversely affect the performance of COVID-19 tests already on the market.

"If it looks like it could [affect a diagnostic], we reach out to the developer for performing additional assessments," Shuren said.

In a late June interview with *Medtech Insight* – our *No. 7 story* from last month – Shuren talked about challenges the device center continues to face as it tackles the still-very-much-with-us pandemic.

"The reality is that many of our staff are burned out and we could very well lose talented people as we continue to prioritize COVID-related work," he said. "I know of some people who have stayed just to help address the pandemic but plan to leave once we are back to the new normal."

Shuren said the CDRH has made changes to its processes and policies to better manage the center's workload.

"We've also focused on wellness for CDRH colleagues, including through the creation of a virtual wellness center, and most recently launching a pilot on giving our staff breaks before and after internal one-hour meetings," he said.

Check out our wide-ranging podcast interview with Shuren below.

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Unique Device Identification Back In The News

It took only half a decade, but the FDA finally got around to finalizing its guidance document on how to put together a Unique Device Identifier. Our story on the eight-page UDI guidance, the draft of which was released in 2016, landed on the top 10 list at *No. 4*.

The guidance, "Unique Device Identification System: Form and Content of the Unique Device Identifier," reminds companies to obtain an identifier from a UDI-issuing agency. The FDA has accredited both the standards organization GS1 and the Health Industry Business Communications Council (HIBCC) to sell UDIs. The document also offers other handy tips as manufacturers work to meet the agency's UDI requirements.

And *in other UDI news*, the FDA said on 29 July that labelers of certain lower-risk medical devices may continue using Universal Product Codes (UPCs) on packaging in lieu of UDIs for another two

years. The agency extended UDI alternatives UDI-A160001 and UDI-A160002 through 24 September 2023 for a range of products; lists of affected devices can be found *here* and *here*.

"This extension means certain nonprescription, over-the-counter devices intended to be sold exclusively through retail establishments may continue to bear a Universal Product Code as their device identifier," the FDA explained.

Other Top Stories

These five articles rounded out our Top 10 list in July:

- *No. 2 story*: The FDA has warned health care providers about potential biocompatibility and design issues with NuVasive's specialized orthopedics Precice devices, which are made from steel and titanium. The agency says adverse events – including pain and changes in the surrounding bone and soft tissue – have been record by patients implanted with the Precice Stryde, the steel version of the product.

- *No. 3 story*: A proposed change to Medicare billing that would go into effect on 1 January could give one maker of implantable stents for glaucoma an edge over its competitor. Listen to our Device Week podcast on this topic below.

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- *No. 6 story*: Problems that have emerged in auto-injectors filled with generics for multiple sclerosis treatment Copaxone (glatiramer acetate) by multiple pharmaceutical firms highlight yet another issue with combination product reviews and regulation at the FDA, an agency official said.

- *No. 9 story*: In comments submitted to the Centers for Medicare & Medicaid Services, industry representatives and other stakeholders support the agency's planned extension of new technology add-on payments for 14 products set to expire at the end of fiscal year 2021, which ends on 30 September.

- *No. 10 story*: "Top leadership" from all commodity centers within the FDA will take part in a new Inspectional Affairs Council that's being stood up by the agency's Office of Regulatory Affairs, an ORA official said. The ORA conducts all of the FDA's field activities.

The 10 most popular US regulation and policy stories in July, as determined by reader interest, are listed in the table below.

Rank	Story

1	*Sweeping Executive Order Puts Hearing Aids Over The Counter; Cracks Down On Internet Providers*
2	*NuVasive Recalls Orthopedics Implants Over Biocompatibility Concerns*
3	*Proposed Medicare Code Change Could Affect Reimbursements On Glaucoma Devices*
4	*After 5 Years Of Waiting, FDA Finally Finalizes Guidance On Constructing Unique Device Identifiers*
5	*'Never Again': Shuren Talks COVID-19 Lessons At FDA Small Business Event*
6	*Auto-Injector Issues Get Cross-Center Investigation From US FDA*
7	*A Chat With Jeff Shuren: FDA Device Center Chief Worries About Agency Staffing; Talks MDUFA V, Pandemic, More*
8	*FDA's 'Clearly Very Concerned' About Delta COVID-19 Variant, CDRH's Shuren Says*
9	*Proposed Changes To Medicare Seek To Extend Add-On Payments, Expand Program For Homebound Patients*
10	*'One FDA': US Agency's New Inspectional Affairs Council Takes Shape*