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Hahn: FDA May Keep Some COVID-19 Reforms Post-Pandemic

by Elizabeth Orr

US FDA commissioner Stephen Hahn said during an 18 June “fireside chat” that he expects closer relationships with industry and a greater reliance on postmarket data to continue even after the COVID-19 pandemic comes to an end.

Changes made in response to the COVID-19 pandemic may be here to stay at the US Food and Drug Administration, commissioner Stephen Hahn said in a presentation organized as part of the Medical Device Innovation Consortium (MDIC)’s annual public forum on 18 June.

Hahn, who was sworn in as head of the agency last December, had only a few months as commissioner under his belt before the COVID-19 crisis reached the US. The oncologist served as the chief medical executive at the University of Texas MD Anderson Cancer Center before joining the FDA. (Also see "*Radiation Oncologist Stephen Hahn Wins Final Senate Confirmation As FDA Commissioner*" - Medtech Insight, 12 Dec, 2019.)

The agency has faced unprecedented challenges in responding to the pandemic, in which urgency, speed, safety and transparency all need to be balanced against a fast-moving background. Hahn said he has focused on making decisions supported by data and science, and updating those decisions as more information became available. “That’s what the agency has always strived to do. It’s just being done in an accelerated timeframe,” he said.

For example, the COVID-19 response has given the FDA much more real-world evidence much faster than is normally available. That plays into a push by the agency’s Center for Devices and Radiological Health to use more postmarket information and RWE to make regulatory decisions, he said. And Hahn anticipates that the role of data collected after devices and drugs reach the market will continue to grow in importance even after the pandemic ends.

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The pandemic has also required greater regulatory flexibility, Hahn noted. For example, the agency needed to quickly authorize personal protective equipment manufactured outside the US because US manufacturers couldn't meet the demand. The agency later updated its emergency use authorization (EUA) to reflect additional data.

"The traditional authorization process assumes you have significant time to collect data before you do the authorization," he said. "But we can adjust what data is needed for an initial approval and what can be collected later."

Hahn didn't give specific examples, but the agency has withdrawn EUAs for several products after they proved to be risky or ineffective. These include some COVID-19 diagnostics as well as N95 respirators made in China. Further, the agency recently revoked an EUA for anti-malarial drugs hydroxychloroquine and chloroquine, which the Trump administration once touted to treat COVID-19 symptoms. (Also see "*FDA Yanks Potentially Faulty COVID-19 Antibody Tests – And More May Be On The Chopping Block*" - Medtech Insight, 22 May, 2020.) and (Also see "*Certain Chinese-Made Respirators No Longer Authorized By FDA*" - Medtech Insight, 8 Jun, 2020.)

Another element of the FDA's COVID-19 response that Hahn foresees carrying forward is a greater interdependence between regulators and industry, as the two collaborate to develop and collect data needed to safely regulate devices. The agency recently announced a public-private partnership to evaluate COVID-19 diagnostics. (Also see "*FDA Enters Public-Private Partnership To Evaluate COVID-19 Tests Amidst Concerns Over Efficacy*" - Medtech Insight, 18 Jun, 2020.)

The commissioner also revealed the agency's system for balancing competing priorities during the pandemic, as other medical product development continued. Earlier this year the agency set up an incident command to manage the FDA's response to the pandemic and asked each center within the agency to create its own prioritization framework. The frameworks were then used to allocate resources such as staff and IT, with COVID-19 as the key priority and other important processes, such as product approvals and data assessment, also being reflected.

"I'm proud of how the agency has responded," he said. "It's been a 24/7 response, and what has been learned can be applied to the future. We're committed to continual improvement and will

be implementing successful measures taken during the pandemic."

Hahn's "fireside chat" was the first in a series of weekly webinars that are standing in for an in-person MDIC annual meeting this year. The full agenda and registration information are available on the *MDIC's website*.