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## Trump Nominates Hahn As New FDA Commish; Acting Head Sharpless Returns To NCI

by Ferdous Al-Faruque

The White House has announced President Trump's intent to nominate MD Anderson's Stephen Hahn as the next FDA commissioner. The position has been held by acting commissioner Ned Sharpless for the past seven months. Admiral Brett Giroir will helm the agency on an acting basis until the new commissioner is confirmed.

After weeks of speculation, President Trump has nominated Stephen Hahn as the next US Food and Drug Administration commissioner. The pick is particularly interesting because, unlike more recent FDA heads, Hahn does not have any government experience – but does have a strong background in research.

On 1 November, the White House issued a statement announcing the president's intent to nominate Hahn to the top FDA spot, which is currently being executed by acting commissioner Ned Sharpless. Despite a letter to Trump from some of the more recent FDA commissioners – Robert Califf, Margaret Hamburg, Andrew von Eschenbach and Mark McClellan – the president decided to go with Hahn.

Media reports had already gotten wind that Hahn was going to be nominated by the president a month ago but was undergoing an FBI background check. (Also see "*MD Anderson Oncologist Stephen Hahn Is Trump's First Choice For FDA Commissioner: Reports*" - Medtech Insight, 2 Oct, 2019.)

Immediately following the news, Department of Health and Human Services (HHS) secretary Alex Azar issued a statement that Sharpless would return to his previous job as director of the National Cancer Institute (NCI). Azar noted that under federal rules, acting commissioners are only allowed to serve for 210 days and that Sharpless' tenure as such would automatically come

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to an end on 1 November.

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Admiral Brett Giroir, the assistant secretary for health, will take the helm as the next acting FDA commissioner to act as a buffer between Sharpless and the next permanent head.

"Under Dr. Sharpless's leadership for the past seven months, FDA has forged ahead in its essential work of protecting the public health. Dr. Sharpless's willingness to step into the role of acting commissioner, and to lead the team at FDA with a steady hand, ensured that the agency did not miss a beat in advancing its vital mission," Azar said. "Admiral Giroir has been an indispensable leader for HHS on a number of public-health priorities. As assistant secretary for health, whose authorities include overseeing the US Public Health Service, he will be able to assume the delegable duties of the commissioner at this time and ensure the FDA's work continues to move forward."

Medical device industry advocacy group AdvaMed congratulated Hahn on his nomination and urged the Senate to move swiftly on his confirmation.

"Dr. Hahn's distinguished career as a health-care provider and researcher gives him a unique perspective on the importance of patient access to the latest medical advances," AdvaMed CEO Scott Whitaker said in a statement. "His extensive management experience and evidence-based approach to addressing the significant health-care challenges we face today will serve him well in his new post. We look forward to working with him on behalf of the patients our industry serves."

Sharpless was named acting commissioner after Scott Gottlieb announced in April he was stepping down from his role as FDA commissioner. At the time there was speculation that Gottlieb had recommended principal deputy FDA commissioner Amy Abernethy to helm the agency, but Sharpless was picked as a compromise to also appease Azar. (Also see "Scott Gottlieb Calls It Quits After An Active Tenure At US FDA" - Medtech Insight, 5 Mar, 2019.)

A source with knowledge of internal HHS politics says picking Hahn over Sharpless makes sense

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because it gives Azar the ability to bring in someone who is more aligned with his vision for the agency. The source says it also makes sense to prime the position with Giroir while Hahn is going through the nomination process in the Senate.

A second source told *Medtech Insight* that while Azar likely had some say in Hahn's selection, the more probable reason for Trump skipping over Sharpless is the president's tendency to go against conventional picks. Further, choosing Sharpless would've created a leadership hole at NCI. The source noted, however, that Hahn is a qualified pick for the post.

While the Alliance for a Stronger FDA said it doesn't endorse candidates for FDA commissioner, the group's deputy executive director, Steven Grossman, says Hahn's background in research is helpful to the FDA's mission.

"Running an academic health center is great preparation for being FDA commissioner," he told *Medtech Insight*.