

HEALTH POLICY

Trump to Nominate Texas Doctor to Lead FDA

Nominee Stephen M. Hahn is chief medical executive at M.D. Anderson Cancer Center



Dr. Stephen Hahn is expected to be nominated to lead the FDA by next week PHOTO: THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

By Thomas M. Burton

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WASHINGTON—President Trump plans to nominate Stephen M. Hahn, a radiation oncologist and chief medical executive at M.D. Anderson Cancer Center in Houston, as the next Food and Drug Administration commissioner, according to people familiar with the situation.

Dr. Hahn, 59, would replace acting FDA commissioner Norman “Ned” Sharpless, whose acting term expires on Nov. 1. He took the acting position after the departure in April of previous commissioner Scott Gottlieb. The appointment requires confirmation by the Senate.

Dr. Hahn is expected to be nominated by next week, the people familiar say. The Journal earlier reported that Dr. Hahn was a leading candidate for the job, along with Dr. Sharpless and Alexa Boer Kimball.

Dr. Hahn previously was chairman of radiation oncology at the University of Pennsylvania Hospital, before heading to the University of Texas-affiliated M.D. Anderson. In those roles he gained experience with federal regulations governing the development of medical devices and of diagnostic equipment.

Colleagues at M.D. Anderson credit the FDA nominee for a positive turnaround in faculty morale during recent years there—and for a raucous laugh that can be heard well down the hallways.

“He’s easily identified and can be geo-located by his laugh,” one said.

If Dr. Hahn is confirmed by the Senate, he will face a number of issues early in his tenure. Chief among them is how to best regulate tobacco and e-cigarettes, especially given the more than 1,000 respiratory diseases that have recently been linked to vaping. Also expected to be central to the job are the safety of medical devices, as well as approvals of generic drugs that can help hold down high drug prices. Another is the regulatory status of hemp-derived CBD, or cannabidiol, for use in foods or other products.

“I think there currently is too much emphasis at the FDA on speed” of approving devices and drugs, said Rita Redberg, editor of the journal JAMA Internal Medicine. The agency, she said, “should get back to its mission of focusing on the public health.”

Current and former colleagues of Dr. Hahn’s describe him as being collegial, funny and intensely smart. He routinely gets up about 4 a.m. to do an intensive workout program called P90X that prescribes a routine of cardio and a variety of upper-body exercises.

Theodore S. Lawrence, chairman of radiation oncology at the University of Michigan, described Dr. Hahn as “a great personality, outgoing and very perceptive on both the medical side and the financial side.” Another doctor who worked with Dr. Hahn for a decade or more described him as “very caring of the people who worked for him, backslapping custodians in the hallways.”

Dr. Hahn was the public face of a medical scandal at the Philadelphia Veterans Affairs Medical Center in 2009 after multiple cases of radiation-seed therapy for prostate cancer went awry in the years before. Dr. Hahn wasn’t personally implicated, but he was chief of radiation oncology at Penn when the University of Pennsylvania, under contract with the VA, provided radiation-oncology doctors who did VA prostate-cancer procedures with radioactive seeds.

One doctor allegedly placed seeds that gave insufficient radiation to prostate tumors or too much to adjacent organs, according to an investigation by the federal Nuclear Regulatory Commission.

In testimony before the House Committee on Veterans’ Affairs, Dr. Hahn described a variety of quality-review steps his department took subsequently, such as creating multiple levels of review to catch anomalies of treatment.

Karen Bird, executive director of the Alliance of Dedicated Cancer Centers, said Dr. Hahn has held overall supervisory authority for more than 1,000 clinical trials at a time at M.D. Anderson. She described him as “really charismatic and genuine.”

Dr. Hahn won the administration’s nod despite public support for Dr. Sharpless from four former FDA commissioners in a recent letter to President Trump, as well as the backing of another former commissioner, Dr. Gottlieb.

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