MEDTECH INSIGHT
CITELINE COMMERCIAL

23 Mar 2021 | **News**

FDA's Second-In-Command, Amy Abernethy, Departing Agency

by Ferdous Al-Faruque

US FDA principal deputy commissioner Amy Abernethy is set to leave the agency by the end of April. The surprise news comes in the midst of the Biden administration still figuring out who they want to lead the FDA.

Amy Abernethy, the principal deputy commissioner of the US Food and Drug Administration, is leaving the agency, according to a *letter* from acting commissioner Janet Woodcock. The surprise news comes in the midst of the Biden administration still deciding on their nominee to lead the agency.

Abernethy was recruited to the FDA from the private sector by former commissioner Scott Gottlieb. It was widely reported that she was being groomed to take the helm following his departure. But that opportunity never came despite changing administrations, and Health and Human Services secretaries. (Also see "*FDA Commissioner Race: Biden Team Trying To Woo Reluctant Dems On Woodcock While Exploring New Options*" - Medtech Insight, 25 Feb, 2021.) and (Also see "*MTI Profile: US FDA's Second-In-Command Has Her Eye On A Tech-Forward Future*" - Medtech Insight, 19 Aug, 2019.)

> ***"Throughout multiple commissioner transitions and a historic pandemic, Amy's focus on the FDA's core technology operations has resulted in a remarkable modernization of the agency's technology and data practices." – Janet Woodcock***

In an agency-wide email on 23 March, Woodcock announced Abernethy's departure from the

© Citeline 2024. All rights reserved.

FDA come mid- to late-April.

“I’m very sorry to see the FDA lose a talented and inspiring senior leader like Amy, but I take heart in Amy’s enduring accomplishments at the agency,” Woodcock wrote. “Amy’s innovative spirit is renowned in the medical field and she has a unique understanding of how to harness new technologies for the benefit of patients and the public health. But those who have worked with her directly know that she is also uniquely skilled as a manager and a mentor.

“Throughout multiple commissioner transitions and a historic pandemic, Amy’s focus on the FDA’s core technology operations has resulted in a remarkable modernization of the agency’s technology and data practices,” she added. “More than anything else, this modernization has been about the people behind technology at the FDA and how they can perform their work to best support our mission.”

Woodcock went on to say that Abernethy has been a “relentless advocate” for improving the regulatory science that FDA relies on to make its decisions.

Part of that advocacy involved taking on the role of the FDA acting chief information officer to help modernize the agency’s data tools and streamline how product sponsors submit applications, as well as how reviewers are able to use that data. (Also see "*FDA Launches Digital Modernization Plan To Complement Its Technology Modernization Plan*" - Medtech Insight, 4 Mar, 2021.) and (Also see "*FDA Wants $18M To Update Outmoded Device Program IT Systems*" - Medtech Insight, 12 Feb, 2020.)

Upon news of Abernethy’s departure, Gottlieb tweeted that Abernethy had expanded the FDA’s ability to make better-informed decisions and will be leaving the agency a better place.

> ***Amy Abernethy was recruited to FDA for her deep public health experience, her commitment to patients, and her long background bringing innovation to large enterprises in how they used of data to make decisions...***
>
> ***— Scott Gottlieb, MD (@ScottGottliebMD) March 23, 2021***

Key Player During Pandemic

A former cancer researcher and professor with a PhD in informatics from Duke University, and

© Citeline 2024. All rights reserved.

later chief medical officer at the oncology analytics company Flatiron Health, Abernethy brought a unique set of skills and experiences that Gottlieb and others hoped would contribute to transforming the way FDA does business. While the commissioner job eventually eluded her, she continued to have a level of autonomy and a mission objective to modernize the FDA's ability to use data in its decision-making processes.

> *"When COVID-19 struck, Amy rapidly assembled flexible teams and projects to understand how novel data and rigorous analysis techniques could be deployed in support of the FDA's response to the pandemic." – Janet Woodcock*

Abernethy has also been critical to the FDA's work in aggregating data under the COVID-19 Evidence Accelerator, a program developed by the Reagan-Udall Foundation, the FDA and the Friends of Cancer Research. The public-private project helps fill in data gaps in evidence generation during the pandemic, especially to help develop new tests and vaccines faster. (Also see "*FDA Enters Public-Private Partnership To Evaluate COVID-19 Tests Amidst Concerns Over Efficacy*" - Medtech Insight, 18 Jun, 2020.)

"When COVID-19 struck, Amy rapidly assembled flexible teams and projects to understand how novel data and rigorous analysis techniques could be deployed in support of the FDA's response to the pandemic," Woodcock wrote. "Amy's insight that a diverse group of public health and data experts from multiple sectors could come together to work on pandemic-related analysis projects in a transparent, collaborative setting led to the creation of the COVID-19 Evidence Accelerator, which has emerged as a unique and promising model for advancing the science of public health.

"I, like many of you who have worked with Amy, will surely miss her inspiring enthusiasm and her principled and pragmatic approach to problem-solving," she added.

Woodcock went on to say that over the next few weeks the agency plans on a "deliberate, well-planned transition" to find a new principal deputy commissioner and chief information officer.

Following news of her departure, Abernethy turned to Twitter to thank the FDA for giving her the opportunity to serve in public health. And while she did not disclose what her next job will be, she said she would "spend some time with my family and do some brainstorming, reading and writing."

© Citeline 2024. All rights reserved.

> *The last 2+ yrs @US_FDA have been some of the most explorative & enlightening of my career. We stood up the tech & data modernization programs, helped launch the #COVID19 Evidence Accelerator, made real progress in big areas like CBD...the list goes on.1/5 https://t.co/oES0CG2f3u*
>
> *— Dr. Amy Abernethy (@DrAbernethyFDA) March 23, 2021*

[Editor's note: *This story is being updated as more stakeholders, including Abernethy, chime in on her decision to leave the FDA.*]

© Citeline 2024. All rights reserved.