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People, FDA+

In a major blow to vaccine efforts, senior FDA leaders stepping down

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Two of the FDA's most senior vaccine leaders are exiting from their positions, raising fresh questions about the Biden administration and the way that it's sidelined the FDA.



Marion Gruber

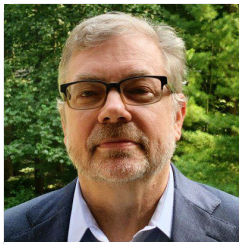
Marion Gruber, director of the FDA's Office of Vaccines Research & Review and 32-year veteran of the agency, will leave at the end of October, and OVRD deputy director Phil Krause, who's been at FDA for more than a decade, will leave in November. The news, first reported by BioCentury, is a massive blow to confidence in the agency's ability to regulate vaccines.

The bombshell announcement comes at a particularly crucial moment, as boosters and children's shots are being weighed by the regulator. The departures also come as the administration has recently jumped ahead of the FDA's reviews of booster shots, announcing that they might be available by the week of Sept. 20.

A former senior FDA leader told Endpoints that they're departing because they're frustrated that CDC and their ACIP committee are involved in decisions that they think should be up to the FDA. The former FDAer also said he's heard they're upset with CBER director Peter Marks for not insist-

ENDPOINTS NEWS

“These two are the leaders for Biologic (vaccine) review in the US. They have a great team, but these two are the true leaders of CBER. A huge global loss if they both leave,” Former BARDA director Rick Bright wrote, weighing in on the news. “Dr. Gruber is much more than the Director. She is a global leader. Visionary mastermind behind global clinical regulatory science for flu, Ebola, Mers, Zika, Sars-cov-2, many others.”



Phil Krause

In a letter from Marks to staff, he explained:

Dear Colleagues,

It is with mixed feelings that I have the news of two retirements to share with you today.

Dr. Marion Gruber has announced to staff that she plans to retire on October 31, 2021. I am incredibly grateful for her efforts as the director of CBER's Office of Vaccines Research and Review. Her contributions throughout her career have been immeasurable, but never more so than during the COVID-19 pandemic. Her leadership in the Center's efforts to authorize three COVID-19 vaccines, and more recently to approve one of those vaccines, ensured that the vaccines met the high standards the public has come to expect from FDA, and has positively impacted the public health in the United States and across the globe. Marion's departure is a huge loss for CBER and FDA. We wish her all the best in her next chapter, and a well-deserved congratulations for a remarkable career.

Dr. Philip Krause has also announced that he will be leaving FDA in November. I can't thank Phil enough for his extraordinary commitment and effort in helping guide OVRP during the ongoing public health emergency. He has also served a key role in our interactions to address critical vaccine-related issues with our public health counterparts around the world. His keen insight and experience in addressing a wide variety of challenges will truly be missed. Sincere thanks and congratulations to Phil for his incredible contributions to public health over the course of his impressive career in the U.S. Public Health Service and with CBER.

Our search for the next office director will begin imminently. I will serve as the acting OVRP office director during this search, and will announce details for an acting deputy director. Recognizing their tremendous efforts to date, I will do everything I can to support the incredible OVRP staff as they continue their critical public health work.

Thank you so much to Marion and Phil for all that they have contributed and continue to contribute to the agency, and thanks so much to each of you for all that you do every day.

Best Regards,
Peter

Peter Marks, MD, PhD