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2 top FDA officials resigned over the Biden administration's booster-shot plan, saying it insisted on the policy before the agency approved it, reports say

Ashley Collman Sep 1, 2021, 6:32 PM



President Joe Biden. Manuel Balce Ceneta/AP

The FDA announced the resignations of Marion Gruber and Philip Krause on Tuesday.

The pair lead the FDA office in charge of approving vaccines.

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The US Food and Drug Administration announced the resignations of two top vaccine officials on Tuesday, and reports said the two were leaving in anger over the Biden administration's plan to roll out COVID-19 booster shots before officials had a chance to approve it.

Dr. Marion Gruber, the director of the FDA's Office of Vaccines Research and Review, and her deputy, Dr. Philip Krause, plan to leave the FDA in October and November. [BioCentury first reported the news](#) on Tuesday.

In a letter announcing the resignations [obtained by the biotech-industry publication Endpoints](#), Dr. Peter Marks, the director of the FDA's Center for Biologics Evaluation and Research, praised the pair for their work during the COVID-19 pandemic. He didn't give a reason for their departures.

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But sources told Endpoints and [Politico](#) that Gruber and Krause were upset with Biden administration's booster-shot plan. The administration announced last month that [most people would be offered a COVID-19 booster shot](#) about eight months after vaccination.

One former senior FDA leader told Endpoints that Gruber and Krause were leaving

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the leader of their division, for not insisting on the agency's oversight.

The source said the final straw was the Biden administration's announcing the booster-shot plan before the FDA had officially signed off on it.

A former FDA official told Politico that the resignations were tied to anger over the FDA's lack of autonomy in booster planning, while a current official told the outlet that the pair were leaving over differences with Marks.

Read more: [Moderna and other top coronavirus drugmakers are boosting their lobbying as they compete for government cash to fuel vaccine work](#)

When asked about these reports on Tuesday, [Jeff Zients](#), the White House's coronavirus czar, said the decision to start booster shots "was made by and announced by the nation's leading public-health officials" including the acting FDA commissioner, the CDC director, the surgeon general, the director of the National Institutes of Health, and others.

"Having reviewed all of the available data, it is in their clinical judgment that it is time to prepare Americans for a booster shot," Zients said.

He said the administration had "also been very clear throughout that this is pending FDA conducting an independent evaluation and CDC's panel of outside experts issuing a booster dose recommendation."

The FDA, Gruber, and Krause did not immediately respond to Insider's request for comment.



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