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Senior Regulators Resign From FDA Over Rushed COVID Booster Rollout

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Two top regulators at the Food and Drug Administration (FDA) are resigning from their positions over disagreement with the White House's pressure to move forward with COVID booster shots without FDA approval, as well as with the Centers for Disease Control and Prevention's (CDC) involvement in the vaccine approval process.

According to a Tuesday letter penned by Peter Marks, chief of the FDA's Center for Biologics Evaluation and Research, Marion Gruber and Phil Krause, director and deputy director of the agency's Office of Vaccines Research & Review, respectively, are leaving their positions this fall.

Even though the letter made no mention of the reasons Gruber and Krause are leaving, sources familiar with the issue told Politico that the two officials were at disagreement with Marks on the issue of COVID booster shots, and were discontented over the roles of the CDC and its Advisory Committee on Immunization Practices in decisions that they believed should be handled by the FDA.

The outlet notes the "exasperation" within the federal regulatory body over the Biden administration's "disjointed process for implementing its booster plan." The outlet notes the staff is quite frustrated with a lack of proper coordination between the agencies on the plan to recommend all eligible populations to take boosters, viewed by some at the FDA as "premature and unnecessary."

The *New York Times'* sources within the FDA said that neither Gruber nor Krause believed there was enough data to justify offering booster shots yet, and perceived their rushed recommendation, much amplified by President Biden's endorsement of the plan, as unacceptable pressure on the FDA to authorize them without the proper review.

CNN, similarly, observes the largest issue concerning the regulators seems to be that by arbitrarily setting a goal for boosters, the White House is "getting ahead of where the science is" and "prejudging what the FDA would say."

In light of the high-profile resignations, acting FDA Commissioner Janet Woodcock reiterated her support to the booster-shots plan. In the memo to the staff, she noted, "The issues are complex and the days are long, but please know the work you all have done to date and will continue to do in the days, weeks and months ahead, will hopefully one day allow us to fully put Covid-19 behind us and better prepare us for future challenges."

The statement seemed to echo the White House COVID-19 Response Coordinator Jeff Zients' words, who said the same day the plan on boosters, as a way to "stay ahead of the virus," "was made by and announced by the nation's leading public health officials." Both statements imply the decision is already made, despite the pending approval from the FDA.

In mid-August, the CDC started recommending immunocompromised people, who make up as many as 44 percent of hospitalized breakthrough COVID infections in the United States, get their third dose of the vaccine. While the CDC does not recommend additional doses or boosters for any other population at this time, the Department of Health and Human Services (HHS), jointly with the CDC and FDA, announced a plan to begin offering boosters to the general population as early as the week of September 20 and starting eight months after an individual's second dose. The statement reads:

> The available data make it very clear that protection against SARS-CoV-2 infection begins to decrease over time following the initial doses of vaccination, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease. For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection and prolong its durability.

President Biden has decided to speed up the rollout of boosters, and implied they should be administered to people not eight, but five, months after the initial inoculation. In his distinct style, Biden's top health advisor, Dr. Anthony Fauci, stated that while the boosters will be certainly needed for everyone, he left room for the timeline at which they should be administered by noting that for now, it is eight months.

CNBC reported many prominent immunologists criticized the rush to administer the little-studied booster shots. Among them is Dr. Anna Durbin, a vaccine researcher at Johns Hopkins University, who said the existing vaccines are enough for protecting people against severe disease. "While the presence of antibodies induced by the vaccine may decline, resulting in a rise in breakthrough infections, the body has other mechanisms, like T cells, that may protect someone from getting seriously sick," she believes. The time to consider boosters would be only when the hospitalizations and deaths increase among the vaccinated, she said.

Medical news outlet the Defender reports on an even larger number of renowned experts that warn against the use of boosters.

For example, Dr. Hooman Noorchasm, a cardiothoracic surgeon and patient safety advocate, insisted the shots may be not just unnecessary, but actually harmful to the general public. Observing that the vaccines have already caused harm to a "non-negligible number of Americans" who already had COVID, he added:

> Now, CDC has announced a policy of blanket "booster shots" in a subset of vaccine-compliant Americans. Using this inadequately calibrated, "one-size-fit-all" approach again, CDC is almost certain to magnify harm to a subset of Americans in whom booster vaccination may be unnecessary or dangerous.

The outlet also quotes the studies that go against the official narrative that unvaccinated people are to blame for "breeding" the virus' variants. On the contrary, some of the recent findings suggest that it is the vaccinated who play a key role in helping SARS-CoV-2 variants evolve into those that evade existing COVID vaccines.