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FDA official pushes for a dedicated emerging pathogens team to prepare for the next pandemic

By Simar Bajaj July 21, 2023

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Peter Marks, director of the FDA's Center for Biologics Evaluation and Research
GREG NASH/POOL VIA AP

WASHINGTON — A top Food and Drug Administration official wants Congress to dedicate full-time staff to emerging pathogens, after the FDA scrambled to find people for Covid-19 priorities like Operation Warp Speed.

"Vaccines were a pretty heavy duty lift during the pandemic," said Peter Marks, director of the Center for Biologics Evaluation and Research, at a Thursday Politico event. "Rather than having to essentially reassign whole groups of people and disrupt things, the idea is to have a group of people who are constantly working on this."

There is reason for optimism. Sens. John Hickenlooper (D-Colo.) and Ted Budd (R-N.C.) successfully added an amendment creating that team to a key pandemic preparedness bill that must be reauthorized by the end of September. It would establish this new program within Marks' division of the FDA, staffed with experts on vaccines, antibodies, diagnostic tests, personal protective equipment, and other medical countermeasures. Among other activities, this team would enhance surveillance programs and prioritize vaccine research and development so that existing platforms can be retooled to fight other viruses.

As a vocal advocate for faster gene therapy approvals, Marks has also been pushing for an Operation Warp Speed for Rare Diseases, where a dedicated team would similarly help ensure faster therapeutic development. "We will be launching a pilot — it'll be a small pilot because it's very resource intensive — for rare diseases with high unmet medical needs this fall," Marks said.

For the emerging pathogens program in particular, the Senate amendment might not survive reconciliation with the House version of the bill, which cleared through the Energy and Commerce Committee on Wednesday.

Marks acknowledged another challenge Thursday. Both programs require the FDA to bolster its recruitment efforts in the face of long-standing staffing challenges.

"The pay at FDA still isn't industry standard — for private industry," Marks said, such that agency talent is regularly poached.

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Still, with the FDA working on the frontier of cutting-edge science and novel technologies, "you actually wake up in the morning and really want to go to work," Marks argued. "That is probably worth something in addition to your salary."

Artificial intelligence might also help with some of these challenges, he suggested. "As opposed to people in Hollywood who really hate AI, for us, AI could potentially be a real game changer." Marks says that the FDA has already been using AI for monitoring drug safety and analyzing complex data like whole genome sequencing.

Marks wasn't sure if Operation Warp Speed for Rare Diseases would ultimately make a difference or if the Emerging Pathogens Preparedness Program would get enacted by Congress. But he was optimistic. "Hopefully this will be something that we will be able to make use of," Marks says, "but we'll see where it goes."

About the Author

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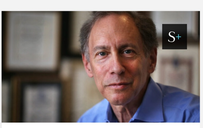

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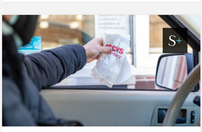

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