

Meet the most important federal official you probably don't know — the man who holds the fate of the coronavirus vaccine in his hands

By Laurie McGinley

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Peter Marks, a self-effacing cancer doctor known for his maniacal work ethic and straight-arrow approach, is sitting on the hottest of hot seats.

A top Food and Drug Administration career official, Marks is likely to decide in the next several months whether a coronavirus vaccine is safe and effective enough to be given to tens of millions of Americans. That may be among the most critical decisions in the history of the agency, one with sweeping health, economic and political consequences.

It's a ruling of intense interest to President Trump, who has not hesitated to attack government health officials he deems politically unhelpful, and who has boasted about pushing officials to speed up vaccine development. Just last week, Trump said in a radio interview that a vaccine might be available "right around" the Nov. 3 election — months earlier than Anthony S. Fauci, the nation's leading infectious-disease expert, has predicted.

Such statements have scientists, health experts and lawmakers watching anxiously for political pressure on the FDA, in addition to possible technical foul-ups and mistakes in scientific judgment. The way the vaccine decision is handled could have an impact on the presidential election and whether enough people are willing to get vaccinated to curb the pandemic and revive the economy. If safety problems are missed, it could be disastrous for this crisis and undermine public confidence in all vaccines.

Thrust into this crucible is a 57-year-old Brooklyn native who oversees a team of experts charged with scrutinizing every bit of data on coronavirus vaccine candidates. Typically, career officials at the FDA, not political appointees, have the final word on medical products.

If historical precedent holds, "the buck will stop" with Marks, said Jason Schwartz, an expert on vaccine decision-making at the Yale School of Public Health. "He will ultimately be the single most critical figure in the vaccine decision."

That makes Marks the most important government employee most people have never heard of.

Scott Gottlieb, Trump's first FDA commissioner, expressed confidence in Marks, saying he was skilled in working in a political environment without advancing his own political agenda. "He'd do what he needed to do to secure our public health prerogatives," Gottlieb said. "And he was always working, always. He would call me at random times when an idea was percolating in his head."

A close associate predicted Marks on vaccines “won’t play the political game one way or another. If he gets pushed, he’ll go public or maybe resign. He won’t be quiet.” The individual spoke on the condition of anonymity to offer a candid assessment.

Still, some scientists remain intensely worried. They say things could go seriously awry in an administration with a track record of politicizing science and an agency accused of caving to pressure on a past presidential priority.

While “I have high faith” in FDA scientists, “I think we are seeing things go on and norms destroyed quite commonly” in the Trump administration, said Jesse Goodman, a Georgetown University professor and former director of the FDA’s Center for Biologics Evaluation and Research, which Marks now heads.

“We have seen the tremendous pressure put on other science-based agencies, and we haven’t always seen them stand up to that,” he said. In his view, the FDA’s reputation was damaged by its emergency authorization, since reversed, of hydroxychloroquine, an unproven drug for the coronavirus that was touted by Trump. “There needs to be no more of that,” he said.

Marks said he understands the stakes: “What I hear in my head is out of a James Bond movie, when M [the head of MI6] says, ‘This is the big one, 007, do not screw it up.’ ”

He said he realizes it is part of his responsibility to make sure a vaccine decision isn’t rushed. “Let’s be realistic,” he said. “There are so many eyes on this vaccine that if somebody decided to go around the process, I think there would be red flags that would be put up by a variety of sources. So I think it’s going to be critical that we work through the process.”

FDA Commissioner Stephen Hahn said in a statement that Marks and his scientists will “call the balls and strikes” on a vaccine and will not cut corners. “There are no circumstances under which the FDA would allow a vaccine to be released for use by the public if it is not shown to be safe,” Hahn said.

Some FDA watchers, predicting mounting pressure as the election approaches, are not assuaged. They note Marks’s political bosses have the legal authority to overrule him. “This is not a hypothetical,” said Arthur Caplan, director of the division of medical ethics at the NYU Grossman School of Medicine. “We already know the administration has staked almost its entire reelection on having a vaccine.”

Edge of the cliff

On Feb. 27, Marks had dinner in New Haven, Conn., with his friend Albert Ko, a Yale University infectious-disease expert. The two had gone through medical training together and taken family vacations in Rhode Island; Marks sailed and Ko fished. But on this night, their jocular conversation turned dark as they contemplated what lay ahead with the looming pandemic.

“You are on the edge of the cliff, and you don’t know what the bottom is going to look like,” recalled Ko. “We were both trying to figure out how to prepare. What has happened subsequently has been horrible.”

Ko went on to advise Connecticut Gov. Ned Lamont (D) on the state’s response to the pandemic. Marks gave a speech at Yale about including minorities in clinical trials. A few days later, authorities confirmed the first coronavirus case in New York.

In April, Marks proposed a crash program for the large-scale development and production of vaccines. Having once worked in the pharmaceutical industry, he believed he knew how to speed up the process.

The long-time Star Trek fan dubbed the idea “Operation Warp Speed” — a name that stuck for the administration’s effort to fast-track a vaccine and other countermeasures. When the effort was put together, Marks was included as a vaccine expert. But after Moncef Slaoui, who worked in vaccines at the pharmaceutical firm GlaxoSmithKline, was named head of the initiative and other experts were hired, Marks returned to his FDA job. Some officials said Marks and Slaoui clashed; Marks has said he decided he was more useful as a regulator.

Supporters welcomed his decision. The vaccine decision is “huge and you want the head of the biologics center to make it,” said Peter Lurie, a top FDA official during the Obama administration.

In June, Marks took the unusual — and many vaccine experts said wise — step of laying out the rules of the road for coronavirus vaccine developers. In a guidance, the FDA said any product would have to be proven safe and at least 50 percent more effective than a placebo in a clinical study in preventing the disease or decreasing its severity. Officials said the requirement applies both to full approval or an emergency authorization — a temporary approval that can be granted more quickly on less extensive data.

Some experts viewed the 50 percent benchmark as too low, while others said it was too high. Marks argues it is reasonable, roughly equivalent to the flu vaccine. He said the agency didn’t want to go lower because getting a vaccine that doesn’t help people “is not a victory in any way. . . . We will just be back in the same mess.” He also said that eradicating the virus will likely require a vaccine closer to 70 percent effective — with 70 percent of the population taking it.

Health experts warn releasing a vaccine that is not effective enough or causes significant side effects could fuel already-roiling anti-vaccine sentiment, with catastrophic consequences. A Gallup poll released Friday showed that 65 percent of Americans said they would take a vaccine, but 35 percent said they would not, even if it were free and approved by the FDA.

To try to bolster public confidence, the FDA said it will publicly consult with its advisory panel of vaccine experts before clearing any vaccines. Paul Offit, a panel member who is director of the Vaccine Education Center at Children’s Hospital of Philadelphia, said he understands there will be an Oct. 22 meeting to consider covid-19 data. But the timing likely depends on whether one or more of the manufacturers in late-stage trials have critical data.

The question of emergency authorization may become a flashpoint. Consumer watchdog group Public Citizen said last week the FDA should announce it won’t authorize a vaccine on an expedited, emergency basis — or risk hurting public trust.

But many health experts say the agency almost surely will use its emergency authority, perhaps for a subgroup of the population especially at risk, considering the urgency of the crisis. And the FDA said it might be an appropriate step after a vaccine is proven safe and effective but before its manufacturer submits an application or the agency completes a full review.

One part of Marks’s job is to oversee an FDA “expanded access” program for the use of convalescent plasma for patients with covid-19. Doctors theorize antibody-rich plasma, derived from the blood of

people who have recovered from the disease, may benefit those who are battling it. Earlier this year, the FDA approved the program, which has been organized by the Mayo Clinic; more than 50,000 patients have received plasma. But scientists say it remains unclear whether the treatment works and that the program has inadvertently made it harder to complete the rigorous clinical trials that would determine efficacy.

Marks said the program was set up because the agency was being overwhelmed by individual requests from doctors trying to help desperately ill patients. He said it was never supposed to replace trials by hospitals that, he said, did not start as quickly as he had hoped.

Late-night calls

Marks came to the FDA eight years ago with a varied background. As an undergraduate at Columbia University, he planned to be a research biochemist. But during a part-time job as a phlebotomist at a local hospital, he found he liked helping patients and went to medical school. He also got a PhD in cell and molecular biology.

Marks wound up at Brigham and Women's Hospital in Boston, where Norman "Ned" Sharpless, director of the National Cancer Institute and former acting FDA commissioner, trained in the late 1990s. He remembers Marks as a young attending physician who often took 3 a.m. calls from doctors who did not know how to stop patients' excessive bleeding.

"We loved Peter," Sharpless said. "He knew everything about every weird blood problem you could call about. He'd give advice, and it usually worked."

At one point, Sharpless realized Marks almost always seemed on call late at night. "I think he had trouble telling people no," Sharpless said. "That, I assure you, he has developed."

After his time at Brigham and Women's, Marks worked for drug companies Genzyme and Novartis but concluded business was not his passion and returned to academic medicine at Yale, becoming chief clinical officer at the cancer hospital there. He applied to the FDA after seeing an ad in the New England Journal of Medicine, thinking his diverse experience might be a good fit.

Since Marks became director in 2016, the center — whose 1,200 employees regulate biological drugs, cellular therapies and blood as well as vaccines — has granted landmark approvals for novel treatments, including the first CAR T-cell therapy for advanced cancer and pioneering gene therapies for a rare form of childhood blindness and spinal muscular atrophy, a devastating illness that can affect infants. Last December, the FDA approved the first Ebola vaccine.

In January 2019, amid a shutdown of the federal government, Marks flew to San Francisco to meet with prominent scientists who were frustrated about what they saw as overly rigid FDA rules on CAR T-cell therapy. The meeting was at times heated, "but he listened, understood the problem and was willing to clarify the FDA's goals," said Ellen Sigal, founder and chairperson of Friends of Cancer Research, the advocacy group that organized the meeting.

Among the other high-pressure situations he has been involved in, former colleagues say, were negotiating in 2016 with congressional Republicans who wanted to sharply reduce FDA's regulations on stem cells and other regenerative therapies and taking steps to safeguard the blood supply during the Zika outbreak.

Within the agency, Marks is known as a popular manager who cackles when he laughs and used to host ice cream socials and cookie exchanges for staffers. "I used to go out and buy Popsicles," he said. "No federal funds were used."

Up at night

Experts say deciding on the first vaccines will be especially difficult if the data isn't clear-cut, and shows so-so efficacy and side effects. "I wouldn't want to be in [Marks's] position," said Lurie, the former FDA official. "It's an awesome responsibility."

Marks is clear about what he can and cannot do, especially when it comes to attitudes about vaccines. He said he doesn't expect to influence die-hard vaccine opponents, but rather is focused on people who are "not so much hard core, but coming along for the ride due to social media and the doubts raised. It's really critical to help those people feel reassured."

Even after the FDA clears the first coronavirus vaccine, the agency will require the manufacturer to conduct safety monitoring for any problems, he noted. And some answers might not be clear immediately: Will the vaccine need to be given every year? Could the virus change genetically?

"All those things keep you up at night," he said. But, he added, "Our job is to do our best, and to deal with first wave of vaccines that are coming through and make sure they are as safe as they can be."