What letting RFK Jr. ‘go wild’ might mean for Trump’s FDA

Kennedy is a longtime vaccine skeptic and a proponent of the ‘Make America Healthy Again’ movement

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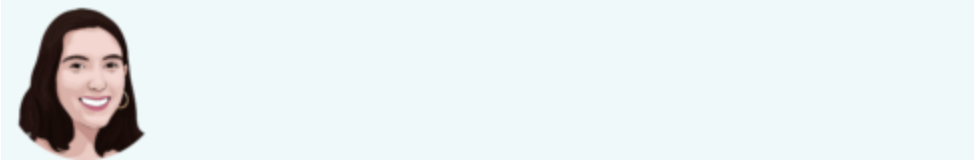

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Nov. 6, 2024
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With Donald Trump's victory in the presidential election, public health experts are anxiously waiting to see whether his embrace of Robert F. Kennedy Jr. will translate into real policy, and perhaps chaos, at the Food and Drug Administration — the regulator tasked with ensuring that America's drugs are effective and its food is safe to eat.

In the weeks leading up to the election, Trump promised supporters that he would give RFK Jr. an important role in his administration and let him "go wild" on health care.

In his victory speech, the president-elect name-checked Kennedy again. "He's going to help make America healthy again," Trump said. "He's a great guy and he really means it. He wants to do some things, and we're gonna let him go to it."

RFK Jr., who aligned himself with Trump after ending his own presidential campaign, proclaimed on X in October that the FDA's "war on public health" was about to end.

"If you work for the FDA and are part of this corrupt system, I have two messages for you: 1. Preserve your records, and 2. Pack your bags," Kennedy wrote.

Based on his public statements, Kennedy's agenda could include an effort to eliminate drug company user fees that help fund the FDA, loosening regulation of raw milk, personally reviewing data on vaccines to judge their safety, and cracking down on ultra-processed foods and food additives.

"The key, which President Trump has promised me, is control of the public health agencies, which is HHS and its sub-agencies, CDC, FDA, NIH and a few others," Kennedy said on a Zoom call with supporters in late October.

Kennedy has been the Trump campaign's primary mouthpiece on the FDA and other health policy issues. He is a longtime vaccine skeptic and a proponent of the "Make America Healthy Again" movement, which focuses on ending chronic disease. Kennedy and others attribute the rise in chronic diseases to unhealthy food, the environment, and most controversially, the pharmaceutical industry. MAHA's anti-pharma messaging has alarmed industry leaders and even former GOP officials.

Experts told STAT they are skeptical Kennedy could win Senate confirmation to lead a health agency himself. They're skeptical, too, that his more ambitious policy ideas, like eliminating user fees, will find traction in Congress. But they can see him wielding influence over the FDA from a White House perch, even if Trump selects a more traditional commissioner.

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Trump transition co-chair Howard Lutnick said Kennedy is not getting a job at the Department of Health and Human Services, but hinted at Kennedy snagging some sort of role allowing him to look into vaccines.

While experts have found a silver lining in Kennedy's focus on improving food regulation, they worry that his distrust of vaccines and FDA civil servants will wreak havoc and delay patient access to critical medicine.

Trump could also bring back an executive order that he issued in his first term, that would let him fire civil servants perceived as "disloyal" to the president.

"If he starts to muck around into the scientific, evidence-based process of how to assess safety and efficacy, he can do tremendous damage," Anand Parekh, chief medical advisor at the Bipartisan Policy Center, said of RFK Jr.

When Trump was elected to his first term, experts' biggest worry was that the agency would go too easy on drugmakers. Trump's pick for FDA commissioner, Scott Gottlieb, was a physician and conservative businessman with close ties to pharma. But Gottlieb ultimately earned praise for his tough regulation of vaping companies, as well as his work to expand access to generic drugs and to fight the opioid epidemic. Even some of Gottlieb's critics are hoping that Trump might select someone like him again.

"The dialogue seems to have shifted from how do you reform an agency to how you dismantle an agency completely," said Holly Fernandez Lynch, a health policy professor at the University of Pennsylvania.

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Fernandez Lynch and Parekh agreed that replacing drug and device industry payments with funding from Congress could reduce companies' influence over the agency and lead to better regulatory decisions.

But the reality of eliminating user fees is more complicated. In fiscal year 2024, user fees accounted for $3.3 billion — around 46% — of the agency's $7.2 billion budget. That money funds thousands of FDA employees who help make the drug and device approval process more efficient. Companies have benefited tremendously from this, whereas lawmakers are less likely to give more taxpayer money to the FDA.

"The drug industry and medical device industry are very happy with user fees," said William Hubbard, former associate FDA commissioner for policy. "It's gotten them a lot. To wreck the drug approval process by firing two-thirds of their staff would be devastating to the industry. They're not going to let that happen."

Other MAHA ideas, like cracking down on food additives and pesticides, may find more support within the agency and from Congress. But Hubbard sees those goals angering industries that are used to a pro-business Republican perspective as well.

"It would be difficult for Trump to adopt most of their policies because he'd be running afoul of people that are big time donors to Republicans, like the pharmaceutical industry, large food processors, the crop-processing and agricultural communities," Hubbard said.

It's very possible Kennedy or others in Trump's orbit will undermine the agency by promoting distrust in FDA-approved vaccines. Lutnick, Trump transition co-chair and CEO of financial services firm Cantor Fitzgerald, questioned the safety of vaccines on CNN the week before the election. FDA's top vaccine regulator Peter Marks told STAT the Monday before the election that he is committed to fighting vaccine misinformation with transparency.

“If we’re honest about this, if we’re transparent, hopefully people will understand the benefits-risk [calculations] here and feel confident in their use, knowing that the risks are very small, the benefits are very much present,” Marks said.

A Trump FDA might also be less willing to defend its authority to allow telehealth orders of the abortion medication mifepristone, a power that was affirmed by the Supreme Court this summer. Access to the drug could still face legal challenges, and Trump’s messaging on the issue has been vague.

Kristie Kuhl, global managing director of health at the PR firm Zeno Group, told STAT that biotech and pharma leaders are most concerned about Trump and Kennedy’s unpredictability when it comes to the FDA. That unpredictability combined with the FDA no longer having the authority to make regulatory decisions based on ambiguous statutes could create an untenable situation for companies, she said.

“Trump moving very close to Robert F. Kennedy, Jr. and saying things like ‘I’ll let him go wild on FDA’ means he’s looking for a different approach,” Kuhl said. “The biggest thing that we will see is instability.”