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The FDA in the Second Trump Administration

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Turnover in control of the executive branch inevitably means change in the agenda of the Food and Drug Administration (FDA), which regulates medical products, most of the food supply, and other products constituting a fifth of the US economy.[1]

However, President Trump's embrace of the "Make America Healthy Again" (MAHA) movement foreshadows unprecedented disruption at the FDA. His nominees for Secretary of Health and Human Services (HHS) and for Commissioner of Food and Drugs are, respectively, Robert F. Kennedy Jr. (RFK Jr.) and Dr. Marty Makary. The former is as unqualified and potentially destabilizing as the latter is conventional.

Trump has declared he would allow RFK Jr. to "go wild on health" through "control of the public health agencies." Because the FDA's authority is delegated by the Secretary and its decisions subject to overrule, Kennedy's views are highly germane to the FDA. RFK Jr. has

- declared that the "FDA's war on public health is about to end";
- asserted "there's no vaccine that is safe and effective" and called the COVID-19 vaccine the "deadliest vaccine ever made;"
- claimed the pharmaceutical industry is "mass poisoning us;" and
- stated "America's public health agencies are corrupt. How can we trust them when they profit from the products they promote (and mandate)?"

Any of these statements could have ruled RFK Jr. out as a serious candidate for secretary in previous administrations.

In contrast, Dr. Makary is a Johns Hopkins professor of surgery, prolific scientific author, and member of the National Academy of Medicine. He has authored an insightful critique of the FDA's postmarket oversight of robotic surgery.[2] While he often questions medical orthodoxy, it was his stance on the public health response to the COVID-19 pandemic – including mischaracterizing efficacy data on the vaccines – that secured him his nomination.

Unlike critics alleging COVID-19 vaccines were unsafe or lacked evidence of effectiveness, Makary opposed immunization mandates and boosters because, as he testified to Congress in 2023, "Nothing speaks more to the intellectual dishonesty of public health leaders than their complete dismissal of natural immunity."

Potential Threats to FDA Authority and Capacity

RFK Jr. would hold sway over the FDA because the agency is within HHS and its budget must secure both HHS and White House approval. The Administration could defund programs and abandon policies, and if a Republican Congress agrees, hollow out the FDA's capacity to regulate. If such changes are pursued, would Makary implement them regardless of their impact on the FDA and on public health, or rely on scientific evidence as an independent, potentially contrarian, decisionmaker?

Even if Makary opposes such cuts or aligns with his career staff on science-based decisions, RFK Jr. could overrule the FDA. When HHS Secretary Sebelius overruled the FDA on over-the-counter (OTC) access to Plan B, it was an exceptional action. But it became almost normative under Trump's HHS Secretary Alex Azar, who broadly withdrew FDA rulemaking authority, overruled the Agency on COVID-19 diagnostics, terminated an unapproved drugs initiative, and exempted 91 medical devices from review.

Even without formally overruling the FDA, RFK Jr. could "fence in" the Agency through public statements or by convening advisory meetings to establish procedural bounds to the FDA's policies or enforcement priorities.

These risks are compounded by the new Department of Government Efficiency (DOGE) led by Elon Musk. DOGE may target the enforcement budgets of agencies like the FDA in a manner reminiscent of Vice President Quayle's Council on Competitiveness and President

Reagan's deregulatory initiatives (under which the FDA's staff declined by one-third).

RFK Jr. placed the FDA's funding in the bullseye in September by calling for "reform" of the Prescription Drug User Fee Act (PDUFA), which funds the FDA's review of new drugs. PDUFA fees and other user fees for medical devices, generic and OTC drugs, and other regulated products were $3.5 billion of the $7.2 billion FDA Fiscal Year 2025 budget request.

RFK Jr. claims PDUFA "puts bureaucrats' purse strings in the hands of the pharmaceutical industry." But more than 30 years of independent reviews and congressional oversight[3] since its 1992 enactment[4] have found no evidence of a "captured agency" co-opted by its regulated industries. Makary's views of user fee funding are unknown, but because these programs must be reauthorized after September 30, 2027, RFK Jr.'s skepticism could jeopardize a critical funding mechanism that has ensured American patients' timely access to the most novel medicines.

RFK Jr.'s vow to "get the corruption out of our government agencies" also amplifies risks to FDA's already challenged recruitment and retention of scientific and medical experts. His campaign staff promises heightened scrutiny of FDA career managers for their former employment by regulated companies with subsequent disclosures, which could subject them to punitive congressional oversight.

Risk of an FDA brain drain is amplified by the expected resurrection of Schedule F to eliminate workforce protections for policymaking managers. Administrative changes claiming "corruption" could also alter FDA policy toward membership of its advisory committees, which is already under reform, and could inhibit FDA's retention of essential staff, but Makary's resistance to HHS and the White House could prevent further damage, including a protracted oversight "witch hunt" intended to punish current or recent Agency managers for their decisions during the COVID-19 pandemic.

Implications of Trump Administration Regulatory "Reform"

Vaccines. The Administration has broad discretion beyond the FDA to cripple federal immunization policy. President Trump recently confirmed that "getting rid of some vaccinations" could occur "if I think it's dangerous, if I think they are not beneficial," presumably by curtailing the Center for Disease Control and Prevention (CDC) pediatric immunization schedule. Trump said he would "be listening to Bobby," who promoted anti-vaccine views in Samoa prior to a 2019 measles outbreak, pursued litigation alleging federal suppression of views critical of COVID-19 vaccines, and lobbied against COVID-19 immunization for children and infants.[4]

Trump spoke approvingly of his nominee's intent to resurrect debunked allegations that childhood vaccines and thimerosal are linked to autism, which are also supported by CDC Director-nominee Dave Weldon, but are based upon discredited publications contradicted by subsequent research and a National Academies' systematic review.

In response to emerging infectious diseases, such as H1N1, RFK Jr. could decline to request emergency funds, block the FDA's use of Emergency Use Authorization (EUAs), or refrain from using expedited contract and acquisition authorities to develop, purchase, and distribute vaccines.

Dr. Scott Gottlieb, Trump's first FDA Commissioner, has stated, "I think if RFK follows through on his intentions, and I believe he will and I believe he can, it will cost lives in this country."

While Makary lacks his prospective colleagues' anti-vaccine credentials, he will have plenary authority to implement his views on natural or herd immunity: ordering revisions to the FDA's procedures for vaccine licensure, reorganizing the vaccine review division, or issuing public health advisories and other product communications.

Trump recently said that "[w]e're going to be able to do very serious testing, and we'll see the numbers", suggesting that the FDA may require new postmarket studies or scientific reviews of childhood vaccines, in advance of restricting the labeling of, and access to,

vaccines. Makary had similarly called on the FDA in 2022 to conduct active surveillance — rather than rely on voluntary adverse event reporting — to assess vaccine safety.

Mifepristone. New restrictions in mifepristone access could easily be reinstated or created *de novo* by the FDA rather than the courts, following the Supreme Court's unanimous June 2024 *FDA v. Alliance for Hippocratic Medicine* decision. The FDA could reverse itself and grant what the courts did not, beginning with reinstatement of an in-person prescribing mandate and disallowing mail-order access to mifepristone. The agency could also mandate new restrictions, such as opening a public docket soliciting adverse data, requiring mifepristone's sponsor to conduct new clinical trials of its safety risks, or initiate new labeling restrictions to limit prescribing and patient eligibility.

Food and food additives. As Sandro Galea has noted, RFK Jr. may be "committed to improving food and nutrition in the country" through reducing consumption of ultra-processed foods, banning or limiting food additives and high-fructose corn syrup, and reducing pesticide residues in food. Makary's views appear to align with Kennedy's on the roles of ultra-processed foods and pesticides in chronic disease. "We have poisoned the food supply," Makary posted in September, "for our nation's children."

While much of this agenda lies outside the FDA's jurisdiction, RFK Jr. has said "there are entire departments, like the nutrition department at the FDA … that have to go." Kennedy and Makary could seek radical change to the Generally Recognized As Safe (GRAS) regulation of food additives, which the FDA plans to improve, but they would need lengthy rulemakings or statutory enactments. Yet the Administration will have a ready legislative vehicle in the user fee reauthorizations that must be enacted before the end of Fiscal Year 2027.

RFK Jr. has even proposed declaring a public health emergency declaration "for chronic disease," which would allow him to waive Medicare and Medicaid requirements and access the Public Health Emergency Fund—but not waive how foods and food additives are regulated.

Conversely, while RFK Jr. views foods and food additives as underregulated, he believes the FDA is "aggressive[ly] suppressi[ng]… psychedelics, peptides, stem cells, raw milk, hyperbaric therapies, chelating compounds, ivermectin, hydroxychloroquine, vitamins…

[and] nutraceuticals." Many of these products have notable, unsubstantiated disease treatment and health claims, including against COVID-19, which render them unapproved new drugs regulable by the FDA.

Just as he rejects overwhelming scientific evidence that AIDS is caused by HIV infection, RFK Jr. could be correspondingly receptive to untrue or exaggerated disease treatment or curative claims for unapproved new drugs on the basis of comparably flimsy evidence.

While Makary has not exhibited similar skepticism of the FDA's regulation of such claims, he has written about the risks of medical dogma and the industrialization of medical care. With broad authority over these products, pharmacy compounding, dietary supplements, and product clinical trials, Makary could loosen evidentiary requirements by having the FDA exercise "enforcement discretion" to allow the marketplace to — in Trump's words, "run wild" and undermine the foundation of evidence-based market entry, patient and provider certainty, and investor expectations that underlie biopharmaceutical innovation.

Conclusion

President Trump's unconventional nominations and embrace of MAHA signal major potential shifts in Federal public health regulation, from a greater emphasis on chronic disease and heightened scrutiny of childhood vaccines, to a deregulatory stance towards "homebrew" lab tests and unapproved dietary supplements. It remains to be seen if the Republican-controlled Congress will confirm his nominations and abet these major policy reforms.

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S.Hrg. 110-384, March 14, 2007; Senate HELP Committee, FDA User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients, April 5, 2022

4. Ironically, RFK Jr.'s late uncle, Senator Edward Kennedy was similarly concerned about the risks of agency capture, but came to author PDUFA and other user fee programs to ensure FDA had the funding to be "strong and vigilant watchdogs for public health to guarantee that new drugs and medical devices are safe and beneficial."
5. Time Magazine. Donald Trump's 2024 Person of the Year Interview With TIME. Published December 12, 2024. https://time.com/7201565/person-of-the-year-2024-donald-trump-transcript

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Paul T. Kim is principal of Kendall Square Policy Strategies LLC, providing advice on the US Food and Drug Administration (FDA) and life science and public health policy to Fortune 500 companies, national patient advocates, trade associations, and emerging companies in the US, Europe, Israel, and Korea. With expertise and publications in drug and device law, orphan drug innovation, immunization policy, and biodefense matters, he is currently a consultant advisor to the National Organization for Rare Disorders and to the Sjögren's Foundation. Paul led the FDA and federal government strategy practices a US law firm for 20 years, following his work as counsel to the late Senator Edward Kennedy, Congressman Henry Waxman, and the late Senator David Pryor. Prior to his work in Congress, Paul worked for the FDA, the American Foundation for AIDS Research, and a European biopharmaceutical company. He earned a J.D. from Georgetown University and a 1990 master's in public policy from the Kennedy School of Government at Harvard University, and is a 1988 graduate of Harvard College.

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