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Making the FDA Great Again

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The US Food and Drug Administration (FDA) is passing through an unsettled period. After a year of confusion that saw thousands of employees either terminated or driven to leave, the agency's depth and accumulated expertise have been thinned. Through a stream of departures, it appears that parts of the FDA have been set back almost 2 decades. As one troubling example, the agency's Oncology Center of Excellence (the medical review group that evaluates new cancer therapies) has seen about half of its clinical review staff leave since January 2025 from a starting strength of around 100.[1]

The Trump administration is now finding that the FDA has struggled to perform basic functions from inspection logistics to product review.[2]

Some of the new leadership at the US Department of Health and Human Services have recognized these challenges and begun to change course. Over the past month, the FDA has watched a succession of its political leadership leave or be terminated as part of a reset, including the FDA commissioner himself. Their departures create an opening for the Department of Health and Human Services to reconsider how the FDA is governed, what kind of leadership it requires, and where the boundary lies between political power and scientific judgment.[3]

One overarching standard to reinstate, which would help restore the FDA to a firm footing, is leadership of the FDA's medical product centers by seasoned scientific and clinical experts. Over the past year, a reflexive belief has taken hold that the surest way to seize control of the FDA's policy agenda is to install political appointees in these posts. That approach mistakes authority for effectiveness.[4]

The medical product review centers function best when their core regulatory decisions are guided by people steeped in the agency's science, traditions, and operational mechanics—leaders who command credibility not because they hold political power but because they possess deep technical expertise and the trust of the professional staff. Presidential administrations from both political parties have sometimes imagined that politically appointed center directors will give the administration more control but the opposite is true. An FDA commissioner championing a novel policy (eg, accelerated approval reforms, a new compounding standard, a more flexible benefit-risk framework) needs scientific leaders whose technical judgment is unimpeachable.

A reform backed by career experts, who have spent decades building credibility in their field, carries weight both inside the FDA and with outside institutions (including Congress, the courts, and industry) that scrutinize what the agency does. The same reform advanced by political appointees alone reads as ideology and meets resistance. The technical machinery works the same way. A new policy does not take effect just because the FDA commissioner announces it. It takes effect through internal operating documents (Good Review Practices and procedural manuals) that tell reviewers how to apply the new strategy to the applications coming before the agency.

Putting political appointees in charge of the medical product centers conflates 2 things that should not be confused. Policy is supposed to apply political judgment to which therapeutic areas need more attention, how flexible the FDA's standard should be for a new area of technology (such as artificial intelligence), and how much regulatory uncertainty society is willing to tolerate to expand patient access. These are policy decisions that elected officials and their appointees should influence.[5] When I led the FDA, we made a concerted effort to streamline review of complex generic drugs, and crafted new policies related to opioid drugs to ensure they were thoroughly evaluated for their potential to be diverted and used illicitly. Both efforts lined up squarely with the first Trump

administration's policy goals of lowering drug costs through generic competition and confronting the opioid epidemic.

However, these policies were implemented in the way the FDA was built to get things done. Draft guidance documents were issued; comments were solicited from sponsors, physicians, patient groups, and other stakeholders; the drafts were revised based on feedback from these groups; and then the documents were finalized. Career FDA staff led the work. The resulting policies reflected what the FDA's own reviewers saw in practice, not just what political appointees wanted on paper. The guidance documents and regulations that were issued were designed to survive changes in presidential administrations and hold up in court if challenged.

In the past year, some parts of the agency have continued to operate in this fashion, notably the FDA's Human Foods Program under the leadership of Kyle Diamantas, a political appointee. Diamantas worked closely with career staff at the FDA to implement new food policies, building internal support, engaging stakeholders, and writing the changes into guidance documents and regulations designed to stick. His tenure shows that politically appointed leaders who possess legal and regulatory expertise and institutional discipline can guide a center effectively, but largely in areas like food and tobacco regulation that are inherently entangled with broader political pressures and considerations. Diamantas is now serving as the FDA's acting commissioner.

For medical products review, implementing new policy depends on decisions that are fundamentally scientific. So, the circumstances are different. Across the drug and biologics centers, including the Center for Biologics Evaluation and Research under Vinay Prasad, the FDA has operated with politically appointed heads that departed from these norms. Traditionally, the FDA commissioner, working under the president's direction, sets broad rules. The medical review centers apply those rules to individual products. Collapse that distinction and every action turns into one perceived as a political decision instead of a regulatory one. That perception hurts the FDA's legitimacy. It also, paradoxically, hurts the political objectives because once decisions appear to be political, they get opposed in ways that regulatory decisions are not.

Every advanced drug regulatory agency in the world structures its scientific review under the leadership of career experts, with political oversight layered above that foundation. This convergence is no accident. An agency's international credibility—and the willingness of foreign regulators to rely on its judgments—depends on its ability to function as a scientific institution informed by evidence and technical expertise, rather than as an instrument of a particular administration's political priorities. Politicizing the centers risks surrendering the US position as the global regulator of reference just as China builds toward replacing the FDA's international role.

The periods of greatest credibility—and greatest administrative and legislative success in modernizing the FDA's practices—have coincided with strong career leadership in the centers paired with effective commissioners. The FDA's historical structure works because it gives political leaders maximum leverage over policy by keeping them out of individual product decisions. Trying to seize control of the medical review centers does not expand the power of political leaders. Rather, it collapses the structure that allows the FDA to achieve reforms that political leaders most want to see.

ARTICLE INFORMATION

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