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# "Whole-of-Government" Approach? How New Leadership at HHS, FDA, and FTC Could Amplify Antitrust Pressure in the Pharmaceutical Sector

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President Trump's selection of Robert F. Kennedy Jr. as Secretary of the Department of Health and Human Services (HHS) marks a dramatic shift in federal health policy, creating a rapidly evolving enforcement landscape for pharmaceutical companies. Kennedy's appointment—alongside President Trump's picks of Dr. Marty Makary to lead the Food and Drug Administration (FDA) and Andrew Ferguson as Chair of the Federal Trade Commission (FTC)—signals a potential recalibration of antitrust and competition policy. These leaders have openly criticized drug pricing practices and alleged anticompetitive conduct in health care markets, aligning closely with President Trump's agenda. Pharmaceutical companies should brace for increased regulatory scrutiny.

On April 15, 2025, President Trump signed the executive order titled "Lowering Drug Prices by Once Again Putting Americans First," aiming to reduce prescription drug costs by aligning U.S. prices with those in other developed countries, accelerating approvals for generics and biosimilars, and enhancing pharmaceutical supply-chain transparency. And on May 12, 2025, President Trump signed another executive order titled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," which aims to reduce prescription drug prices for Americans by requiring drugmakers to offer U.S. patients the lowest price available in comparable countries through a most favored nation policy, threatening regulatory actions, tariffs, and importation measures if companies do not comply. Both executive orders reflect an aggressive strategy to lower drug costs through a number of means, including threats toward companies that do not comply.

As the administration implements its health care agenda, pharmaceutical companies should prepare for significant regulatory changes. The convergence of leadership at HHS, FDA, and FTC—all sharing a critical stance on drug pricing and competition—suggests a coordinated approach to enforcement, including antitrust, with potentially far-reaching implications for the pharmaceutical sector.

## New Leadership Brings Controversial, but Shared Views to the Table

### Robert F. Kennedy Jr.

RFK Jr. has asserted controversial views over the years, including on vaccines, antidepressants, and ADHD medications. His outspoken criticism of pharmaceutical companies has already impacted vaccine uptake, increasing consumer skepticism and potentially exacerbating public health risks.[1] Kennedy has pledged to overhaul the FDA and other agencies, including purging the agencies of officials he deems too close to industry interests.[2] He has also pledged extensive personnel changes across HHS agencies, which have reportedly affected approximately 10,000 employees, including significant cuts at the FDA, Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Centers for Medicare & Medicaid Services (CMS).

### Dr. Marty Makary

RFK Jr. is not alone in his criticism of regulatory agencies and the pharmaceutical industry. Dr. Marty Makary, recently confirmed as FDA Commissioner, echoes Kennedy's concerns about regulatory agencies and pharmaceutical practices. A former surgeon at Johns Hopkins Hospital, Makary criticized the FDA and CDC for their decision-making during the COVID-19 pandemic, pointing to the broad vaccine mandates and vaccination policies as examples of the federal agency overreach.[3] Additionally, he accused pharmaceutical companies of "gaming the system to use the [Orphan Drug Act] for mainstream drugs," exploiting orphan status benefits and patent exclusivity.[4]

Makary emphasizes the need for competition-related reform, criticizing the Orphan Drug Act for hyperextending government-sponsored monopolies rather than fostering genuine innovation and allowing pharmaceutical companies to generate significant profits. His stance aligns with Kennedy's, suggesting an increased push toward promoting generic and biosimilar competition and revising pharmaceutical industry-friendly policies.

### Andrew Ferguson

FTC Chair Andrew Ferguson's views on health care also appear to align with RFK Jr.'s and Makary's, as he too has signaled an openness to aggressive enforcement, stating: "Every American is a consumer of prescription drugs and healthcare, and the prices for those goods and services are out of control . . . we owe it to Congress and the American consumers to do what we can within our statutory mandate to confront this challenge."[5] In a recent dissent, he cautioned colleagues not to be surprised when the FTC implements President Trump's vision with "equal vigor."[6]

## Impact of the Appointments on Agency Actions Against the Pharmaceutical Industry

While the FDA typically operates as an independent agency, the HHS, now led by RFK Jr., retains the authority to oversee and influence FDA decisions. Although historically rare, HHS has occasionally intervened to alter FDA rulings, reclassify medical devices, or adjust regulatory oversight. Given RFK Jr.'s vocal criticism of pharmaceutical industry practices, similar interventions from HHS may increase.

On competition policy specifically, the appointments of Kennedy, Makary, and Ferguson suggest heightened efforts to accelerate generic and biosimilar drug approvals, closely examine drug pricing and exclusivity, and aggressively address alleged anticompetitive practices. The precise impact of these reforms remains uncertain, but rapid policy shifts suggest significant changes should be anticipated.

## A "Whole–of–Government" Approach to Competition in the Pharmaceutical Sector?

President Trump has frequently criticized high drug prices, declaring in multiple speeches how drug prices in America are out of control and vowing to bring them down for consumers. His administration’s broader regulatory push aligns closely with the stances of RFK Jr., Makary, and Ferguson, who have collectively targeted the pharmaceutical industry's pricing and competition practices.

The real question is whether their statements will lead to concrete regulatory actions or merely represent political rhetoric. Regardless of the answer, the fact remains that if it is not all bark, then the bite will hurt existing players in the health care and pharmaceutical sectors, potentially extending beyond drug pricing to broader competitive practices in health care.

## History of FDA–FTC Collaboration on Enforcement Around the Pharmaceutical Sector

Since 1971, the FDA and FTC have collaborated on pharmaceutical competition enforcement, operating under a formal Memorandum of Understanding (MOU). This agreement clarifies each agency's jurisdiction by assigning the FDA primary responsibility for drug safety, efficacy, and labelling, while granting the FTC authority over pharmaceutical advertising, deceptive marketing, and anticompetitive conduct. In practice, this means that while the FDA regulates what drug companies can say about their products, the FTC polices whether those claims mislead consumers or distort competition. Over time, this partnership has expanded into broader competition-related enforcement, particularly in cases where drug companies exploit regulations to delay generic entry or maintain monopoly pricing.

This coordination has played a crucial role in key enforcement efforts over the past two decades. In 2017, the two agencies hosted a joint workshop addressing barriers to generic drug competition, focusing on pay-for-delay settlements, Risk Evaluation and Mitigation Strategies (REMS) abuses, and other tactics that delay generic market entry. In 2020, they issued a joint policy statement pledging to crack down on misleading biosimilar advertising, prevent anticompetitive patent settlements, and

facilitate biosimilar market entry. Most recently, in 2023, the FTC, supported by the FDA, challenged more than 100 Orange Book patent listings, asserting that the drug companies were strategically misusing certain patents to delay generic competition.

Under the new leadership, intensified collaboration between FDA and FTC is likely, potentially leading to stricter merger reviews and heightened scrutiny of practices like patent thickets, reverse-payment agreements, and restrictive rebate structures.

## Important Considerations for In-House Counsel Going Forward

Pharmaceutical companies and their legal teams should pay close attention to these appointments and anticipate increased regulatory scrutiny. Ferguson's leadership signals a more aggressive FTC stance toward pharmaceutical and health care entities, requiring companies to closely monitor developments and proactively ensure compliance.

Beyond mergers, lifecycle management strategies and pricing practices—including rebate agreements with pharmacy benefit managers or insurers—will likely face intensified scrutiny. The administration's alignment across agencies suggests coordinated regulatory actions. However, legal and institutional constraints may moderate the administration's initiatives. For instance, the courts have historically reined in agency overreach, particularly when regulatory actions exceed statutory authority. Recent losses by the FTC in merger challenges and antitrust cases highlight that courts continue to demand strong economic evidence before approving expansive competition theories.

While RFK Jr. has considerable influence over the FDA as HHS Secretary, attempts to drastically change regulatory policy through executive action often faces legal challenges and will likely continue to do so. Therefore, his power to intervene in FDA decision-making—while real—is still subject to legal and procedural safeguards. Any attempts to exceed regulatory authority will likely be met with strong opposition from the pharmaceutical industry, which possesses significant legal resources.

Ultimately, while the new leadership may attempt to reshape pharmaceutical competition policy, they will still have to operate within the confines of existing laws or face judicial scrutiny. In-house counsel must stay proactive in compliance efforts, monitoring cross-agency coordination, and preparing for increased regulatory scrutiny, while also recognizing that companies have viable legal defenses if enforcement actions do go too far.

## Conclusion

The new leadership is clearly determined to shake up health policy, but legal reality is stubborn, and major regulatory shifts don't happen overnight. Pharmaceutical companies should nonetheless prepare for heightened scrutiny, potentially tougher merger reviews, and increased pressure on pricing and exclusivity strategies. But they should also recognize that antitrust law remains a powerful check against regulatory overreach, and the courts have historically enforced these boundaries. The coming months may clarify whether this administration's ambitions result in lasting policy change or face adjustment due to legal and institutional constraints.

[1] Michelle Duff, *"We learned the hard way': Samoa remembers a deadly measles outbreak and a visit from RFK Jr.*, The Guardian (Nov. 25, 2024), https://www.theguardian.com/world/2024/nov/26/rfk-jr-samoa-visit-measles-outbreak-vaccines. *See generally* Moises Velasquez-Manoff, *The Anti-Vaccine Movement's New Frontier*, N.Y. Times Mag. (May 25, 2022), https://www.nytimes.com/2022/05/25/magazine/anti-vaccine-movement.html (describing the impact of vaccine misinformation on public health); Mary Van Beusekom, *Survey reveals growing American distrust in vaccines for COVID, other infectious diseases*, Ctr. for Infectious Disease Rsch & Pol'y (Aug. 29, 2024), https://www.cidrap.umn.edu/covid-19/survey-reveals-growing-american-distrust-vaccines-covid-other-infectious-diseases (showing a growing number of Americans refusing to vaccinate due to vaccine misinformation).

[2] RFK Jr., Instagram (Oct. 8, 2024), https://www.instagram.com/robertfkennedyjr/reel/DA3-IE8vLTQ/.

[3] Dr. Marty Makary, *Opinion: Why COVID-19 Vaccines Should Not Be Required for All Americans*, U.S. News (Aug. 5, 2021, 11:27 AM), https://www.usnews.com/opinion/is-it-time-to-require-covid-19-vaccines.

[4] Dr. Martin A. Makary et al., *The Orphan Drug Act Restoring the Mission to Rare Diseases*, 39.2 Am. J. Clinical Oncology 210, 210–11 (Apr. 2016), https://journals.lww.com/amjclinicaloncology/abstract/2016/04000/the_orphan_drug_act__restoring_

[5] Andrew Ferguson, Comm'r, Fed. Trade Comm'n, Concurring Statement Regarding the Pharmacy Benefit Managers Interim Staff Report ( July 9, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Ferguson-Statement-Pharmacy-Benefit-Managers-Report.pdf.

[6] Andrew Ferguson, Comm'r, Dissenting Statement of Ferguson Regarding the January 16, 2025 Closed Commission Meeting ( Jan. 16, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-ccm-dissent.pdf.

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