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July 15, 2026

Kyle A. Diamantas, J.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Diamantas,

I write to you today as the Representative of California's 15th Congressional District, home to the birthplace of the biotechnology industry, to express my concerns about the management of the U.S. Food and Drug Administration (FDA) and resulting negative impacts to a vital domestic industry. Scientific discovery and drug development is an inherently uncertain process, with more failures than successes. However, the FDA should not inject more uncertainty into the process by causing foreseeable delays as a result of reductions in staff, issuing inconsistent guidance, or maintaining unstable leadership. I implore you to preserve the FDA's reputation as the gold standard of regulators to reestablish certainty into the drug review process and fortify American's leadership in the biotechnology industry.

The life sciences ecosystem is developing products that quite literally are saving lives. It is also a major economic engine across the United States. This is acutely true across California's Bay Area, where in 2025 the industry generated $121.6 billion in economic output and accounted for the direct employment of over 135,000 workers.[1] In my home of San Mateo County, there are over 700 biotechnology companies,[2] many of which are small businesses that are particularly vulnerable to changes in the market brought on by regulators and larger economic trends. The Bay Area's concentration of innovative companies that are advancing scientific progress exists, in part, because of the FDA's role in fostering a national biotechnology industry.

[1] Biocom California, "2026 Life Science Economic Impact Report: Bay Area," June 23, 2026, https://www2.biocom.org/l/54352/2026-06-17/n7dx9h/54352/17817232829os1bC5U/2026_Biocom__EIR_Bay_Area_Fact_Sheet.pdf?utm_source=Website&utm_medium=Biocom+Site&utm_content=2026+Bay+Area+Fact+Sheet&utm_campaign=2026+EIR.
[2] Ibid.

This homegrown industry is developing therapies that will save lives and drastically improve patients' quality of life. For example, in my district, a company has developed a new form of pre-exposure prophylaxis (PrEP) to prevent HIV infections that only needs to be administered twice a year.[3] This new form of PrEP will likely help to reduce HIV infection rates and is furthering the work to end the HIV epidemic once and for all. Another company in my district has recently received the FDA's approval on a product that is the first of its kind to cross the blood-brain barrier,[4] which could unlock new ways of treating neurological disorders. These are just two examples indicative of a larger industry that is pushing the barriers of science to make people healthier. These successes rely on, in part, a predictable regulatory environment where companies and their partners understand the standards they must meet and the processes they need to follow.

The former FDA Commissioner, under the direction of Secretary Kennedy, pursued unwarranted layoffs and the pushing out of career staff, which have led to unprecedented staffing shortages. Predictably, this has raised serious concerns about the agency's ability to be an effective regulator. In 2025, the FDA lost about 4,000 employees to firings, buyouts, and other departures, equating to about 20 percent of the agency's total workforce.[5] Within that total, the Center for Drug Evaluation and Research (CDER) lost over 1,000 employees, bringing CDER down to staffing levels from a decade ago.[6] These departures include seasoned career staff with decades of experience, which a former commissioner argued could set "the agency back a decade plus."[7] Inadequate staffing levels and loss of regulators with highly specific expertise and institutional knowledge raises concerns that the FDA is less prepared than it was prior to 2025 to conduct effective oversight of drugs entering the U.S. market. While the damage has already been done, it is now incumbent upon the FDA to ensure companies are not left to bear the burden of preventable drug delays.

In addition to staffing shortages, the instability in the FDA's leadership since the start of the Trump Administration and the injection of inconsistent standards for drug reviews coming from those in leadership are increasing uncertainty around what companies should expect when engaging with the FDA. Most recently, the resignation of Commissioner Marty Makary after a tumultuous 13-month tenure characterized by pressures to prioritize political considerations over

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[3] Liam Connolly, "Lenacapavir Approved by FDA: What It Means for HIV Prevention," *UC Davis Health News*, July 1, 2025, https://health.ucdavis.edu/news/headlines/lenacapavir-approved-by-fda-what-it-means-for-hiv-prevention-/2025/07.
[4] Denali Therapeutics, "Denali Therapeutics Announces U.S. FDA Approval of AVLAYAH™ (tividenofusp alfa-eknm) for Treatment of Hunter Syndrome (MPS II)," news release, March 25, 2026, https://investors.denalitherapeutics.com/news-releases/news-release-details/denali-therapeutics-announces-us-fda-approval-avlayahtm.
[5] Christina Jewett, "F.D.A. Turmoil Keeps Spotlight on Its Commissioner," *New York Times*, December 19, 2025, https://www.nytimes.com/2025/12/19/health/fda-marty-makary-kennedy.html.
[6] Ibid.
[7] Ibid.

scientific judgment[8,9] has intensified concerns over the FDA's future direction.[10] In addition, CDER and Center for Biologics Evaluation and Research (CBER) have also experienced destabilizing leadership changes, leaving both centers currently without confirmed directors. CDER has had five directors since January 2025, while CBER's previous director stepped down twice after being embroiled in controversies over changing regulatory standards.[11] By fostering a culture of inconsistent leadership seemingly driven by politics, companies are struggling to anticipate how best to engage with the FDA and what will be asked of them during the review process.

The FDA's current path is endangering the United States' leadership in the life sciences. Industry leaders have sounded the alarm that the current regulatory environment is slowing down investment in biotechnology development. A recent Rare Disease Advocacy, Biotechnology, and Investor Coalition survey found that 84% of investors had "decreased, paused, or exited rare disease investments due to recent FDA regulatory uncertainty."[12] Another survey of investors conducted by the Incubate Coalition and Manatt Health again found that the FDA was "directly undermin[ing confidence in regulatory predictability"[13] and "diminished the attractiveness of investments in the biopharmaceutical industry."[14] Uncertainty about the FDA's regulatory practices leads to market volatility, which ultimately deters investment and slows scientific innovation. The FDA's actions are harming the United States' life sciences ecosystem, which could be preventing future lifesaving therapies from ever getting to patients.

Given the vital role life sciences companies play in protecting public health and furthering our domestic economic development, I implore you to preserve the FDA's reputation for being the world's gold standard of leadership in the regulatory space. Biotechnology companies require a consistent and reliable regulator to ensure that the safest and most effective drugs are getting to

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[8] Lizzy Lawrence, "FDA voucher program has become vehicle for political interference in drug review decisions, staffers say," *STAT News*, December 19, 2025, https://www.statnews.com/2025/12/19/fda-voucher-program-political-interference/.
[9] Brian Castrucci, "How A Leadership Change At The FDA Could Impact Daily Lives," *Forbes*, May 18, 2026, https://www.forbes.com/sites/briancastrucci/2026/05/18/how-a-leadership-change-at-the-fda-could-impact-daily-lives/.
[10] Jonathan Gardner, "FDA's Leadership Void Leaves Biotech with Renewed 'Uncertainty,'" *BioPharma Dive*, May 13, 2026, https://www.biopharmadive.com/news/makary-fda-resign-biotech-impact/820090/.
[11] Coral Murphy Marcos, "Trump administration's embattled FDA vaccine chief departing for the second time," *The Guardian*, March 6, 2026, https://www.theguardian.com/us-news/2026/mar/06/fda-vaccine-chief-ousted-vinay-prasad.
[12] The Rare Disease Advocacy, Biotechnology, and Investor Coalition to President Donald J. Trump et al., April 1, 2026, https://www.rtwinstitute.org/media/v4zoajqw/restoring-rare-disease-flexibility-and-innovation-at-the-fda_letter-follow-up.pdf.
[13] Incubate Coalition, "One Pager & Complete Report: Regulatory Instability at FDA Is Reshaping Biotech Investment," April 21, 2026, https://www.incubatecoalition.org/post/one-pager-complete-report-regulatory-instability-at-fda-is-reshaping-biotech-investment#viewer-yeodl1532.
[14] Ibid.

patients. Political whims cannot be allowed to continue to unnecessarily hinder this important domestic industry. Patients' lives depend on timely scientific progress.

Sincerely,

Kevin Mullin
Member of Congress