

March 2, 2025

Dr. Marty Makary
Nominee for Commissioner, Food and Drug Administration
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Dr. Marty Makary:

Congratulations on your nomination to serve as Commissioner of the Food and Drug Administration (FDA). If confirmed, the American people will expect you to uphold the FDA's mission solely in the public's interest — ensuring the safety of food, drugs, and medical devices and making decisions about which pharmaceutical products patients can access. Entering this role with other motivations would put Americans' health and safety at risk. To avoid this, I request that you agree to recuse from matters involving your former clients and, for at least four years after you leave office, to not work as a lobbyist or join the industries that you regulated at the FDA.

The FDA has long had a revolving door problem: nine of the last ten FDA Commissioners went on to work for the pharmaceutical industry or serve on the boards of drug companies that they once regulated directly after leaving the FDA.¹ FDA Commissioners who come from Big Pharma or enter the industry soon after leaving the agency heighten the risk of industry capture at the FDA. To mitigate such concerns, your predecessor Dr. Robert Califf made voluntary ethics commitments beyond those required under ethics law, the presidential ethics pledge, and even agreements with the Office of Government Ethics and the Designated Agency Ethics Officials.² I urge you to do the same.

First, I ask that you commit to recuse from all particular matters involving your former clients and employers for at least four years. You serve as Chief Medical Officer at Sesame Care, a direct-to-consumer health care company that connects patients with providers who virtually prescribe Sesame's medicine. Sesame's business model appears to be designed to "steer patients toward particular medications and creates the potential for inappropriate prescribing that can increase

¹ National Public Radio, "A Look At How The Revolving Door Spins From FDA To Industry," September 28, 2016, <https://www.npr.org/sections/health-shots/2016/09/28/495694559/a-look-at-how-the-revolving-door-spins-from-fda-to-industry>; BMJ, "Revolving doors: board memberships, hedge funds, and the FDA chiefs responsible for regulating industry," Peter Doshi, May 8, 2024, <https://www.bmj.com/content/385/bmj.q975>.

² See, e.g., Office of U.S. Senator Elizabeth Warren, In Response to Senator Warren, FDA Commissioner Nominee Dr. Robert Califf Makes Strongest Ethics Commitments of Any Senior Biden Administration Official, January 31, 2022, Press Release, <https://www.warren.senate.gov/newsroom/press-releases/-in-response-to-senator-warren-fda-commissioner-nominee-dr-robert-califf-makes-strongest-ethics-commitments-of-any-senior-biden-administration-official>.

spending for federal health care programs.”³ Notably, in 2024, Sesame launched a program to sell compounded versions of GLP-1, the active ingredient found in Ozempic and Wegovy.⁴ The FDA has been weighing potential enforcement actions against companies like Sesame that supply compounded drugs.⁵ Your prior relationship with Sesame will present an overt conflict of interest if you work on matters that involve or directly impact Sesame. Additionally, you serve on the board of Harrow, an ophthalmic company that relies on the FDA to approve its ophthalmic therapeutics.⁶ You earned \$40,000 from Harrow in 2023, and while you would resign before taking office, your relationship with Harrow will raise reasonable concerns about your impartiality in regulatory decisions impacting Harrow as long as that relationship remains fresh.⁷

Given these conflicts and in order to maintain public trust in the FDA's impartiality and integrity, you should commit to recuse from such matters involving Sesame, Harrow, and any other entities for which you have worked that may have business before the FDA, for at least four years. Your predecessor, Dr. Califf, agreed to recuse from his former clients' specific-party matters for four years — going beyond the two-year recusal requirement in former President Biden's ethics pledge — as did over a dozen other Biden appointees.⁸ You should do the same.

Second, you should commit to not seek compensation from any company that you regulated or otherwise interacted with while serving as FDA Commissioner for at least four years after leaving office. For example, if you were to join a drug company soon after leaving the FDA, the public would reasonably question whether the decisions you made in office were influenced by the prospect of future compensation from a company you regulated. The public may also question whether you were cashing in on your executive-branch connections and government expertise to help your new company benefit from insider information to skirt rules that you helped oversee or

³ Office of U.S. Senator Dick Durbin, “Durbin Leads Senators In Demanding Answers From Pfizer, Eli Lilly On New Telehealth Platforms Amid Concerns Of Inappropriate Prescribing,” October 22, 2024, press release, <https://www.durbin.senate.gov/newsroom/press-releases/durbin-leads-senators-in-demanding-answers-from-pfizer-eli-lilly-on-new-telehealth-platforms-amid-concerns-of-inappropriate-prescribing>.

⁴ Sesame Care, “Meet Success by Sesame, Sesame's New Weight Loss Program,” Leah Rosenfield, August 21, 2024, <https://sesamecare.com/blog/sesame-launches-success-by-sesame>.

⁵ Food and Drug Administration, “FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss,” December 18, 2024, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss>; PharmaVoice, “FDA's GLP-1 decision kicks off ‘unprecedented’ tussle over shortage,” October 21, 2024, <https://www.pharmavoice.com/news/fdas-glp-1-tirzepatide-shortage-ozempic-mounjaro/730342/>.

⁶ Ophthalmology Times, “Harrow launches trio of ophthalmic therapeutics in US,” David Hutton, May 2, 2023, <https://www.opthalmologytimes.com/view/harrow-launches-trio-of-ophthalmic-therapeutics-in-us>.

⁷ U.S. Centers for Medicare & Medicaid Services, Martin Makary National Provider Identifier (NPI), <https://openpaymentsdata.cms.gov/physician/1184030>; BioPharmaDive, “With conflicts of interest in focus, Trump's pick to run FDA could face scrutiny of his own industry ties,” Amy Baxter, December 6, 2024, <https://www.biopharmadive.com/news/makary-fda-commissioner-hearings-conflicts-interest/734827/>; Politico, “Makary for FDA. Here's what you need to know,” David Lim, Lauren Gardner, and Ben Leonard, November 26, 2024, <https://www.politico.com/newsletters/prescription-pulse/2024/11/26/makary-for-fda-heres-what-you-need-to-know-00191580>.

⁸ See, e.g., Office of U.S. Senator Elizabeth Warren, In Response to Senator Warren, FDA Commissioner Nominee Dr. Robert Califf Makes Strongest Ethics Commitments of Any Senior Biden Administration Official, January 31, 2022, Press Release, <https://www.warren.senate.gov/newsroom/press-releases/-in-response-to-senator-warren-fda-commissioner-nominee-dr-robert-califf-makes-strongest-ethics-commitments-of-any-senior-biden-administration-official>.

to curry favor with the FDA. For example, President Trump’s prior FDA Commissioner Scott Gottlieb joined the pharmaceutical giant Pfizer just weeks after leaving the FDA, sparking concerns of revolving-door corruption.⁹

To avoid this, you should follow the example of former FDA Commissioner Califf, who agreed to not seek compensation from any pharmaceutical or medical device company that he interacted with during his time in government for four years after leaving government service —as well as former NIH Director Monica Bertagnolli who agreed not to work for “any pharmaceutical company with annual revenues at or above \$10 billion” for four years after leaving office.¹⁰ Even Robert F. Kennedy Jr., who refused to give up some of his egregious conflicts, still agreed to not work for a drug company after leaving office. By doing the same, you can mitigate concerns about your potential conflicts of interest in this role.

Finally, you should commit to not lobbying the FDA for at least four years after leaving office. The rampant revolving door of former government leaders lobbying the agencies they once led, while their government relationships remain fresh, erodes Americans’ faith in the federal government. To mitigate that concern, multiple Biden appointees agreed to a post-employment lobbying ban, including Treasury Assistant Secretary for Investment Security Paul Rosen, Chairman of the Joint Chiefs of Staff Charles Q. Brown, and Defense Secretary Lloyd Austin.¹¹ You should commit to not lobbying the NIH for at least four years after leaving office, either as a formal registered lobbyist or informal “shadow lobbyist” — given that former high-level officials can leverage their influence not only by directly lobbying but through facilitating others to do so.

⁹ Office of U.S. Senator Elizabeth Warren, Letter to Scott Gottlieb re. Joining Board of Directors of Pfizer, July 1, 2019, <https://www.warren.senate.gov/imo/media/doc/2019.07.01%20Letter%20to%20Scott%20Gottlieb%20re%20joining%20board%20of%20Pfizer.pdf>.

¹⁰ Letter from Director NIH Nominee Monica Bertagnolli to Senator Elizabeth Warren, August 11, 2023, <https://www.warren.senate.gov/imo/media/doc/Bertagnolli%20Letter%20to%20Senator%20Warren%2008.2023.pdf>; Letter from Ambassador to the OECD Nominee Sean Patrick Maloney to Senator Elizabeth Warren, February 9, 2024, <https://www.warren.senate.gov/imo/media/doc/Signed%20Warren%20Letter.pdf>; Office of Senator Elizabeth Warren, “In Response to Senator Warren's Questions, Secretary of Defense Nominee General Lloyd Austin Commits to Recusing Himself from Raytheon Decisions for Four Years,” press release, January 19, 2021, <https://www.warren.senate.gov/newsroom/press-releases/in-response-to-senator-warrens-questions-secretary-of-defense-nominee-general-lloyd-austin-commits-to-recusing-himself-from-raytheon-decisions-for-four-years>; Office of Senator Elizabeth Warren, “In Response to Senator Warren, Federal Reserve Nominees Make Historic Ethics Commitments,” press release, February 10, 2022, <https://www.warren.senate.gov/newsroom/press-releases/in->


¹¹ Office of Senator Elizabeth Warren, “In Response to Senator Warren's Questions, Secretary of Defense Nominee General Lloyd Austin Commits to Recusing Himself from Raytheon Decisions for Four Years,” press release, January 19, 2021, <https://www.warren.senate.gov/newsroom/press-releases/in-response-to-senator-warrens-questions-secretary-of-defense-nominee-general-lloyd-austin-commits-to-recusing-himself-from-raytheon-decisions-for-four-years>; Office of Senator Elizabeth Warren, “Questions for Mr. Paul M. Rosen, of California, to be Assistant Secretary of the Treasury for Investment Security, Department of the Treasury, from Senator Elizabeth Warren,” https://www.warren.senate.gov/imo/media/doc/paul_rosen_-_revised_responses_to_questions_for_the_record_from_senator_warren.pdf; Office of Senator Elizabeth Warren, “At Hearing, Warren Secures Ethics Commitment Joint Chiefs of Staff Nominee General Brown; Reiterates Concern over Senior Military Holds,” press release, July 11, 2023, <https://www.warren.senate.gov/newsroom/press-releases/at-hearing-warren-secures-ethics-commitment-joint-chiefs-of-staff-nominee-general-brown-reiterates-concern-over-senior-military-holds>.

[response-to-senator-warren-federal-reserve-nominees-make-historic-ethics-commitments.](#)

By making these commitments, you would increase Americans' trust in your ability to serve the public interest during your time at the FDA — rather than the special interests of large FDA contractors or regulated drug companies. I urge you to demonstrate a commitment to public health and integrity and request that you reply to the following questions in writing by March 10, 2025:

1. Will you commit to recuse from all particular matters involving your former clients and employers for at least four years?
2. Will you commit to not seek employment or board membership with, or another form of compensation from, a company that you regulated or otherwise interacted with while in government, for at least four years after leaving office?
3. Will you commit to not lobby the FDA — including through work as an informal “shadow lobbyist” — for at least four years after leaving office?

Sincerely,



Elizabeth Warren
United States Senator