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HOUSE COMMITTEE ON ENERGY AND COMMERCE

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February 3, 2026

Marty Makary, M.D., M.P.H.
Commissioner, Food and Drug Administration (FDA)
U.S. Department of Health and Human Services (HHS)
10903 New Hampshire Avenue, Building 32, Room 2356
Silver Spring, MD 20993

Dear Commissioner Makary,

I write to follow up on two letters I sent you last year on the Commissioner's National Priority Voucher (CNPV) program.[1] [2] My office has not received a response to date.

The public must have transparency about the CNPV program, under which drug approvals have been made almost wholly and in an unprecedented manner by the FDA's political leadership.[3] CNPV selections, the role and decisions of political appointees, and particularly whether scientists and clinicians have been overruled, are currently shrouded in secrecy. In the interests of greater transparency and accountability, I have investigated and drawn conclusions on several of my original queries. Please respond to confirm or refute the following findings no later than **Wednesday, February 11, 2026.**

1. Public investigative reporting identified the following eight individuals as having votes on CNPV drug approvals:[4] **Sara Brenner**, Principal Deputy Commissioner*;* **Richard Iorio**, Principal Medical Adviser in the Commissioner's Office; **Vinay Prasad**, Chief Medical and Scientific Officer (CMSO) and Director of the Center for Biologics Evaluation and Research (CBER); **Mallika Mundkur**, Vinay Prasad's Deputy Chief Medical Officer; **George Tidmarsh**, former Director of the Center for Drug Evaluation and Research (CDER) *(and was initially replaced by Rick Pazdur and later, Tracy Beth Høeg);* **Michael Davis**, Deputy CDER Director; **Tracy Beth Høeg**, Acting Director of CDER and former aide to the FDA Commissioner*;* and the **CDER Deputy Director** of the reviewing office.

   You and **Sanjula Jain-Nagpal**, the Associate Director of Policy & Advocacy under the Office of the Commissioner, were reportedly present as non-voting members.

[1] Letter from Representative Auchincloss, September 4, 2025, https://auchincloss.house.gov/imo/media/doc/auchincloss_cnpv_letter_to_fda.pdf.
[2] Letter from Representative Auchincloss, November 20, 2025, https://auchincloss.house.gov/imo/media/doc/jake_auchincloss_letter_to_commissioner_makary.pdf.
[3] Lawrence, Lizzy. "FDA reviewers didn't get to vote on first priority voucher drug | STAT." STAT News, 21 November 2025, https://www.statnews.com/2025/11/21/top-leaders-not-fda-reviewers-voted-on-first-priority-voucher-drug/. Accessed 1 December 2025.
[4] Lawrence, Lizzy. "FDA reviewers didn't get to vote on first priority voucher drug | STAT." STAT News, 21 November 2025, https://www.statnews.com/2025/11/21/top-leaders-not-fda-reviewers-voted-on-first-priority-voucher-drug/. Accessed 1 December 2025.

All of these named individuals are Presidentially Appointed, Senate-Confirmed (PAS) officials and/or Senior Executive Service (SES)–level positions. Both PAS and SES positions are legally required to submit OGE Form 278e annually,[5] which becomes part of the public record. Please confirm or refute that:

a. The above list of political appointees involved in CNPV drug approvals is complete.

b. The FDA has not otherwise confirmed who has been involved in any stage of the CNPV process for the 18 vouchers awarded to date.[6] [7] [8]

c. The FDA has not complied with federal law and published the required ethics disclosure forms for any PAS-level individual involved, nor has it responded to requests for the disclosures of SES-level individuals involved.[9] [10] [11]

d. The FDA has not responded to Congressional requests for this information.

2. The FDA Office of Ethics and Integrity (OEI), in consultation with the HHS Designated Agency Ethics Official, may grant Conflict-of-Interest Waivers for FDA officials on tumor board-style review panels. These waivers are not automatic. Therefore, the OEI has the responsibility to ensure that all conflicts are disclosed and managed; otherwise, FDA personnel involved in CNPV decisions could be in violation of 18 U.S.C. § 208. Please confirm or refute that:

a. The current OEI Director is Asim Akbari. Additional personnel-interfacing individuals include Melanie Keller, Associate Commissioner for Operations and Deputy Chief Operating Officer, and Barclay Butler, the Deputy Commissioner for Operations and Chief Operating Officer.

b. The OEI has not issued a Conflict of Interest Waiver to any FDA official involved in the CNPV, including any tumor board-style reviews.[12]
c. The Office of Government Ethics (OGE) has not issued a Conflict of Interest Waiver to any non-FDA officials involved.[13]

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[5] U.S. Office of Government Ethics (OGE). "For Ethics Officials." OGE, 2026, https://www.oge.gov/web/278eGuide.nsf/For_Ethics_Officials. Accessed 13 January 2026.
[6] U.S. Food and Drug Administration (FDA). 2025. "FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests." FDA Newsroom. https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests.
[7] U.S. Food and Drug Administration (FDA). "FDA Awards Second Batch of National Priority Vouchers." FDA, 6 November 2025, https://www.fda.gov/news-events/press-announcements/fda-awards-second-batch-national-priority-vouchers. Accessed 1 December 2025.
[8] U.S. Food and Drug Administration (FDA). "FDA Grants Two National Priority Vouchers." FDA, 19 December 2025, https://www.fda.gov/news-events/press-announcements/fda-grants-two-national-priority-vouchers. Accessed 13 January 2026.
[9] U.S. Office of Government Ethics (OGE). "Officials' Individual Disclosures Search Collection." OGE, 2026, https://www.oge.gov/web/oge.nsf/Officials%20Individual%20Disclosures%20Search%20Collection?OpenForm. Accessed 13 January 2026.
[10] Letter from Representative Auchincloss, September 4, 2025, https://auchincloss.house.gov/imo/media/doc/auchincloss_cnpv_letter_to_fda.pdf.
[11] Letter from Representative Auchincloss, November 20, 2025, https://auchincloss.house.gov/imo/media/doc/jake_auchincloss_letter_to_commissioner_makary.pdf.
[12] U.S. Office of Government Ethics (OGE). "Officials' Individual Disclosures Search Collection." USOGE, 2026, https://www.oge.gov/web/oge.nsf/Officials%20Individual%20Disclosures%20Search%20Collection?OpenForm. Accessed 14 January 2026.
[13] U.S. Office of Government Ethics (OGE). "Officials' Individual Disclosures Search Collection." USOGE, 2026, https://www.oge.gov/web/oge.nsf/Officials%20Individual%20Disclosures%20Search%20Collection?OpenForm. Accessed 14 January 2026.

3. FDA has cited its statutory authority for establishing the CNPV program as two-fold: (1) its general authority to implement the *Federal Food, Drug, and Cosmetic Act* (FFDCA) and the *Public Health Service Act* (PHSA) consistent with its mission to promote and protect the public health, as well as (2) its authority to review applications submitted for approval for a drug under section 505 of the FDCA [21 U.S.C. § 355] or a biological product under section 351 of the PHSA [42 U.S.C. § 262]. Please confirm or refute that:

    a. The FFDCA and the PHSA do not provide the FDA authority to establish the CNPV program as written.

    b. There is no statutory authority for the FDA to award CNPV vouchers based on post-approval drug pricing and Most Favored Nation Pricing.

    c. FDA's Office of Chief Counsel was not consulted nor provided findings to support the Agency's claim of statutory authority for the CNPV program.

4. Per the FDA's original announcement, the Commissioner of Food and Drugs would be able to issue CNPV vouchers to companies aligned with the Agency's selected national priorities to shorten review time for a drug application. Please confirm or refute that:

    a. The FDA has failed to publicly post any documents related to company applications for the CNPV program, its subsequent selection process, the FDA's letters to applicants granting vouchers, or the conduct of the new drug reviews, including the proceedings of any tumor board-style review panels.

    b. Factors beyond scientific or clinical merit, including political considerations and pricing, influenced decisions in the CNPV program.

In the past year, the FDA has captured national attention with its chaos and volatility. My office has repeatedly received concerns that the CNPV program may divert resources from standard accelerated reviews, confuse innovators about how to navigate the regulatory process, and strain staff capacity.[14]

Compounding these issues, the DOGE reductions-in-force and reversals of personnel actions have disrupted and demoralized staff, already taxed by poor leadership – this includes investigative reports that found that many scientists want to leave the CBER specifically because of Dr. Vinay Prasad's abrasive leadership style.[1512]

By replacing the scientific experts who make decisions in any FDA review process with political officials, the FDA has injected politics into what has long been an apolitical and science-based process.

[14] Owens, Caitlin, and Peter Sullivan. "New FDA turmoil throws agency's reliability into question." Axios, 4 November 2025, https://www.axios.com/2025/11/04/fda-staff-exits-george-tidmarsh-hhs. Accessed 19 December 2025.

[15] Lawrence, Lizzy. "Insiders: Vinay Prasad 'wreaking havoc' at FDA after return from exile | STAT." STAT News, 31 October 2025, https://www.statnews.com/2025/10/31/vinay-prasad-fda-cber-management-issues-insiders-say/. Accessed 5 November 2025.

The FDA is making public health decisions, guided not by science but by the goals of an Administration whose top officials are in conflict with one another.[16] [17] [18] [19] This turmoil ultimately discourages and inhibits sponsors and investigators who are trying to navigate the FDA's regulatory process to deliver their medical discoveries to patients who depend on the FDA for timely access to novel, lifesaving innovations. This politicization has set back the Agency's competence and credibility in an unprecedented, generational manner.

My investigation has revealed an FDA replete with conflicts of interest, illegal maneuvers, and political interference. **If you fail to respond to this inquiry, Congress and the American people will have to take your silence as confirmation of the findings of my investigation.**

If you have any questions or concerns, please do not hesitate to contact my staff, Nikita Varman, at nikita.varman@mail.house.gov or at 202-225-5934.

Sincerely,

Jake Auchincloss

Member of Congress

CC: Robert F. Kennedy, Jr., Secretary, U.S. Department of Health and Human Services (HHS)
Elizabeth D. Horton, Legislative Affairs Liaison, U.S. Office of Government Ethics
Gretchen H. Weaver, Alternate Designated Agency Ethics Official, HHS

[16] Brennan, Zachary. 2025. "Political or professional? Makary's overhaul of CDER, CBER may reshape leadership norms." EndPointsNews. https://endpoints.news/political-or-professional-makarys-overhaul-of-cder-cber-may-reshape-leadership-norms/.
[17] Gardner, Lauren. "The White House has asked for the resignation of a top aide to FDA chief." PoliticoPro, 21 November 2025, https://subscriber.politicopro.com/article/2025/11/the-white-house-has-asked-for-the-resignation-of-a-top-aide-to-fda-chief-00664719. Accessed 1 December 2025.
[18] Röhn, Tim. "RFK Jr. is in a power struggle." *Politico*, 20 November 2025, https://www.politico.com/news/2025/11/19/rfk-vaccines-fda-makary-hhs-00660487. Accessed 16 January 2026.
[19] Reuters. "RFK Jr. discussed scaling back the role of FDA chief Makary, WSJ reports." *Reuters*, 15 November 2025, https://www.reuters.com/world/us/rfk-jr-discussed-scaling-back-role-fda-chief-makary-wsj-reports-2025-11-15/. Accessed 16 January 2026.