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November 18, 2025

Commissioner Marty Makary, M.D., M.P.H.
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 a letter I sent you in September on the Commissioner's National Priority Voucher (CNPV) program.[1] [2] My office has not received a response to date. Your unresponsiveness escalates my concerns regarding the integrity of this program.

As you know, the Food and Drug Administration (FDA) announced the first nine sponsors and therapies that would be awarded the new national priority vouchers on October 16, 2025.[3] The selection process, including who was involved in the decision-making and how the decisions were made, was not transparent. The CNPV program also promises an accelerated review timeline of one- to two-months, which is significantly shorter than the typical timeline of 10- to 12-months, but fails to explain how that will happen or who will be conducting the reviews.[4]

For every priority review voucher and expedited review pathway, Congress has historically granted specific authority, criteria, and directives to the FDA on what each program and pathway should do and what drugs or which sponsors are eligible based on explicit criteria.[5] However, the CNPV program was created entirely by FDA political leadership and offers no transparency into the decision-making process.[6]

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[1] Letter from Representative Auchincloss, September 4, 2025, https://auchincloss.house.gov/imo/media/doc/auchincloss_cnpv_letter_to_fda.pdf.
[2] Usdin, Steve. "Rep. Auchincloss challenges FDA's new priority voucher program." *BioCentury*, 4 September 2025, https://www.biocentury.com/article/656914/rep-auchincloss-challenges-fda-s-new-priority-voucher-program. Accessed 5 November 2025.
[3] 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.
[4] U.S. Food and Drug Administration (FDA). 2025. "Commissioner's National Priority Voucher (CNPV) Pilot Program." FDA | For Industry. https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program.
[5] Lisi, Donna M. 2023. "The FDA Accelerated Drug Approval Program Explained." PowerPAK. https://journalce.powerpak.com/ce/the-fda-accelerated-drug-approval.
[6] The FDA cites authorities under *Federal Food, Drug, and Cosmetic Act* (FFDCA) and the *Public Health Service Act* (PHSA) but lacks specifics.

This CNPV program goes beyond the FDA's statutory mission by introducing pricing considerations. The FDA must continue to operate on the basis of science alone and should not be involved in pricing or any other political directives of the Trump Administration.[7] It is antithetical to the FDA's statutory mission to promote and protect public health by ensuring that drugs, biologics, medical devices, and other products are safe, effective, and properly labeled.[8]

I am deeply concerned that the CNPV program, in combination with your gutting of the agency's top leadership, are consequences of the politicization of the FDA. The concerns raised here are shared by others. Reporting published throughout the weekend of October 31, 2025, revealed that Dr. George Tidmarsh, the former director for the Center for Drug Evaluation and Research (CDER), questioned the legality of the CNPV program which allegedly upset FDA leadership.[9] [10] [11] Reportedly, Dr. Tidmarsh said the CNPV program "was a total mess... [and] shrouded in secrecy and paranoia."[12] Dr. Tidmarsh also expressed deep fear about the future of the FDA and the uncertainty of the U.S. regulatory environment, calling the CNPV program, "an existential threat to the FDA."[13] Dr. Tidmarsh is no longer an FDA employee.

Given the agency's failure to respond and the compounding concerns surrounding the competency of FDA leadership, I reiterate the same questions I raised in September.[14] The American people deserve assurances that all decisions are based on evidence and science and truly meet the nation's emergent public health needs. Therefore, I request that you provide responses to the following questions no later than **Wednesday, November 26, 2025**.

1. You serve as the FDA Commissioner, a Presidentially Appointed, Senate-Confirmed (PAS) official. Dr. Vinay Prasad was reinstated as the Chief Medical and Scientific Officer (CMSO) and Director of the Center for Biologics Evaluation and Research (CBER),[15] both of which are Senior Executive Service (SES)–level positions. Both PAS and SES positions are legally required to submit OGE Form 278e annually, which becomes part of the public record.

    a. Will you commit to posting online the OGE Form 278e for yourself, for Dr.

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[7] The White House. 2025. "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients." The White House | Presidential Actions. https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/.

[8] 21 U.S.C. § 393(b)(2), 21 U.S.C. § 355, 21 U.S.C. § 393

[9] Lawrence, Lizzy, and Adam Feuerstein. "FDA's top drug regulator, George Tidmarsh, resigns amid probe." *STAT News*, 2 November 2025, https://www.statnews.com/2025/11/02/fda-george-tidmarsh-regulator-kevin-tang/. Accessed 5 November 2025.

[10] Jewett, Christina. "F.D.A. Drug Unit Chief Resigns, and Is Sued by Drug Company." *The New York Times*, 2 November 2025, https://www.nytimes.com/2025/11/02/health/fda-drug-unit-chief.html. Accessed 5 November 2025.

[11] Brennan, Zachary, and Max Bayer. "Day after resigning, Tidmarsh now says he'll fight exit from FDA." *Endpoints News*, 3 November 2025, https://endpoints.news/day-after-resigning-tidmarsh-now-says-hell-fight-exit-from-fda/. Accessed 5 November 2025.

[12] See footnote 7.

[13] See footnote 7.

[14] Letter from Representative Auchincloss, September 4, 2025, https://auchincloss.house.gov/imo/media/doc/auchincloss_cnpv_letter_to_fda.pdf.

[15] The U.S. Food and Drug Administration (FDA). "Vinay Prasad." *FDA*, 10 September 2025, https://www.fda.gov/about-fda/fda-organization/vinay-prasad. Accessed 5 November 2025.

Prasad, and for whoever was involved in selecting the nine awardees announced October 16, 2025?

2. Waivers for conflict-of-interest disclosures for FDA officials on tumor board-style review panels can only be granted by the FDA Office of Ethics and Integrity (OEI), which is under the Office of the Commissioner (OC) in consultation with the HHS Designated Agency Ethics Official. The OEI Director is appointed by the FDA Commissioner and is usually held by a career staffer.

    a. As part of the sweeping layoffs and restructuring of HHS, the Trump Administration eliminated 3,500 jobs at the FDA, most of which were administrative and within the OC.

        i. Who is the current OEI Director, and how long have they been in service?

        ii. How will you ensure OEI remains impartial, responsive, and available to inquiries from the public, given significant reductions in capacity?

3. FDA has cited its 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].

    a. Can you please describe how the CNPV program fits within the authorities you identified and how the CNPV review and approval decisions can be made without Congressional approval fit into these authorities?

4. There is no statutory authority in the FFDCA for the FDA to consider drug pricing in its new drug reviews.

    a. What authority is the FDA utilizing to award CNPV vouchers based on post-approval drug pricing and MFN pricing?

    b. How does incorporating drug pricing into application reviews fit within the FFDCA 1962 amendment tasking the FDA to evaluate new drugs and biologics for safety and efficacy?

5. Per the FDA's original announcement, the FDA Commissioner would be able to issue CNPV vouchers to companies aligned with their selected national priorities to shorten review time for a drug application.

    a. How will you define each of the national priorities as applicable to drug applications (initiatives to address a public health crisis, bring forward a potential innovative therapy, address an unmet medical need, onshore drug development and manufacturing to strengthen the supply chain, and increase affordability)?

6. Review and selection of applications for CNPV must be made by impartial experts, not political appointees. The public must have transparency throughout the entire process of

the CNPV program – from application selections, to safety and efficacy reviews, to the tumor-board review.

a. As proposed, what personnel in OCMSO were reading and selecting each of the nine selected applications? Who will be conducting the one- to two-month safety and efficacy reviews? Who will be involved in the tumor-board style decision-making after safety and efficacy are confirmed?

b. You and Dr. Prasad have advocated using generative artificial intelligence (AI) to modernize the FDA and radically increase efficiency in the review process.[16] How does the FDA intend to use AI in the CNPV process? Will it be used to read/select applications, review the safety and efficacy, or perform other tasks?

c. Does the FDA intend to make the OCMSO decision-making meetings/reviews public?

    i. Will meeting agendas, minutes, recordings, or transcripts be available on the website?

7. I have received concerns from potential biotech innovators that the CNPV program may divert resources from standard and existing accelerated reviews and further strain the agency's capacity. Since the beginning of the Trump Administration, the reductions in force and sweeping restructuring have already diminished the agency's ability to meet drug approval timelines (e.g., KalVista,[17] Novavax,[18] and GSK[19]). Another biotech company in my district, Stealth BioTherapeutics, had a Prescription Drug User Fee Action (PDUFA) review date of January 29, 2025, which the FDA delayed twice, missing its first extension in April[20] and again when it missed that date as well.[21] [22] Compounded by the disruption of staffing challenges, including Dr. Tidmarsh's departure and allegations that many scientists want to leave the CBER under the supervision of Dr. Vinay Prasad,[23] sponsors and patients need assurance that FDA will do everything within

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[16] Makary, Marty, Vinay Prasad, and U.S. Food and Drug Administration (FDA). 2025. "Priorities for a New FDA." *JAMA* 334, no. 7 (June): 565-566. doi:10.1001/jama.2025.10116.

[17] Karins, Jessica. 2025. "FDA Missed PDUFA Date Due To 'Limited Resources,' Sponsor Says." Inside Health Policy. https://insidehealthpolicy.com/daily-news/fda-missed-pdufa-date-due-limited-resources-sponsor-says.

[18] Kansteiner, Fraiser, and Patrick van Katwijk. 2025. "FDA misses decision deadline for Novavax COVID vaccine." Fierce Pharma. https://www.fiercepharma.com/pharma/fda-misses-decision-deadline-novavaxs-covid-shot-approval-shortly-after-top-vaccine.

[19] Manalac, Tristan. 2025. "FDA Delays Continue as Regulator Misses Review Date for GSK's Nucala." BioSpace. https://www.biospace.com/fda/fda-delays-continue-as-regulator-misses-review-date-for-gsks-nucala.

[20] Stealth BioTherapeutics. 2025. "Stealth BioTherapeutics Announces Delay in FDA Action Date for Barth Syndrome Application." Stealth BioTherapeutics. https://stealthbt.com/stealth-biotherapeutics-announces-delay-in-fda-action-date-for-barth-syndrome-application/.

[21] Masson, Gabrielle. 2025. "UPDATE: FDA misses PDUFA date for Stealth's ultra-rare disease candidate, delaying approval decision—again." Fierce Pharma. https://www.fiercebiotech.com/biotech/fda-misses-pdufa-date-stealths-ultra-rare-disease-candidate-delaying-approval-decision.

[22] Stealth BioTherapeutics. 2025. "Stealth BioTherapeutics Announces Delay in FDA Action Date for Barth Syndrome Application." PR Newswire. https://www.prnewswire.com/news-releases/stealth-biotherapeutics-announces-delay-in-fda-action-date-for--barth-syndrome-application-302440425.html.

[23] Lawrence, Lizzy. "Insiders: Vinay Prasad 'wreaking havoc' at FDA after return from exile | STAT." *STAT News*,

its capacity to meet PDUFA dates and deliver safe access to lifesaving innovations.

a. In an August 27, 2025, podcast, you stated, "We are on track to meet all those target dates this year, and we may have a record number of approvals this year."[24] Can you please explain why the FDA missed these deadlines?

b. What steps does the FDA plan to take to prevent further delays of all drug approvals?

The FDA must uphold its statutory mission and ensure the American people have confidence in the ethical and scientific integrity of the nation's public health system. Thank you for your attention and prompt response.

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

31 October 2025, https://www.statnews.com/2025/10/31/vinay-prasad-fda-cber-management-issues-insiders-say/. Accessed 5 November 2025.

[24] Lim, David. 2025. "FDA reinstated roughly a quarter of initial DOGE job cuts." POLITICO Pro. https://politicopro.com/article/2025/07/fda-reinstated-roughly-a-quarter-of-initial-doge-job-cuts-00474273.