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September 4, 2025

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

Dear Commissioner Makary,

I write to request information regarding the Commissioner's National Priority Voucher (CNPV) program. This type of program is unprecedented and has potential to be exploited and misused. It is critical that the American people have confidence in the integrity of the FDA's approvals process.

As you know, the FDA announced the new CNPV program on June 17, 2025.[1] Based on publicly available information, it is set to launch this year and expand after a one-year pilot phase.[2] As Commissioner, you are responsible for establishing the national priorities for the CNPV program, including 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.[3] The voucher will be eligible for a product at any stage in development and will allow the receiving company to utilize enhanced communication with the FDA to accelerate the product's approval. This month, on the record with *Bloomberg*, you noted that the CNPV program will "shorten [FDA]'s review time… to 1-2 months," and will be tied to and awarded explicitly on post-approval drug pricing and Most Favored Nation (MFN) pricing concessions.[4]

Historically, for every priority review voucher (PRV) and every expedited review pathway for new drugs, Congress has granted specific authority, criteria, and directives to FDA on what each program and pathway should do, and what drugs or which sponsors are eligible based on explicit

[1] 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.
[2] U.S. Food and Drug Administration (FDA). 2025. "FAQs: Commissioner's National Priority Voucher Pilot Program." FDA Newsroom. www.fda.gov/news-events/press-announcements/faqs-commissioners-national-priority-voucher-pilot-program.
[3] 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.
[4] Zhang, Rachel C., and Sam Hornblower. 2025. "FDA Offers to Trade Faster Drug Reviews for Lower US Prices." Bloomberg. https://www.bloomberg.com/news/articles/2025-07-11/fda-offers-to-trade-faster-drug-reviews-for-lower-us-prices.

criteria (with a notable exception for accelerated approval through the rulemaking process in response to the HIV/AIDS epidemic, where the FDA amended its review standards for endpoints but did *not* grant expedited review).[5] None of the existing PRVs and designations for expedited review are decided by the Commissioner or other political appointees. Instead, they are determined by highly qualified review teams, in consultation with regulatory policy and legal staff, and Center leadership.[6] However, for the CNPV program, the FDA has stated that evaluation and approval decisions will be made by a senior, multi-disciplinary review committee led by the FDA's Office of the Chief Medical and Scientific Officer (OCMSO), so that "rather than a standard review system of an application being sent to numerous FDA offices staffed by discipline teams with primary and secondary reviewers juggling competing priorities."[7] I am deeply concerned that this decision-making process for CNPV, in combination with your gutting of the agency's top leadership, will politicize the FDA's approval process. Regulators are expected to operate based on science and public health needs, independent of political influence. However, the CNPV's review structure risks decisions being made according to the goals of the Administration, which has proven time and time again to rebuke public health and science.[8] A former FDA official shares the same concerns, stating that, "[the] scientific judgments typically handled by physicians on the professional staff would begin to shift from administration to administration, injecting more politics into what has long been an apolitical process."[9]

Further, under the *Federal Advisory Committee Act* (FACA), the FDA must manage conflicts of interest when appointing members to advisory committees and must publicly disclose when it exempts people from these disclosures or restrictions.[10] However, the FDA has historically granted exemptions for FDA personnel who participate in "tumor board-style," multidisciplinary review processes to expedite decision-making on complex drug or biologic reviews (often in oncology).[11] This cannot happen for the CNPV. Given that the review committee is under the OCMSO, the public needs assurances that all decisions are based in evidence and science and truly meet the emergent public health needs of the nation. Even the selection of products and review of applications must be impartial, conducted by scientific and medical experts, and based in science. As such, I urge FDA to ensure public records of the members of the tumor board-style review panel, their potential conflicts of interest, and/or their financial disclosures.

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[5] Lisi, Donna M. 2023. "The FDA Accelerated Drug Approval Program Explained." PowerPAK. https://journalce.powerpak.com/ce/the-fda-accelerated-drug-approval.

[6] U.S. Food and Drug Administration (FDA) | Center for Biologics Evaluation and Research (CBER). 2023. "SOPP 8216: Fast Track Development Programs - Designation and Management." CBER Standard Operating Policy and Procedure. https://www.fda.gov/media/163325/download.

[7] 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.

[8] Rovner, Julie, Sarah Karlin-Smith, Shefali Luthra, and Alice M. Ollstein. 2025. ""What the Health?" | Thursday, Aug. 14," Podcast. In *KFF Health News*. MSN. https://www.msn.com/en-us/health/other/kff-health-news-what-the-health-trump-further-politicizes-science/ar-AA1KxihX?ocid=BingNewsSerp.

[9] 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/.

[10] 5 U.S.C. App. §§ 1–16

[11] U.S. Food and Drug Administration (FDA). 2014. "Expedited Programs for Serious Conditions – Drugs and Biologics." FDA. https://www.fda.gov/media/86377/download.

Most importantly, no Commissioner, Chief Medical Officer, Chief Scientific Officer, or Administration has ever linked FDA's approvals and the eligibility for expedited review with drug pricing, which is beyond the FDA's statutory authority and mission. These approvals should remain solely based on scientific evidence evaluating the safety and efficacy of drugs. People and their families need assurance that FDA's approval decisions are based solely in science and not on press releases about pricing or other political directives of the Trump Administration.[12] FDA, as an agency within the Department of Health and Human Services (HHS), should not be involved in pricing in any capacity. It is antithetical to 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.[13]

Due to the concerns laid out, I request you provide responses to the following questions no later than **Friday, September 19, 2025**.

1. You serve as the FDA Commissioner, a Presidentially Appointed, Senate-Confirmed (PAS) official. Dr. Vinay Prasad was formerly the Chief Medical and Scientific Officer (CMSO) and Director of the Center for Biologics Evaluation and Research (CBER), both of which are Senior Executive Service (SES)–level positions. However, since Dr. Prasad's resignation and reinstatement as just the Director of CBER, the role of the CMSO remains vacant.[14] Both PAS and SES positions are legally required to submit OGE Form 278e annually, which becomes part of the public record. Yet neither are available online.

    a. Will you commit to posting online the OGE Form 278e for both yourself and for whoever assumes the role of the CMSO?

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 (DAEO). 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 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

[12] 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/.
[13] 21 U.S.C. § 393(b)(2), 21 U.S.C. § 355, 21 U.S.C. § 393
[14] Brennan, Zachary. 2025. "Prasad's return to FDA comes with fewer titles and a seemingly lower profile." EndPointsNews. https://endpoints.news/vinay-prasad-drops-two-of-his-titles-in-return-to-fda/.

general authority to implement the *Federal Food, Drug, and Cosmetic Act* (FDCA) 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 Commissioner's and the CMSO's review and approval decisions made without Congressional approval fit into these authorities?

4. There is no statutory authority in the *Federal Food, Drug and Cosmetic Act* (FFDCA) for FDA to consider drug pricing in its new drug reviews.

   a. What authority is 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 FDA to evaluate new drugs and biologics for safety and efficacy?

5. Per 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. It is critical that the public has transparency in 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 are reading and selecting each application? Who is conducting the safety and efficacy reviews? Who is involved in the tumor-board style decision-making?
   b. You and Dr. Prasad have advocated using generative artificial intelligence (AI) to modernize the FDA and radically increase efficiency in the review process.[15] 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 other tasks?
   c. Does the FDA intend to make the OCMSO decision-making meetings/reviews public? Will meeting agendas, minutes, recordings, or transcripts be available on the website?
   d. How does FDA intend to preserve trade secret protection laws while ensuring transparency?

[15] 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.

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,[16] Novavax,[17] and GSK[18]). Another biotech company in my district, Stealth BioTherapeutics, had a a Prescription Drug User Fee Action (PDUFA) review date of January 29, 2025, which FDA delayed twice, missing its first extension in April[19] and again when it missed that date as well.[20] [21]

    a. However, 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."[22] 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?

8. How will you ensure existing PRV programs that have lapsed (Rare pediatric PRV expired last year[23] and Medical Countermeasure PRV expired in 2023[24]) and existing expedited review pathways can continue or be harmonized with each other?

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[16] 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.
[17] 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.
[18] 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.
[19] 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/.
[20] 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.
[21] 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.
[22] 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.
[23] U.S. Food and Drug Administration (FDA). 2024. "Medical products for rare diseases and conditions - Rare Pediatric Disease Designation and Priority Review Voucher Programs." FDA | For Industry. https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/rare-pediatric-disease-designation-and-priority-review-voucher-programs#2024update.
[24] 21 U.S. Code § 360bbb-4a

Ensuring health care accountability and confidence in the integrity of our public health systems includes guaranteeing that all the aforementioned conflicts of interest have, in fact, been resolved. 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