Congress of the United States
Washington, DC 20515

November 20, 2025

Martin Makary, M.D., M.P.H.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Makary:

We write to express our deep concerns and request additional information about the Commissioner's National Priority Voucher (CNPV) program that the Food and Drug Administration (FDA) announced on June 17, 2025.[1] You have claimed this pilot program, which lacks Congressional authorization, is to "accelerate drug review for companies supporting U.S. national interests"[2] by reducing drug and application review timelines. As of November 6, 15 vouchers have been awarded. We have significant concerns that this program will enable corruption by creating a new, lucrative gift for drugmakers and allies politically favored by President Trump.[3] We also fear the addition of yet another expedited review program, particularly one with absurdly short timelines that are inconsistent with those in the user fee agreements.[4] This program could undermine public confidence in FDA's decisions and raise safety concerns, including rushed reviews by an agency whose staff have been decimated by this administration's cuts.[5]

Experts have warned of CNPV's potential for corruption and misuse as a tool of political favoritism given the limited information on the program, the lack of meaningful transparency about the criteria for qualifying for the CNPV, the broad scope of the announced categories, and

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[1] U.S. Food and Drug Administration, *FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests* (June 2025) (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, *Commissioner's National Priority Voucher (CNPV) Pilot Program* (https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program) (accessed Oct. 29, 2025).

[3] *Id.*

[4] Brookings, *FDA's new Commissioner's National Priority Voucher has lofty goals. Can it deliver?* (Oct. 3, 2025) (https://www.brookings.edu/articles/fdas-new-commissioners-national-priority-voucher-has-lofty-goals-can-it-deliver/).

[5] Daniel Carpenter, Thomas J. Hwang, and Aaron S. Kesselheim, *Flaws in the FDA's New Priority Voucher Program*, New England Journal of Medicine (Oct. 25, 2025); Doctors for America, *FDA Commissioner's National Priority Vouchers Will Endanger Americans* (June 20, 2025) (https://doctorsforamerica.org/sr-npv/).

your self-appointed role adjudicating "U.S. national health priorities."[6] FDA's focus must be on its statutory responsibilities to approve safe and effective medical products and the CNPV program should not serve as a means for you and the President to exercise leverage over companies.

With the creation of CNPV, FDA has self-selected such broad and expanding priorities for the program that you could award a voucher to any drug. FDA's opaque process of selecting and distributing CNPVs heightens our concerns about the potential misuse of this program and corruption of FDA's drug review process. You and this administration have done no rulemaking, issued no guidance, or taken any other action to make clear to the public what are the specific criteria for qualifying for this voucher. Of the nine companies that were awarded the first vouchers in October, only five actively applied, while four said they were "surprised" to learn they were selected. Some of these companies noted that they had been talking to officials in the Trump administration prior to the announcement of the voucher program or had already submitted their products for review under an expedited pathway.[7]

Experts also fear that "speed will be traded for review quality and confidence."[8] While existing statutory priority review programs provide a six month review timeline, decreasing that review period to one or two months "almost by definition suggests that reviewers will need to take shortcuts."[9] For example, FDA typically works with a company on their drug label after issuing a decision to approve a drug. You have noted that FDA intends on reviewing—and potentially approving—CNPV products before clinical trials have been completed. Experts have noted, however, that it is "impossible to write and review a drug label without a thorough understanding of all the clinical trial data."[10] In addition, given recent reports about AI systems at the agency that have "hallucinated" nonexistent studies, we are concerned reviewers may feel pressured to take harmful shortcuts in order to meet an unreasonable review timeline, which ultimately could waste taxpayer funds and harm Americans.[11] Following the administration's mass terminations and significant voluntary departures, FDA is already operating with a limited staff. The demands of a faster review timeline with limited staff could create safety oversights

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[6] Becker's Hospital Review, *FDA floats fast-track incentives for drugmakers that lower prices* (July 14, 2025) (https://www.beckershospitalreview.com/pharmacy/fda-floats-fast-track-incentives-for-drugmakers-that-lower-prices/).

[7] STAT, *How the first nine drug companies won priority review vouchers from Marty Makary's FDA* (Oct. 24, 2025) (https://www.statnews.com/2025/10/24/how-pharmaceutical-companies-won-fda-priority-review-vouchers/).

[8] MedPage Today, *How Fast Is Too Fast for FDA Drug Review?*(June 24, 2025) (https://www.medpagetoday.com/opinion/second-opinions/116218).

[9] STAT, *Does the FDA commissioner's new voucher program open a Pandora's box?* (June 18, 2025) (https://www.statnews.com/2025/06/18/fda-new-priority-review-voucher-program-analysis-of-risks-questions/).

[10] Brownstein, *A Tale of Three Vouchers* (Sept. 29, 2025) (https://www.bhfs.com/insight/a-tale-of-three-vouchers/).

[11] Applied Clinical Trials, *FDA's Elsa AI Tool Raises Accuracy and Oversight Concerns* (July 23, 2025) (https://www.appliedclinicaltrialsonline.com/view/fda-elsa-ai-tool-raises-accuracy-and-oversight-concerns).

and pressure to cut corners.[12] The Center for Drug Evaluation and Research reported a net loss of over 1,000 staff in fiscal year (FY) 2025[13] and the agency is already experiencing delays in reviewing applications.[14]

Your creation of a priority review program with potentially massive financial benefits to pharmaceutical companies without any demonstrable transparency or criteria for awarding the vouchers demands scrutiny. As you have acknowledged, these voucher programs are extremely valuable to companies.[15] Even though these CNPVs are not transferrable, unlike the other voucher programs previously authorized by Congress, experts say these are still "likely worth millions of dollars to the companies who receive them."[16]

In order to better understand this program, its legal basis, and its actual goals, we request the following documents and responses to the questions below by December 11, 2025:

1. Please provide the agreements between FDA and each CNPV recipient.

2. Please provide all communications, including but not limited to emails, internal messages, calendar invitations, and meeting notes, with or regarding CNPV recipients from January 1, 2025 onward.

3. Please provide the following information on CNPV recipients:

   a. Which companies have been approached regarding applying for a CNPV voucher?

   b. Which companies proactively applied?

   c. What was the basis for selecting CNPV recipients?

   d. Please disclose what – if any – commitments were made by companies in exchange for receiving this voucher.

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[12] Pharma Voice, *FDA's new mission to speed drug reviews* (June 30, 2025) (https://www.pharmavoice.com/news/fda-drug-reviews-marty-makary-vouchers/751895/).

[13] U.S. Food and Drug Administration, *Center for Drug Evaluation and Research & Center for Biologics Evalution and Research Net Hiring Data (FY2023-2027)* (Oct. 16, 2025) (https://www.fda.gov/industry/fda-user-fee-programs/center-drug-evaluation-and-research-center-biologics-evaluation-and-research-net-hiring-data-fy-2023).

[14] The Wall Street Journal, *Drug Development Is Slowing Down After Cuts at the FDA* (April 17, 2025) (https://www.wsj.com/health/healthcare/drug-development-is-slowing-down-after-cuts-at-the-fda-f22369cf); STAT, *FDA review of drugs is slowing while application delays are growing, analysis finds* (Oct. 20, 2025) (https://www.statnews.com/pharmalot/2025/10/20/fda-drug-approvals-slowing-rejections-rising/).

[15] *See* note 7.

[16] Regulatory Affairs Professionals Society, *Questions remain as FDA opens submissions for new priority voucher program* (July 24, 2025) (https://www.raps.org/news-and-articles/news-articles/2025/7/questions-remain-as-fda-opens-submissions-for-new).

e. What guardrails has FDA put in place to prevent political interference in the selection of CNPVs, or in the approval of drugs submitted under this program?

4. Why has the number of vouchers awarded differed from the number initially planned?

5. Please provide the following information on priority areas:

a. What process did FDA use to develop its CNPV priority areas?

b. Who in the administration was involved in developing these priority areas?

c. Were any stakeholders—including manufacturers, distributors, insurers, providers, or patient groups—consulted in determining these priorities?
Does FDA plan to release additional guidance for industry and the public on how it is evaluating submissions for a CNPV against the priority areas? Why was there no guidance or rulemaking undertaken to establish this program and its criteria?

6. FDA's press release announcing the initial batch of CNPV awards states that some voucher recipients can increase medication affordability with Most Favored Nation (MFN) pricing. Is there a relationship between who has been awarded CNPVs and those who have reached a "Most Favored Nation" pricing agreement with the Trump administration?

7. Please provide the following information on review teams:

a. Who will comprise the CNPV review teams and how will they be selected?

b. Will politically appointed staff be involved in selection of the council or serve on the council?

c. How does FDA anticipate one day as sufficient to review submitted information?

d. Under what circumstances will the review team be permitted to extend the review window?

8. What processes has FDA put in place to monitor and evaluate conflicts of interest among product reviewers and applicants? Is FDA adding, removing, or modifying any existing ethics or transparency requirements in its implementation of the CNPV pilot program?

9. FDA's website states that the "CNPV pilot program will not affect other [expedited review] programs."[17] However, even the initially planned five vouchers were expected to strain FDA's capacity, but with the addition of more vouchers, resources will necessarily be diverted from other priority reviews, as well as review timelines made pursuant to user fee agreements.[18]

a. How does FDA intend to prioritize resources amongst all expedited programs?

b. How is FDA ensuring that CNPV reviews do not affect other review work, including reviews for statutorily authorized programs?

c. How many staff across each center will be assigned CNPV reviews, and what percentage of their time is expected to be spent on CNPV responsibilities?

d. Has FDA deprioritized any products for review as it allocates staff time and resources for CNPV reviews?

10. How does the agency intend to determine the indication, limitations on use or its contraindications, side effects and other relevant labeling information for a product that submitted its application for a CNPV prior to all clinical trial information being completed?

11. Given the condensed review timeline and data gaps at the time of approval, has FDA set up specialized processes for monitoring contraindications and side effects for approved CNPV products?

12. Describe any systems FDA has put in place to monitor the effectiveness of the program in meeting its published goals.

13. Which parts of the drug review process will be shortened or eliminated for products with CNPV vouchers?

14. How will you evaluate the impacts of changes to the drug review process on patient safety?

15. Are user-fee dollars being used to conduct these CNPV reviews? If so, please provide the exact amount FDA plans to expend.

[17] U.S. Food and Drug Administration, *FAQs: Commissioner's National Priority Voucher Pilot Program* (https://www.fda.gov/news-events/press-announcements/faqs-commissioners-national-priority-voucher-pilot-program) (accessed Oct. 29, 2025).

[18] *See* note 4.

16. Will any CNPV recipients that were announced during the government shutdown trigger collection of a FY 2026 user fee?

If you have any questions about this request, please contact the Senate HELP Committee Democratic Staff at (202) 224-5141 and the House Energy and Commerce Committee Democratic staff at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Ranking Member
House Committee on Energy and Commerce

Bernard Sanders
Ranking Member
Senate Committee on Health, Education, Labor, and Pensions