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The Commissioner's National Priority Voucher Pilot Program: Comments to the Food and Drug Administration (FDA-2026-N-2366-0001)

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Public Citizen, a national nonprofit consumer advocacy organization with over one million members and supporters nationwide, submits the following comments on the Commissioner's National Priority Voucher (CNPV) pilot program at the Food and Drug Administration (FDA). The comments address five aspects of the program:

1. Creation of the CNPV pilot without statutory authorization from Congress
2. Unclear and changing eligibility criteria that include policy considerations unrelated to the safety and effectiveness of drugs
3. Review timelines of one to two months that are unnecessarily and dangerously short
4. Inappropriate involvement of political appointees and center directors in voucher selection and the review of products receiving vouchers
5. Initiation of the CNPV pilot without notice-and-comment rulemaking

Public Citizen urges the FDA to pause the CNPV pilot, refrain from granting additional vouchers, and discontinue the program.

Background

The FDA announced the CNPV pilot on June 17, 2025, stating that the agency would shorten review times from approximately ten to twelve months to one to two months for a limited number of products that meet four criteria: [1]

- Addressing a health crisis in the United States
- Delivering more innovative cures for the American people
- Addressing unmet public health needs

[1] Food and Drug Administration. FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests. June 17, 2025. https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests. Accessed June 9, 2026.

- Increasing domestic drug manufacturing as a national security issue

The program description of the accelerated pathway noted enhanced communication, rolling review, and a multidisciplinary "tumor board" style discussion of potential vouchers with senior agency leadership.[2]

1. Creation of the CNPV pilot without statutory authorization from Congress

Congress has created other FDA priority review programs through specific provisions of the Food, Drug, and Cosmetic Act.[3] Congress has not enacted legislation to authorize the CNPV pilot.

The FDA has instead created the CNPV pilot by relying on its general authority to administer the drug-review process. In a March 2026 Federal Register notice, the agency stated that "the FDA's authority for the CNPV Pilot Program stems from its general authority to implement the FD&C Act and the Public Health Service Act."[4] The agency also explained that the pilot is "consistent with FDA's authority to review applications" for drugs and biologics.

Although these statements identify the FDA's general authority to review drug applications, they do not identify a statute specifically authorizing the CNPV pilot.

2. Unclear and changing eligibility criteria that include policy considerations unrelated to the safety and effectiveness of drugs

When the FDA announced the CNPV pilot in June 2025, one of the priorities was "increasing domestic drug manufacturing as a national security issue." The FDA therefore made the location of a company's manufacturing operations a factor in deciding which products would receive consideration under the program.[5]

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[2] *Ibid*.
[3] Food and Drug Administration, Department of Health and Human Services. Fee Rate for Using a Priority Review Voucher in Fiscal Year 2024. *Federal Register*. September 29, 2023. https://www.federalregister.gov/documents/2023/09/29/2023-21513/fee-rate-for-using-a-priority-review-voucher-in-fiscal-year-2024. Accessed June 8, 2026.
[4] Food and Drug Administration, Department of Health and Human Services. Commissioner's National Priority Voucher (CNPV) Pilot Program; Public Hearing; Request for Comments. *Federal Register*. March 23, 2026. https://www.federalregister.gov/documents/2026/03/23/2026-05573/commissioners-national-priority-voucher-cnpv-pilot-program-public-hearing-request-for-comments. Accessed June 9, 2026.
[5] Food and Drug Administration. FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests. June 17, 2025. https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests. Accessed June 9, 2026.

The location of drug manufacturing is not a standard the FDA should use when reviewing an application for a new drug or biologic. The FDA's review should focus on whether products meet statutory and regulatory standards for approval, including safety, effectiveness, and manufacturing quality.[6] A product does not become safer or more effective based on where it is manufactured. A company's decision to manufacture in the United States or elsewhere is unrelated to the necessary scientific evidence that would support a drug or biologic's approval.

In October 2025 the FDA expanded the CNPV pilot criteria to include "reducing downstream health care utilization" and "increasing medication affordability."[7] In November 2025 then-FDA Commissioner Dr. Martin A. Makary said vouchers were granted "to a select group of products where the company has agreed to increase affordability, domesticate manufacturing as a national security issue, or address an unmet public health need."[8]

Although reducing unnecessary health care utilization and increasing medication affordability are desirable, neither criterion is relevant to the clinical and public health reasons why the FDA should consider a drug or biologic for an accelerated approval pathway. Moreover, the arbitrary and ad hoc revision to the criteria for the CNPV pilot undermined the program's credibility.

3. Review timelines of one to two months that are unnecessarily and dangerously short

The CNPV pilot aims to reduce FDA review times from approximately ten to twelve months to one to two months.[9] As a result, review teams have substantially less time to evaluate clinical evidence, safety data, and address concerns raised during the review process. Indeed, the FDA has acknowledged that it may extend review timelines under the CNPV pilot when an application is incomplete, complex, or scientifically uncertain.[10]

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[6] Food and Drug Administration. What We Do. https://www.fda.gov/about-fda/what-we-do#mission. Accessed June 9, 2026.
[7] Food and Drug Administration. FDA Awards First-Ever National Priority Vouchers to Nine Sponsors. October 16, 2025. https://www.fda.gov/news-events/press-announcements/fda-awards-first-ever-national-priority-vouchers-nine-sponsors. Accessed June 9, 2026.
[8] Food and Drug Administration. FDA Awards Second Batch of National Priority Vouchers. November 6, 2025. https://www.fda.gov/news-events/press-announcements/fda-awards-second-batch-national-priority-vouchers. Accessed June 15, 2026.
[9] Office of the Chief Medical Officer and Office of the Commissioner, Food and Drug Administration. The Commissioner's National Priority Voucher (CNPV) Pilot Program. *CNPV Town Hall Program Overview*, February 3, 2026. https://www.fda.gov/media/190927/download. Accessed June 9, 2026.
[10] Food and Drug Administration. FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests. June 17, 2025. https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests. Accessed June 9, 2026.

FDA review times for drugs and biologics are already fast compared with those of drug regulatory agencies in other countries. In January 2026 *Reuters* reported that the FDA delayed two drug reviews under the CNPV pilot after agency scientists raised safety and efficacy concerns.[11] The events described in the *Reuters* article underscore our concerns that completing drug reviews within one to two months is unrealistic and increases the chance that FDA scientists will make mistakes that could endanger patient safety. Drugs approved under an FDA expedited regulatory pathway are associated with a 48% higher rate of safety-related label changes than drugs that are not approved through these pathways.[12]

The FDA already has multiple expedited regulatory pathways for drug review, including Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review. Although the FDA has described the CNPV pilot as complementing these programs, the agency has offered no convincing evidence that existing pathways are insufficient or why one-to-two-month drug reviews would lead to improvements in patient care. Moreover, the CNPV pilot needlessly burdens the agency's already reduced staff. The FDA lost 3,859 employees in 2025 and 473 in 2026.[13]

4. **Inappropriate involvement of political appointees and center directors in voucher selection and the review of products receiving vouchers**

As stated in the FDA's Staff Manual Guide, the FDA Commissioner chairs the CNPV Review Council, moderating discussions relating to voucher selection and issues raised during the review of vouchers. The Council also includes senior agency officials and the leadership of the FDA's Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research.[14]

Decisions about voucher selection and product review should be led by career scientists applying clear and consistent scientific standards. Although career scientists review CNPV pilot applications, a February 2026 FDA overview of the program included a slide stating

[11] Wingrove, Patrick. Exclusive: US FDA Delays Two Drug Reviews in New Voucher Program After Safety, Efficacy Concerns. *Reuters*. Updated January 16, 2026. https://www.reuters.com/sustainability/boards-policy-regulation/us-fda-delays-two-drug-reviews-new-voucher-program-after-safety-efficacy-2026-01-15/. Accessed June 9, 2026.
[12] Mostaghim SR, Gagne JJ, Kesselheim AS. Safety-related label changes for new drugs after approval in the US through expedited regulatory pathways: retrospective cohort study. *BMJ.* 2017;358:j3837. https://pmc.ncbi.nlm.nih.gov/articles/PMC5588044/. Accessed June 10, 2026.
[13] Inklebarger, Timothy. Trump purge at FDA and USDA triggers food safety 'brain drain.' *FoodNavigator-USA*. February 16, 2026. https://www.foodnavigator-usa.com/Article/2026/02/16/fda-and-usda-staff-cuts-under-trump-raise-food-safety-risks/. Accessed June 10, 2026.
[14] Food and Drug Administration. SMG 2010.23: Commissioner's National Priority Voucher Review Council. *FDA Staff Manual Guides*. January 9, 2026. https://www.fda.gov/media/190099/download?attachment. Accessed June 15, 2026.

that "the management chain may override pursuant to existing procedures."[15] The review structure allows political appointees and senior officials to intervene in application-specific decisions that should be made by career scientists. In June 2026, a news media report highlighted a memorandum written by the acting director of CDER about his predecessor's repeated intervention in the review of a supplemental biologics license application for teplizumab (Tzield), an immunotherapy for type 1 diabetes, and repeated overruling of career staff.[16]

5. Initiation of the CNPV pilot without notice-and-comment rulemaking

The FDA initiated and began operating the CNPV pilot without notice-and-comment rulemaking, which is the standard procedure by which to propose and finalize federal regulations. Moreover, the agency awarded vouchers before even publishing draft guidance about how the program would work or seeking public comment on the program's criteria and design.

In February 2026, about six months after the pilot began, the FDA stated that it would issue additional documentation, including draft guidance, as the program matured.[17] Only now, about a year after the pilot began, is the FDA seeking public comment about the CNPV pilot.[18] By establishing the CNPV pilot before seeking input through standard regulatory processes, the FDA has undermined the credibility of the program and further eroded public confidence in the agency, which has already declined in recent years.[19]

[15] Office of the Chief Medical Officer and Office of the Commissioner, Food and Drug Administration. The Commissioner's National Priority Voucher (CNPV) Pilot Program. *CNPV Town Hall Program Overview*. February 3, 2026. https://www.fda.gov/media/190927/download. Accessed June 9, 2026.
[16] Usdin S. Memo details Hoeg's role in blocking Tzield approval. Biocentury. June 17, 2026. https://www.biocentury.com/article/659804. Accessed June 28, 2026.
[17] Food and Drug Administration. FAQs: Commissioner's National Priority Voucher Pilot Program. *C*ontent current as of February 9, 2026. https://www.fda.gov/news-events/press-announcements/faqs-commissioners-national-priority-voucher-pilot-program. Accessed June 9, 2026.
[18] Food and Drug Administration, Department of Health and Human Services. Commissioner's National Priority Voucher (CNPV) Pilot Program; Public Hearing; Request for Comments. *Federal Register*. March 23, 2026. https://www.federalregister.gov/documents/2026/03/23/2026-05573/commissioners-national-priority-voucher-cnpv-pilot-program-public-hearing-request-for-comments. Accessed June 9, 2026.
[19] Feldman WB, Rand LZ, Carpenter D, et al. Trust in the Food and Drug Administration: A national survey study. *Clin Pharmacol Ther. 2024*. 116(2): 408–414.

Conclusion

Public Citizen urges the FDA to pause the CNPV pilot, refrain from granting additional vouchers, and discontinue the program. The FDA's established pathways to expedite the review of drugs and biologics can be effectively used to advance innovative therapies for serious and life-threatening conditions, unmet medical needs, and public health priorities.

Thank you for considering our comments about these important issues.

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