CENTER FOR
Science IN THE
Public Interest
Your Food and Health Watchdog

June 4, 2026
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852

Re: Commissioner's National Priority Voucher (CNPV) Pilot Program (Docket No. FDA-2026-N-2366)

Dear Dockets Management Staff,

Thank you for the opportunity to share our perspective on the Commissioner's National Priority Voucher (CNPV) pilot program in written comments and at the public meeting.

The undersigned individuals write to share our concerns and opposition to the Food and Drug Administration's (FDA's) CNPV pilot, particularly relating to the politicization of voucher selection by the inclusion of national priorities falling outside of FDA's remit, an expedited review timeline that poses dangers to consumers, and the lack of transparency in the implementation of the pilot.

The Center for Science in the Public Interest (CSPI) is a non-profit consumer education and advocacy organization. Since 1971, CSPI has advocated for evidence-based policies to improve health, nutrition, and food safety. CSPI is an independent organization that does not accept any corporate funding.

In this comment, we provide feedback on the CNPV pilot program's scope, voucher selection process, the review council's role, expedited timelines, and future programmatic directions.

1. **Eligible Applications and Program Scope**

We oppose the pilot program and believe that FDA should focus on its statutory responsibility to ensure the safety and efficacy of drugs. FDA's mandate is to protect public health through evaluating the safety and effectiveness of drugs, but several of the five national priorities included in the pilot program fall outside of the agency's purview.

Specifically, the CNPV pilot program prioritizes drugs that address public health crises, constitute innovative breakthroughs, address large unmet medical needs, promote onshoring and supply chain resilience, and improve drug affordability.[1] The first three of these are already addressed by existing agency programs: Emergency Use Authorizations,[2] Breakthrough Therapy designations,[3] and the agency's various expedited programs,[4] respectively. But the agency has historically only evaluated the benefit-risk profile of drugs based on safety and efficacy data, rather than political goals such as drug pricing and domestic manufacturing.[5,6] FDA has itself conceded that the agency "has no statutory authority to investigate or control the prices charged for marketed drugs."[7]

FDA's other priority review programs were created by Congress, with explicit eligibility criteria for qualifying drugs and sponsors.[8,9] In contrast, the inclusion criteria for the CNPV pilot program are vague and opaque and simply brought into effect by a series of voucher selection considerations outlined in a Staff Manual Guide in January 2026, after 18 of the 22 CNPV drugs had already been selected and 1 approved (Table 1).[10] For example, what factors does the agency consider when selecting drugs that address "large

unmet medical needs" or constitute "innovative breakthrough therapies?"[1] Despite the publication of the Staff Manual Guide, the statutory basis for the CNPV pilot program and how the agency considers a drug's alignment with the stated national priorities remain unclear.

2. Voucher Selection Process and Role of the CNPV Council

The way the CNPV voucher selection and drug review process has been implemented to date magnifies our concerns that non-scientific considerations will enter the drug review process. Of the 22 drugs awarded vouchers through the CNPV pilot program so far (Table 1), 10 are marketed by companies that have made deals with the White House on drug pricing.[6]

On April 18, 2026, President Trump issued an Executive Order directing FDA to grant national priority review vouchers to "appropriate psychedelic drugs" which have Breakthrough Therapy designations and fulfill the CNPV program criteria.[11] Six days later, FDA duly announced three vouchers awarded to companies researching psychedelic drug candidates.[12]

According to the CNPV Review Council Staff Manual Guide, both voucher selection and drug approval discussions involve senior agency leaders, many of whom report directly to the Commissioner.[10,13] Although the guide states that "the Commissioner will not vote on discussions relating to approvability," as Chair of the Council, the Commissioner is involved in moderating "discussions relating to voucher selection" and "discussion of review issues with the primary review team"[10] and is likely to exert heavy influence over the Council's recommendations. The participation of the Commissioner and other senior agency leaders (who, increasingly, are political appointees)[14] in the CNPV pilot program introduces political pressures in the voucher selection and drug review process. This is in marked contrast to FDA's historical practices, which went to great lengths to insulate drug review and approval processes from inappropriate political intervention. Recent reports that a sponsor has sought to withdraw their drug from the CNPV pilot due to involvement from former acting Center for Drug Evaluation and Research Director, Tracy Beth Høeg, exemplify a breach in the firewall between political appointees and review staff.[15] We urge the agency to center career scientists and subject matter experts in the approval process to ensure that drug approvals are guided by scientific, rather than political considerations.

3. CNPV Timeline and Process

The expedited timeline of the CNPV pilot risks endangering patients and consumers. Under the CNPV pilot program, FDA aims to complete the review within 1-2 months, compared to the typical timeline that is 6-10 months, the product of extensive user fee negotiations with industry.[1,16] Using public information from FDA (including press releases, databases, and approval documents), we identified at least 9 of the 22 drugs (41%) in the CNPV pilot that were already part of another FDA expedited or special review program (Table 1). Because of data limitations, this is likely an underestimate of actual participation, but we are concerned that the CNPV pilot introduces additional risks in the drug review process by condensing already short review timelines. Furthermore, we have found that for the 7 CNPV products approved so far, an average of 102 days (around three months) elapsed between FDA's announcements of the voucher awards and the drug approval decisions (Table 1).

Yet, more rapid approval may be associated with safety risks. Researchers have found that novel drugs approved between 1997 and 2014 through FDA's expedited pathways were associated with a 38% higher rate of post-approval safety label changes compared to drugs approved through FDA's standard review process.[17] These findings underscore the risk that prioritizing review speed can endanger patient safety.

In addition, the promised 1–2 month review timeline may strain FDA's staff and resources. The extremely compressed timeline for this pilot raises concerns about whether FDA scientists and subject matter experts have sufficient time to review the drug application materials prior to the internal deadline and target action date. A 2016 report published by the Government Accountability Office highlighted workload challenges at FDA resulting from the expedited review of applications filed with the pediatric priority review vouchers.[18] FDA officials interviewed for the report cited the resource-intensive priority review process as interfering with the agency's "ability to set priorities on the basis of public health needs."[18] Similarly, the accelerated review timeline for the CNPV pilot could divert agency personnel from drugs with the greatest public health impact, particularly if the voucher is awarded for political reasons. Already, news outlets have reported that FDA's Division of Dermatology had to focus exclusively on reviewing Disc Medicine's CNPV drug bitopertin, and ultimately asked for more time to complete its review.[19]

Exemplifying the hurried review process, the CNPV Review Council Staff Manual Guide states that "the review team will share background material with the Deputy Chief Medical Officer at least 3 to 5 days before the Council meeting" and that the discussion of approvability will take place "1-2 weeks before the target action date."[10] The allotted time for the Review Council to evaluate the drug application is worrisome, as complex safety and efficacy data may warrant further consideration and deliberations. Similarly, the short time between Review Council meeting and final decision date leaves little time to resolve any outstanding issues.

4. Lack of Transparency

We were disappointed by the lack of transparency and standardization in the agency's communications about the CNPV pilot program. For example, the rationale for voucher selection for some products were mentioned on some FDA Direct podcasts, but these episodes only covered 15 of the 22 voucher recipients and did not always disclose the rationale in a consistent manner.[20,21] Others were only announced in press releases. After consulting the podcast transcripts and the press releases announcing the voucher awards, we were unable to establish a reason for FDA granting a voucher for 13 of the 22 drugs included in the CNPV pilot program (Table 1). In one instance, on May 8, 2026, FDA appears to have approved zenocutuzumab-zbco (Bizengri) as a CNPV drug three days after announcing on X that it had granted a voucher to the sponsor (no press release was issued).[22,23] We urge the agency to compile a full list of drugs selected for the CNPV pilot program, the justification for invoking the CNPV program, and, once approved, the time from application filing to approval decision. Such a list should reside on the CNPV pilot program landing page and would be a meaningful step towards agency transparency.

In conclusion, FDA has an obligation to protect public health by ensuring that drugs that come to market are safe and effective. Given concerns about politicization, lack of transparency, and strained agency resources that could endanger patients and consumers, we encourage the agency to wind down the CNPV pilot and ensure sufficient funding and staffing for the agency's existing workload.

Sincerely,

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Table 1. Details of Drugs Granted Commissioner's National Priority Review Vouchers (as of 5/20/2026)

Date of CNPV Announcement	Generic Name (Brand Name, if available)	Sponsor	Disease Area/Purpose of Drug	Reason for CNPV*	Approved? (Approval Announcement Date)	Days between CNPV Announcement to Approval Press Release	Part of Expedited Programs**	Part of Other Special Programs ***
10/16/2025	follitropin alfa and lutropin alfa (Pergoveris)	Merck Serono	Infertility	Not stated			None reported	None reported
10/16/2025	teplizumab-mzwv (Tzield)	Sanofi	Type 1 diabetes	Not stated			None reported	None reported
10/16/2025	cytisinicline	Achieve Life Sciences	Nicotine vaping addiction	Large unmet medical needs			None reported	None reported
10/16/2025	lunsotogene parvec-cwha (Otarmeni)	Regeneron Pharmaceuticals	Genetic hearing loss	Affordability	Yes (4/23/2026)	189	Fast Track, Accelerated Approval	Orphan Drug, Rare Pediatric Disease, Regenerative Medicine Advanced Therapy (RMAT)
10/16/2025	cenegermin-bkbj (Oxervate)	Dompé	Non-arteritic anterior ischemic optic neuropathy (NAION)	Not stated			None reported	None reported
10/16/2025	daraxonrasib	Revolution Medicines	Pancreatic cancer	Large unmet medical needs			Breakthrough Therapy	Orphan drug
10/16/2025	bitopertin	Disc Medicine	Porphyria	Not stated	No		None reported	Orphan drug
10/16/2025	ketamine	Phlow Corp	General anesthesia	Onshoring			None reported	None reported

10/16/2025	amoxicillin clavulanate potassium (Augmentin XR)	US Antibiotics	Antibiotic	Onshoring	Yes (12/9/2025)	54	None	None
11/6/2025	zongertinib (Hernexeos)	Boehringer Ingelheim	HER2 lung cancer	Not stated	Yes (2/26/2026)	112	Breakthrough Therapy, Priority Review, Accelerated Approval	Real-Time Oncology Review (RTOR) pilot, Project Orbis
11/6/2025	bedaquiline (Sirturo)	Johnson & Johnson	Drug resistant tuberculosis in young children	Not stated			None reported	None reported
11/6/2025	dostarlimab (Jemperli)	Glaxo-Smith Kline	Rectal cancer	Not stated			None reported	None reported
11/6/2025	exagamglogene autotemcel (Casgevy)	Vertex Pharmaceuticals	Sickle cell disease	Not stated			None reported	None reported
11/6/2025	orforglipron (Foundayo)	Eli Lilly	Obesity and related health conditions	Affordability, domestic manufacturing, large unmet medical needs	Yes (4/1/2026)	146	None	None
11/6/2025	semaglutide (Wegovy)	Novo Nordisk	Obesity and related health conditions	Affordability, domestic manufacturing, large unmet medical needs	Yes (3/19/2026)	133	None	None
12/15/2025	teclistamab and daratumumab hyaluronidase-fihj combination (Tecvayli)	Janssen Biotech	Relapsed/refractory multiple myeloma	Not stated	Yes (3/5/2026)	80	Breakthrough Therapy, Priority Review	Orphan drug, Project Orbis, real-time oncology review (RTOR) pilot

12/19/2025	enlicitide decanoate	Merck	High LDL cholesterol	Affordability			None reported	None reported
12/19/2025	sacituzumab tirumotecan	Merck	Cancer	Affordability			None reported	None reported
4/24/2026	psylocibin	Compass Pathways	Treatment-resistant depression	Not stated			Breakthrough Therapy	None reported
4/24/2026	psylocibin	Usona Institute	Major depressive disorder	Not stated			Breakthrough Therapy	None reported
4/24/2026	methylone	Transcend Therapeutics	Post-traumatic stress disorder	Not stated			Breakthrough Therapy	None reported
5/5/2025	zenocutuzumab-zbco (Bizengri)	Partner Therapeutics	Neuregulin 1 (NRG1)-fusion positive cholangiocarcinoma	Not stated	Yes (5/8/2026)	3	Breakthrough Therapy, Priority Review	Orphan drug

* Based on reasons provided in FDA Direct podcast episodes and press releases.

** Expedited pathways were determined using FDA sources and were Fast Track designation, Breakthrough Therapy designation, Accelerated Approval, and Priority Review.

*** Other special programs were determined using FDA sources and were Orphan Drug designation, Pediatric Rare Disease priority review voucher, Real-Time Oncology Review (RTOR) pilot, Regenerative Medicine Advanced Therapy (RMAT), and Project Orbis.

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