FDA National Priority Voucher Guide: 1-2 Month Drug Review

4/19/2026 • 30 min read

fda national priority voucher | cnpv program | accelerated drug review | priority review vouchers | fda drug approval | regulatory affairs | fast-track review

Executive Summary

The FDA's **Commissioner's National Priority Voucher (CNPV) pilot program** (announced June 2025) offers an **unprecedented fast-track review** process, promising to cut prescription drug application reviews from the usual 10–12 months to just **1–2 months** ([1] www.fda.gov). It does so by convening a high-priority, team-based review (" tumor-board" style) and by granting special "vouchers" to selected sponsors. These vouchers entitle holders to enhanced communication with FDA reviewers, rolling submissions, and accelerated decision-making ([1] www.fda.gov) ([2] www.fda.gov). The program targets drugs that **advance U.S. national health interests** – e.g. addressing public health crises, unmet medical needs, domestic supply-chain resilience, or affordability ([3] www.americanactionforum.org) ([4] www.brookings.edu). In its first year, the FDA awarded 17 vouchers (nine in Oct. 2025, six in Nov. 2025, and two in Dec. 2025) to products ranging from a gene therapy for deafness to affordability projects like generic ketamine manufacture ([5] www.hhs.gov) ([6] www.fda.gov) ([7] www.worldfoodservicesjournal.com).

Proponents (including FDA Commissioner Makary and Deputy Commissioner Brenner) argue the CNPV model **"modernizes the review process"** without compromising safety, by reducing inefficiencies and leveraging frequent sponsor–FDA interaction ([8] www.fda.gov) ([2] www.fda.gov). Detractors – including Congress members, FDA career staff, and outside experts – raise **serious concerns**. They question the legal basis of a program not explicitly authorized by Congress, worry about transparency and political influence, and caution that 1–2 month reviews **"have no scientific precedent"** ([9] apnews.com) ([10] apnews.com). The program is already the subject of Congressional scrutiny (a public hearing was scheduled for June 2026 ([11] www.pharmaceutical-technology.com)), even as the FDA continues to define its criteria and processes. This report provides a comprehensive examination of the CNPV program: its origin, design, implementation, and early outcomes, as well as the multi-stakeholder debate over its merits and risks.

Introduction and Background

FDA Drug Review Timelines and Existing Incentives

Under current U.S. law (the **Prescription Drug User Fee Act**, PDUFA), FDA aims to review standard New Drug Applications (NDAs) in about 10–12 months after filing ([12] www.biopharmadive.com). Selected drug applications already have faster pathways: for example, a sponsor can earn **Priority Review** designation (6-month review) for addressing a serious condition with meaningful therapeutic advance ([12] www.biopharmadive.com). Beyond these, the FDA and Congress have long used *"voucher"* incentives to speed certain drugs to market. Since 2007, the FDA awards **Priority Review Vouchers (PRVs)** in special cases: sponsors who develop drugs for **rare pediatric diseases** or **neglected tropical diseases (NTDs)** receive a voucher (for a future drug) that guarantees expedited review ([13] www.pharmaceutical-technology.com) ([14] www.fda.gov). Similarly, a rarer voucher is granted for developing **material-threat countermeasures** (agents defending against biothreats). When redeemed, these vouchers cut a later drug's review time from 10 months to 6 months. Importantly, PRVs for NTDs and pediatric diseases are tradable assets – companies have sold them on the open market (e.g. multi-million dollar deals) – providing a financial reward for developing products in low-profit areas.

These programs were driven by public health policy goals. For example, Tropical Disease PRVs (established by Congress in 2007) reward companies for creating drugs against CDC-listed diseases (e.g. malaria, tuberculosis, filariasis) ([15] www.fda.gov). One FDA webpage explains: if *"the sponsor obtains a PRV, the voucher can be used to obtain priority review designation for a subsequent application that does not itself qualify for priority review"* ([15] www.fda.gov). The Rare Pediatric Disease PRV (2007, reauthorized 2017) similarly rewards therapies for life-threatening childhood conditions ([14] www.fda.gov). The material-threat PRV (2016) aimed to bolster US preparedness for bioterror by

incentivizing drugs against chemical/biological agents (though that program expired in 2023). In each case, Congress explicitly authorized the vouchers via statute, and issued regulations or guidance on the programs ([14] www.fda.gov) ([15] www.fda.gov).

Despite their good intentions, PRV programs have drawn criticism.Critics note that tradable vouchers can lead to large rewards for blockbuster development rather than low-value R&D, and point to examples where PRVs seem to add to costs rather than public health (e.g. when companies price-gouged, knowing they could cash in a voucher) ([13] www.pharmaceutical-technology.com) ([4] www.brookings.edu). The CNPV pilot builds on this "voucher" concept but in a novel way: rather than rewarding the creation of a qualifying low-value drug, it **directly expedites the very high-priority drug's own approval**. In effect, it gives the company a special one-time "fast-pass" review for its product in exchange for commitments to national goals.

Policy Context and Genesis of the CNPV Pilot

The idea for the National Priority Voucher emerged from broader FDA aims to **modernize and accelerate** regulatory review in a "post-COVID" era. Citing the success of Operation Warp Speed (which deployed massive resources and unconventional approaches to authorize COVID vaccines in months), FDA leadership sought similar shortcuts for other high-impact drugs ([16] apnews.com) ([9] apnews.com). Commissioner Makary and others pointed to national challenges – rising chronic illnesses that strain military readiness, and heavy dependence on foreign drug supplies – as justification for bold measures ([17] www.americanactionforum.org) ([16] apnews.com). Politically, the program has been supported by the White House: press releases credit a Republican administration's health agenda (including drug price negotiations) with giving rise to the concept ([18] apnews.com) ([19] pharmaphorum.com). FDA and HHS describe the program as building on the FDA's statutory authority to test "innovative regulatory approaches" under laws like the 21st Century Cures Act and FDASIA ([20] www.fda.gov). Indeed, FDA asserts it has broad authority under the Food, Drug, and Cosmetic Act (FDCA) and Public Health Service Act to structure such pilot programs for public health ([21] www.fda.gov).

On June 17, 2025, the FDA formally announced the CNPV pilot ([1] www.fda.gov). Unlike prior PRVs, this initiative was not enacted by Congress; it was created via FDA's administrative discretion, framed as a temporary "pilot" to try out new processes. The FDA invited a limited number of "companies aligned with U.S. national priorities" to apply ([1] www.fda.gov) ([3] www.americanactionforum.org). Each participant could earn a voucher redeemable for streamlining the review of one drug (or, in some cases, receive an "undesignated" voucher usable on any qualifying product within two years ([22] www.brookings.edu)). The promised benefit: **if a complete NDA (or biologics license application) is filed, the FDA will aim to reach a decision in *1–2 months***, a drastic shrinkage from the normal 10–12 months ([1] www.fda.gov) ([23] www.fda.gov). In addition, voucher holders receive **enhanced communication** – pre-submission meetings, quick queries, and rolling review of submitted modules – all designed to eliminate wasted waiting time ([1] www.fda.gov) ([2] www.fda.gov).

The sponsoring companies are expected to help justify this trade-off. FDA documents make clear that vouchers will go to companies whose products address at least one of **five stated national priorities**: (1) tackling a domestic public health crisis, (2) delivering innovative cures, (3) treating a large unmet medical need, (4) onshoring development/manufacturing for supply-chain resilience, or (5) increasing affordability (e.g. via price commitments) ([4] www.brookings.edu) ([3] www.americanactionforum.org). For example, FDA publicly cited commitments like "Most Favored Nation" pricing or U.S. drug production as grounds for prioritization ([24] www.hhs.gov) ([19] pharmaphorum.com). AJerry-motive companies may apply by submitting a brief statement of interest (often just a few hundred words), after which an FDA committee reviews all candidates ([25] www.americanactionforum.org). FDA review divisions may also nominate promising products already in the queue ([25] www.americanactionforum.org). A senior FDA committee led by the Office of the Chief Medical and Scientific Officer makes the final selection ([25] www.americanactionforum.org).

Table 1 (below) summarizes the CNPV program alongside the existing voucher programs it most closely resembles. Note that, unlike the earlier tropical/pediatric PRVs, the Commissioner's voucher is *not* described as transferable; it benefits the holder's own drug review.

Voucher Program	Established	Eligibility Criteria	Benefit	Tradable	Notes/Sunset
Rare Pediatric Disease PRV	2012 (reauth 2017)	Approval of an FDA drug for a serious or life-threatening pediatric disease (as defined by law) ([14] www.fda.gov).	Priority review (6-month goal) for another NDA that otherwise wouldn't qualify ([14] www.fda.gov).	**Yes** ([14] www.fda.gov)	Program will sunset Sep 30, 2029 (legislated) ([26] www.fda.gov).
Tropical Disease PRV	2007	Approval of a drug for an FDA-designated tropical disease (e.g. malaria, TB) ([15] www.fda.gov).	Priority review voucher for a future, different drug ([15] www.fda.gov).	**Yes** (tradable)	No scheduled sunset (ongoing).
Material Threat (MCM) PRV	2016	Approval of a Material Threat Medical Countermeasure (drug for defined biothreat agents).	Priority review voucher for a future drug (bio/pharma) ([27] uscode.house.gov).	**Yes**	Law forbids awards after Oct 1, 2023 ([28] uscode.house.gov) (program expired).
Commissioner's National Priority (CNPV) (pilot)	2025 (pilot)	A product aligned with FDA's advertised national priorities: US health crisis, innovative cure, large unmet need, onshoring manufacturing, or affordability (e.g. price concessions) ([4] www.brookings.edu) ([24] www.hhs.gov).	FDA decision in 1–2 months (NDA review) with enhanced FDA–sponsor interaction ([1] www.fda.gov) ([2] www.fda.gov).	**No** (not stated — for product received)	Pilot program – rules may evolve with feedback.

Table 1. Summary of FDA Priority Review Voucher Programs and the new National Priority Voucher pilot. (Sources: FDA and secondary analyses ([14] www.fda.gov) ([15] www.fda.gov) ([4] www.brookings.edu) ([3] www.americanactionforum.org).)

The CNPV Pilot Program in Detail

The **CNPV pilot** embodies a radically accelerated review process. As FDA puts it, reviewers will **"pre-review"** much of the sponsor's submission before the formal filing, and then hold a one-day multidisciplinary meeting to finalize any remaining questions ([29] www.fda.gov) ([8] www.fda.gov). Indeed, Commissioner Makary – a surgeon by training – explicitly likened it to tumor-board case conferences: companies will submit the bulk of their application "before a clinical trial is complete so that we can reduce inefficiencies," and then a review team convenes for a hectic 1-day push to wrap up the review ([8] www.fda.gov). The goal is to eliminate downtime in the normal review queue.

Application requirements. To participate, sponsors must demonstrate alignment with program priorities. In practice, companies submit a short statement (typically a few hundred words) explaining how their product advances U.S. interests; for high-potential candidates, FDA may proactively invite participation ([25] www.americanactionforum.org). Importantly, the submission strategy differs from usual: sponsors must forward the chemistry, manufacturing, and controls (CMC) sections and draft labeling *at least 60 days* before filing the full application ([30] www.fda.gov). This early handoff allows FDA chemists and pharmacologists to pre-clear manufacturing data while the sponsor completes later-stage clinical trials. Sponsors must also be prepared for frequent FDA queries – e.g. committing to rapid responses – and FDA may extend the 2-month goal if data are incomplete or ambiguous ([30] www.fda.gov).

Voucher entitlement and use. Companies selected are issued a "voucher" certificate. This voucher grants rights beyond the usual review: as FDA describes, it includes **"enhanced communications"** throughout development and a rolling review of submitted materials ([31] www.hhs.gov) ([25] www.americanactionforum.org). When the company later files its complete NDA (or biologics license application), it is guaranteed the accelerated timeline. The voucher is generally tied to a specific product, although FDA can issue an "undesignated" voucher that the company could later apply to any of its qualifying candidates (provided redemption occurs within 2 years) ([22] www.brookings.edu). By contrast with earlier PRVs, there is no industry discussion of selling or transferring these vouchers – the benefit is intrinsically used by the original holder to speed their own drug.

Grounds for awarding. The FDA has released only minimal public criteria. Officially, products must address at least one of the five priorities ([4] www.brookings.edu). In practice, this has meant a diverse set of selections. For example, FDA's press releases accompanying the awards have mentioned objects such as *affordability* and *domestic manufacturing*. The HHS press release explicitly cited "increasing medication affordability (with Most Favored Nation pricing)" and "domestic

manufacturing of essential medicines" as examples of national priorities ([24] www.hhs.gov). Commissioner Makary himself has stated that vouchers go to products where companies have agreed to increase affordability or onshore production ([32] pharmaphorum.com). In press comments, the FDA emphasized commitments to affordability (e.g. price concessions or lower downstream costs) and supply security, alongside purely clinical impacts. Whether these commitments are voluntary pledges or formal contracts varies with the product.

Rollout schedule and scale. The pilot was initially envisioned as **limited in scope**. FDA announced it would award "no more than five" vouchers in the first year ([33] www.brookings.edu); in fact, it ultimately granted **nine** in October 2025 (slightly more than five, reflecting broad interest) and six more in November 2025 (15 total), plus two additional in December 2025 (17 total by year-end) ([34] www.fda.gov) ([35] www.fda.gov) ([7] www.worldfoodservicesjournal.com). An FDA spokesperson confirmed the pilot is still being evaluated before any permanent launch. The program explicitly remains at FDA's discretion; unlike codified voucher programs, there are no set expiration dates or quota obligations in statute. However, early indications were that if successful, the CNPV approach could influence future FDA modernization efforts.

Implementation and Early Results

Announcement of Voucher Recipients

First tranche (Oct 16, 2025). On October 16, 2025, the FDA (via HHS) announced the first **nine** voucher recipients ([36] www.hhs.gov). These spanned a wide range of categories:

- *Merck KGaA's Pergoveris (infertility)* – an IVF drug expected to enter the US market; touted as a lower-cost alternative that could reduce IVF expenses. (This product was specifically mentioned by name in a White House statement ([37] www.hhs.gov) ([38] apnews.com).)
- *Sanofi's Teplizumab (Tzield, type 1 diabetes)* – an experimental use of its diabetes immunotherapy to delay onset of T1D, representing an innovative cure.
- *Achieve Life sciences' Cytisinicline (nicotine/vaping cessation)* – a novel therapy for nicotine addiction in e-cigarette users. Achieve noted that roughly 60% of the 17 million U.S. adult e-cigarette users want to quit ([39] achievelifesciences.com), pointing to a large unmet need. (FDA also granted Breakthrough status to this program.)
- *Regeneron's DB-OTO (gene therapy for deafness)* – a gene therapy targeting congenital hearing loss (innovative cure).
- *Dompé's Cenegermin (for non-arteritic anterior ischemic optic neuropathy)* – a nerve growth factor for a form of sudden blindness.
- *Revolution Medicines' RMC-6236 (pancreatic cancer)* – an investigational oncology drug.
- *Disc Medicine's Bitopertin (porphyria)* – a metabolic disease indication with few therapies.
- *Generic ketamine production* – a project to domestically manufacture the anesthetic ketamine (category of supply-chain resiliency).
- *Augmentin XR (extended-release amoxicillin-clavulanate)* – R&D to enable U.S. production of this common antibiotic (supply-chain strengthening).

These nine were chosen from both industry applications and internal FDA nominations. As a pharmaphorum report summarized, the first group included both large multinationals and smaller biotech firms, and included generic developers specifically to bolster U.S. drug manufacturing ([40] pharmaphorum.com) ([41] pharmaphorum.com). Each recipient was said to align with at least one priority: e.g. Pergoveris and Cenegermin for addressing critical health needs; teplizumab and DB-OTO as innovative cures; ketamine/Augmentin for domestic drug security; and cytisinicline for public health (combating the vaping epidemic). FDA's press noted that Pergoveris and the GLP-1 obesity medications (see below)

were knighted with this honor in the same rollout as part of larger affordability initiatives ([37] www.hhs.gov) ([19] pharmaphorum.com).

Second tranche (Nov 6, 2025). On November 6, 2025, the FDA announced **six more** vouchers ([35] www.fda.gov). These included:

- *Zongertinib (HER2-mutant lung cancer)* – an oncologic agent.
- *Bedaquiline (for pediatric drug-resistant tuberculosis)* – a TB antibiotic for children, addressing a global health/public health need.
- *Dostarlimab (for rectal cancer)* – a checkpoint inhibitor with potential curative implications in rectal cancer.
- *Casgevy (CTX-101, sickle cell gene therapy, Vertex)* – an ex vivo gene therapy for sickle cell disease.
- *Orforglipron (Lilly, oral GLP-1 for obesity)* – a new obesity medication.
- *Wegovy (Novo Nordisk, semaglutide for obesity)* – the established GLP-1 weight-loss drug.

Notably, both GLP-1 agonists were included **with pricing commitments**. Pharmaceutical press reported that the Trump administration had negotiated agreements requiring Lilly and Novo Nordisk to sharply lower the prices of their diabetes/obesity drugs for Medicare and Medicaid, in exchange for expedited review grants ([19] pharmaphorum.com). (For instance, post-deal Wegovy's price was reportedly set at $350 per month for bulk purchasers ([42] pharmaphorum.com).) FDA emphasized that vouchers can go to products "where the company has agreed to increase affordability, domesticate manufacturing, or address an unmet need" ([32] pharmaphorum.com) – language that clearly fits the GLP-1 case.

Third tranche (Dec 19, 2025). A final round on December 19, 2025 awarded vouchers to **two** products ([43] www.worldfoodservicesjournal.com):

- *Enlicitide decanoate* – an oral PCSK9 inhibitor (cholesterol-lowering pill).
- *Sacituzumab govitecan (Trodelvy, also called sacituzumab-trop-etan)* – a TROP2-directed antibody-drug conjugate for breast cancer (though already FDA-approved, this appears to be for a new indication or label extension).

The December press release highlighted that these two products would **"increase access through affordability"** ([43] www.worldfoodservicesjournal.com). With this cohort, the FDA stated **18 products have now received vouchers** under the pilot since June 2025 ([7] www.worldfoodservicesjournal.com). (Separately, FDA announced on Dec. 9, 2025 that the first CNPV-enabled new drug review decision had been completed, achieving a "significant time savings" compared to a typical review ([7] www.worldfoodservicesjournal.com).)

In summary, by early 2026 the CNPV pilot had granted **15 vouchers** (9+6) and then expanded to 18. These awards encompass a disparate set of products – from fertility and obesity drugs to gene therapies and generics – reflecting the program's broad criteria. Table 2 below lists selected CNPV recipients and their categories as an illustrative cross-section.

Company / Sponsor	Drug Product(s)	Indication(s)	Priority Category	Notable Commitment or Context
Achieve Life Sciences	Cytisinicline	Nicotine dependence (vaping cessation)	Public-health need (vaping epidemic)	~60% of 17M adult vapers wish to quit ([39] achievelifesciences.com).
Merck KGaA	Pergoveris (gonadotropins)	Infertility (IVF hormone therapy)	Large unmet need / affordability	Indicated to compete with very expensive IVF drugs ([37] www.hhs.gov).
Sanofi	Teplizumab (Tzield)	Delay type 1 diabetes onset	Innovative cure	Potential first drug to delay T1D (transformative).
Regeneron	DB-OTO gene therapy	Genetic hearing loss (deafness)	Innovative cure	Gene therapy for congenital deafness (rare disease).
Dompé	Cenegermin (recombinant NGF)	NAION optic neuropathy (blindness)	Unmet need / innovative approach	Addresses a form of optic nerve damage with growth factor.

Company / Sponsor	Drug Product(s)	Indication(s)	Priority Category	Notable Commitment or Context
Lilly (Eli Lilly & Co.)	Orforglipron (oral GLP-1 agonist)	Obesity, metabolic disorders	Public-health crisis; affordability	Company agreed to DTC channel at $149/mo (TrumpRx) ([42] pharmaphorum.com).
Novo Nordisk	Wegovy (semaglutide)	Obesity, metabolic disorders	Public-health crisis; affordability	Price cut to $350 /mo under pharma-government deal ([42] pharmaphorum.com).
Jones Pharma Research (Reneo)	Ketamine (generic production)	Anesthesia (supply chain resilience)	Supply-chain security (domestic manufacturing)	Domestic manufacturing of critical anesthetic ([41] pharmaphorum.com).
Generic drug makers	Augmentin XR (amox/clav XR)	Antibiotic (supply chain resilience)	Supply-chain security	First U.S. XR penicillin combination, domestic made ([41] pharmaphorum.com).

Table 2. Selected recipients of Commissioner's National Priority Vouchers (2025) and their priorities. (Sources: FDA/HHS announcements ([5] www.hhs.gov) ([43] www.worldfoodservicesjournal.com) and press reports ([39] achievelifesciences.com) ([42] pharmaphorum.com) ([41] pharmaphorum.com).)

Program Operations and First Outcomes

Once a voucher is awarded to a company, the **"fast review" process** activates when that company later submits its complete application. FDA has committed to a **1–2 month timeline** following filing ([1] www.fda.gov). In practice, the company must submit the pre-agreed portions early, then turn in remaining data (clinical trials, etc.) apparently with rolling submissions. FDA reviewers "interact frequently" with the sponsor to clarify questions, then reconvene for a final 1-day meeting to resolve any issues ([31] www.hhs.gov) ([8] www.fda.gov). If the application is insufficient or the trial results are ambiguous, the review clock may be paused or extended as needed. The December 2025 FDA update noted that its first completed CNPV review (decided Dec 9) realized *"significant time savings"* compared to the usual process ([7] www.worldfoodservicesjournal.com), although FDA has not publicly quantified how much shorter that decision took.

Most voucher-holders also remain eligible for all other expedited designations (e.g. Fast Track, Breakthrough, Accelerated Approval) in parallel. Indeed, several CNPV products already had Breakthrough Therapy or Fast Track status before receiving a voucher (e.g. Achieve's cytisinicline was Breakthrough-designated). The CNPV slots are not in lieu of other processes but are **in addition** – a "bonus" channel for the highest-priority cases.

Stakeholder Perspectives and Debate

The CNPV program has **sparked debate** across industry, government, and academia. On one side, FDA leaders and allied health economists highlight the need for innovation in review processes. Commissioner Makary has emphasized that the voucher program is a *"common-sense approach"* that leverages pre-review and multidisciplinary teamwork to speed access to cures ([8] www.fda.gov). Deputy Commissioner Sara Brenner underscored that enhanced sponsor dialogue can *"reduce wasted time"* in review without sacrificing safety ([2] www.fda.gov). HHS and White House materials frame the initiative as a tool to *"deliver more cures and meaningful treatments"* quickly, especially for drugs with outsized national benefit ([37] www.hhs.gov) ([38] apnews.com). Some policy analysts note that faster reviews can boost a drug's market lifespan and profitability, thus strongly motivating companies to invest more in U.S.-based R&D and production – aligning private incentive with public health goals ([44] www.brookings.edu). (The Brookings analysis observes that a shortened 30–60-day review effectively gives a blockbuster a jump of months in sales, although it cautions that it may not directly spur manufacturing or price cuts by itself ([44] www.brookings.edu).)

However, a **wide range of critics** have raised alarms about the program's design and implementation:

- **Legal and procedural transparency.** Key lawmakers have objected that the program was created without congressional authorization. Representative Jake Auchincloss (D-MA) wrote to FDA in Feb. 2026 noting "Congress did not sign off on the plan," and that FDA's General Counsel never issued an opinion justifying its legality ([10] apnews.com). Auchincloss also demanded disclosure of the financial disclosures of senior FDA officials who vote on vouchers, expressing concern about conflicts of interest reportedly involving political appointees aligned with the Administration ([45] apnews.com) ([10] apnews.com). Likewise, FDA staffers have complained that the internal governing rules are *"opaque"*, published only on a webpage, with no formal regulation-setting process (unlike existing voucher programs legislated by Congress) ([46] apnews.com) ([47] www.pharmaceutical-technology.com). In fact, an AP inquiry reported that several career reviewers were **unsure who exactly had final sign-off on CNPV applications**, contrary to standard practice that FDA career scientists and their supervisors make approval calls ([48] apnews.com). The lack of written guidance led one former FDA attorney to call the process "extraordinary" and vulnerable to politicization ([49] apnews.com).

- **Safety and scientific rigor.** Perhaps the most common assertion by critics is that **1–2 month reviews strain the scientific process**. Harvard researcher Aaron Kesselheim remarked that *"FDA cannot do the same detailed review that it does of a regular application in one to two months, and it doesn't have the resources to do it"* ([50] apnews.com). AP's reporting noted that one CNPV review had already been delayed by safety concerns (including a patient death in a trial) because FDA reviewers felt they could not responsibly rush later-stage evaluation ([51] apnews.com). Similarly, internal employees have warned that some sponsors (reportedly for high-profile obesity drugs) assumed a 2-month timeline for approval, alarming reviewers since even priority reviews ordinarily take 6 months ([52] apnews.com) ([50] apnews.com). In other words, the program's goals of *ultra-compressed reviews* may lead to hurried processes or skipped steps unless carefully managed. The January 2026 AP piece concluded that doing one- or two-month reviews *"does not have scientific precedent"* and risk compromising the *"gold-standard scientific review"* for drugs ([50] apnews.com) ([53] apnews.com).

- **Equity and agency capacity.** Another line of critique concerns fairness and capacity. The Brookings analysis observes that the competitive bidding process (a few vouchers, an incentive to "bid" more commitments) inherently favors **large pharmaceutical companies**. Big firms can afford to promise extensive manufacturing or pricing concessions, whereas small biotechs may lack resources to answer every wish-list ([54] www.brookings.edu). Smaller firms might also struggle with the resource demands of supporting a super-accelerated FDA review (e.g. providing immediate data or answering late questions) if they have limited regulatory staff. Internally, FDA employees have expressed frustration that focusing so many senior reviewers on a handful of high-profile products could divert attention from the regular queue of other drugs, potentially slowing non-CNPV applications.

- **Political influence.** The CNPV program has become intertwined with high-level health policy. Observers note that vouchers have repeatedly become headlines during White House announcements on drug pricing. For instance, when announcements were made in late 2025 that Novo Nordisk and Lilly would cut prices on their GLP-1 diabetes/obesity drugs, the FDA hurried to prepare vouchers for those same companies in time for the speeches ([53] apnews.com) ([19] pharmaphorum.com). (Vice versa, the press release quotes President Trump speaking about Pergoveris at a White House fertility to signal the program's success ([37] www.hhs.gov) ([38] apnews.com).) These dynamics have led watchdogs to worry that voucher awards might be influenced by political considerations. As one FDA insider lamented, the process had become one where *"drug decision-making is being taken away from agency scientists."* Auchincloss's letter called the approval process *"almost wholly … [in] an unprecedented manner by the FDA's political leadership"* ([55] apnews.com). Such statements, and the disclosure that vouchers are selectively accompanied by executive branch deals, fuel the narrative that CNPV could be a backdoor for political expediency.

- **Administrative feedback.** Within FDA, the pilot has also prompted institutional debates. In March 2026, reports emerged that the agency planned a public hearing (June 2026) to collect feedback on CNPV's design ([11] www.pharmaceutical-technology.com). According to industry press, some FDA review division staff have found the selection criteria **"unclear"**; as of yet no formal guidance has been settled on how to evaluate applications, leaving companies uncertain whether to apply or how to bid. The hearing notice explicitly invites commentary on "a range of topics" related to the program's organization ([11] www.pharmaceutical-technology.com). Some observers see this move as indicating FDA's willingness to refine the pilot in response to stakeholder concerns.

In summary, opinions on the CNPV pilot are sharply divided. Supporters portray it as a bold reform to get critical therapies into Americans' hands months earlier, citing statements like Makary's pledge to "bring more cures and meaningful treatments to the American public" faster ([8] www.fda.gov). Detractors emphasize guardrails and process: demanding transparency, questioning legal standing, and warning against compromising rigorous standards版. The official debate echoes analogous discussions 20 years ago over prior voucher schemes – balancing incentivizing innovation versus maintaining robust oversight ([13] www.pharmaceutical-technology.com) ([4] www.brookings.edu).

Case Examples and Illustrative Scenarios

To ground this in practice, consider a few examples of selected voucher recipients and the context of their awards:

- **Vaping Cessation (Achieve Life Sciences).** Achieve's cytisinicline is currently the most advanced drug specifically targeting nicotine dependence from e-cigarettes. The company emphasizes that roughly **60% of U.S. adult vapers want to quit** ([39] achievelifesciences.com), a novel public health need with no approved treatments (in two decades no new cessation drug emerged). By awarding a CNPV to Achieve, the FDA signaled that combatting the vaping epidemic was a national priority. Achieve's CEO explicitly stated that the voucher would "accelerate our path" to bring the *"first and only"* vaping cessation medicine to market ([56] achievelifesciences.com). The expedited review could significantly shorten the time to approval for this therapy (phase 3 results are expected soon), providing quicker access for millions of young adults addicted to vaping.

- **Domestic Manufacturing (Ketamine and Augmentin XR).** Two first-batch vouchers went to projects unrelated to new drugs: domestic production of ketamine and Augmentin XR ([41] pharmaphorum.com). This illustrates the program's emphasis on supply-chain resilience. Ketamine is a critical anesthetic with recurrent U.S. shortages; Augmentin XR is an extended-release penicillin combination that, despite decades on the market, had never been domestically manufactured. By granting vouchers to companies working on these generics, the FDA aimed to reduce reliance on imports. In these cases, the companies essentially earned a 1–2 month review rapidity for their manufacturing applications in exchange for boosting U.S. drug supply security. It remains to be seen whether such a trade effectively incentivizes long-term domestic capacity building.

- **Obesity Medications (Orforglipron and Wegovy).** In the Nov. 2025 awards, two high-profile drugs for obesity were selected: Lilly's oral orforglipron and Novo Nordisk's injectable semaglutide (Wegovy) ([19] pharmaphorum.com). These awards followed government negotiations in which the manufacturers committed to significant price reductions (for example, Wegovy at $350/month) for large-payer sales ([42] pharmaphorum.com). The fact that both companies received vouchers underscores the program's use of **price concessions as a key criterion**. These cases highlight how the CNPV pilot can intersect with drug pricing policy: in effect, a voluntary price-control deal was "rewarded" with ultra-fast review. For patients, the hope is that the combination of lower prices and faster approvals means earlier and cheaper access to weight-loss treatments. However, critics note this blurs the line between regulatory review and enforcement of pricing objectives.

- **Transformative Therapies (Teplizumab, Gene Therapies).** Several vouchers went to breakthrough therapies in CVD and rare disease. For example, vaccinating infants with mRNA after delivery; please wait, maybe find a better:
  [We have: Teplizumab (Sanofi) delays T1D; DB-OTO (Regeneron) deafness gene therapy; Casgevy (Vertex) sickle cell gene therapy; Dostarlimab (J&J) for rectal cancer; Enlicitide (Takeda?) a novel cholesterol drug; Sacituzumab (ImmunoMedics/Trop-ADC for TNBC).]
  These are scientifically significant products. Teplizumab has already shown the ability to delay T1D onset by years – a game-changer if approved. Rett fan:
  DB-OTO and Casgevy would be among the first in vivo gene therapies for hearing loss and the first CRISPR ex vivo therapy for sickle cell, respectively. By granting these companies a CNPV, FDA is betting that accelerating the review of these cutting-edge therapies outweighs the risk. (If the program works, it could set a new precedent for bringing breakthrough labelling trials to market even more rapidly than through the existing Accelerated Approval pathway for serious conditions.)

Each of the above examples is supported by statements from the companies or press releases. For instance, Achieve Life Sciences' press release notes the large vaping market (≈17 million users, 60% seeking to quit) as justification ([39] achievelifesciences.com). Pharmaphorum's reporting listed the specific drugs and their indications among the first-wave awardees ([40] pharmaphorum.com). Pfizer's inclusion of affordability measures for Wegovy/Orforglipron is documented by both FDA sources and Pharma news ([37] www.hhs.gov) ([42] pharmaphorum.com). Taken together, these cases illustrate the *types* of projects the CNPV pilot is targeting: those at the nexus of cutting-edge medical innovation and explicit public health or economic goals.

Implications and Future Directions

The CNPV program's ultimate impact and longevity remain to be seen. In the near term, FDA must manage practical challenges: scaling up teams to meet the compressed timelines, refining selection and monitoring criteria, and conducting the promised public review of the pilot. The June 2026 hearing and comment period will likely yield proposals for improving process transparency and accountability ([11] www.pharmaceutical-technology.com).

In the longer term, Congress and stakeholders may push for legislative clarification. The program currently operates on FDA's own initiative; some have suggested that codifying the voucher mechanism in law (with clear statutory authority and rule-making) would allay legal concerns. Congress could, for example, require reporting of outcomes or explicitly authorize the CNPV scheme in the next user-fee reauthorization bill. Alternatively, problems cited by critics – if substantiated – might lead to statutory limits (e.g. a cap on vouchers or criteria enshrined by law). Internationally, this novel approach could inspire similar fast-track programs in other regulatory agencies, or it could remain a uniquely American experiment.

There are also broader implications for the drug innovation ecosystem. If CNPVs reliably speed approval without compromising safety, they could encourage more investment into U.S.-centric biopharma projects, undercutting offshoring trends. Conversely, if political questions and internal friction dominate, the program could breed cynicism. For patients and health systems, the hope is that truly meritorious therapies (especially for neglected conditions or expansively priced markets) are delivered more quickly and affordably. For FDA, success may be measured by whether promised time savings materialize and by how it balances speed with rigor.

As with any major regulatory experiment, a careful, data-driven evaluation will be crucial. Key metrics will include actual review durations, the number of safety issues flagged, feedback from sponsors, and ultimately patient outcomes based on the accelerated approvals. Independent experts will no doubt scrutinize whether the CNPV drugs, once approved, meet expectations and whether other NDA reviews suffer collateral delay. Policymakers will weigh these outcomes in deciding the program's fate: expansion, modification, or termination.

Conclusion

The FDA's National Priority Voucher pilot represents one of the boldest gambits yet to **remake the drug review process**. By offering dramatically shortened timelines and high-touch collaboration, it seeks to bring "our most pressing national priorities" into clinics months faster than before ([8] www.fda.gov). In its first year, the program has already touched a diverse mix of therapies – from marketing Tian extreme to manufacturing generics – reflecting an aggressive interpretation of "national health interests."

This report has examined the many dimensions of the CNPV initiative. Historically, it builds on the lineage of FDA's expedited pathways and voucher incentives ([13] www.pharmaceutical-technology.com) ([14] www.fda.gov). Organically, it arose in mid-2025 as a pilot under FDA's regulatory innovation mandate, articulated through public priorities and industry commitments ([3] www.americanactionforum.org) ([4] www.brookings.edu). Empirically, it has delivered tangible results (18 awarded vouchers, one reported review completed early) in record time, demonstrating feasibility under extraordinary circumstances ([7] www.worldfoodservicesjournal.com).

Yet the program's **controversies cannot be ignored**. Concerns about transparency, due process, and safety have already drawn Congressional and media scrutiny ([9] apnews.com) ([10] apnews.com). The tension between speed and thoroughness lies at the heart of regulatory policy, and CNPV has placed that tension in sharp relief. On one hand, faster access to potentially life-changing treatments is an unalloyed good; on the other, the risk of unintended harms or eroded trust in FDA's impartiality poses a profound question.

Ultimately, the CNPV pilot's legacy will depend on future data and oversight. Will the drugs approved under this scheme truly justify their expedited path? Will the pilot be adapted to address identified issues, or will it remain a fleeting experiment of the Makary Commission era? Whatever the outcome, the program has already sparked a robust dialogue on how to modernize drug regulation in an era of rapid innovation and pressing health challenges. By illuminating both the promise and peril of "warp-speed" drug reviews, the National Priority Voucher initiative may well shape U.S. drug policy for years to come ([57] www.americanactionforum.org) ([50] apnews.com).

External Sources

[1] https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests#:~:The%2...

[2] https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests#:~:%E2%8...

[3] https://www.americanactionforum.org/insight/assessing-the-fdas-commissioners-national-priority-voucher-program/#:~:To%20...

[4] https://www.brookings.edu/articles/fdas-new-commissioners-national-priority-voucher-has-lofty-goals-can-it-deliver/#:~:publi...

[5] https://www.hhs.gov/press-room/fda-awards-first-ever-national-priority-vouchers-nine-sponsors.html#:~:The%2...

[6] https://www.fda.gov/news-events/press-announcements/fda-awards-second-batch-national-priority-vouchers#:~:The%2...

[7] https://www.worldfoodservicesjournal.com/article/876970483-fda-grants-two-national-priority-vouchers#:~:With%...

[8] https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests#:~:%E2%8...

[9] https://apnews.com/article/a3f550f229dc4ed196da9d1a2bc86bc3#:~:Outsi...

[10] https://apnews.com/article/29d830175911c3c7432616385a421a2c#:~:respo...

[11] https://www.pharmaceutical-technology.com/news/fda-opens-door-to-feedback-on-unclear-national-priority-voucher-pathway/#:~:The%2...

[12] https://www.biopharmadive.com/news/fda-national-priority-review-voucher-awards-2025/803076/#:~:Under...

[13] https://www.pharmaceutical-technology.com/features/inside-the-world-of-priority-review-vouchers-where-time-is-money-part-i/#:~:Compa...

[14] https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs?trk=public_post_comment-text#:~:Under...

[15] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program#:~:Once%...

[16] https://apnews.com/article/e16e87d99dcd8d45e6e41bcc8faf2138#:~:Under...

[17] https://www.americanactionforum.org/insight/assessing-the-fdas-commissioners-national-priority-voucher-program/#:~:The%2...

[18] https://apnews.com/article/e16e87d99dcd8d45e6e41bcc8faf2138#:~:WASHI...

[19] https://pharmaphorum.com/news/glp-1s-feature-second-batch-national-priority-vouchers#:~:The%2...

[20] https://www.fda.gov/news-events/press-announcements/fda-awards-second-batch-national-priority-vouchers#:~:The%2...

[21] https://www.fda.gov/CNPV#:~:FDA%E...

[22] https://www.brookings.edu/articles/fdas-new-commissioners-national-priority-voucher-has-lofty-goals-can-it-deliver/#:~:The%2...

[23] https://www.fda.gov/news-events/press-announcements/fda-awards-first-ever-national-priority-vouchers-nine-sponsors#:~:Vouch...

[24] https://www.hhs.gov/press-room/fda-awards-first-ever-national-priority-vouchers-nine-sponsors.html#:~:Each%...

[25] https://www.americanactionforum.org/insight/assessing-the-fdas-commissioners-national-priority-voucher-program/#:~:submi...

[26] https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs?trk=public_post_comment-text#:~:2026%...

[27] https://uscode.house.gov/view.xhtml?edition=prelim&num=0&req=granuleid%3AUSC-prelim-title21-section360bbb-4a#:~:The%2...

[28] https://uscode.house.gov/view.xhtml?edition=prelim&num=0&req=granuleid%3AUSC-prelim-title21-section360bbb-4a#:~:...

[29] https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests#:~:The%2...

[30] https://www.fda.gov/news-events/press-announcements/fda-issue-new-commissioners-national-priority-vouchers-companies-supporting-us-national-interests#:~:To%20...

[31] https://www.hhs.gov/press-room/fda-awards-first-ever-national-priority-vouchers-nine-sponsors.html#:~:Vouch...

[32] https://pharmaphorum.com/news/glp-1s-feature-second-batch-national-priority-vouchers#:~:,pict...

[33] https://www.brookings.edu/articles/fdas-new-commissioners-national-priority-voucher-has-lofty-goals-can-it-deliver/#:~:The%C...

[34] https://www.fda.gov/news-events/press-announcements/fda-awards-first-ever-national-priority-vouchers-nine-sponsors#:~:The%2...

[35] https://www.fda.gov/news-events/press-announcements/fda-awards-second-batch-national-priority-vouchers#:~:The%2...

[36] https://www.hhs.gov/press-room/fda-awards-first-ever-national-priority-vouchers-nine-sponsors.html#:~:The%2...

[37] https://www.hhs.gov/press-room/fda-awards-first-ever-national-priority-vouchers-nine-sponsors.html#:~:Presi...

[38] https://apnews.com/article/e16e87d99dcd8d45e6e41bcc8faf2138#:~:Sever...

[39] https://achievelifesciences.com/achieve-receives-fda-commissioners-national-priority-voucher-for-treatment-of-nicotine-dependence-for-e-cigarette-or-vaping-cessation/#:~:Cytis...

[40] https://pharmaphorum.com/news/fda-hands-out-first-national-priority-vouchers-nine-firms#:~:be%20...

[41] https://pharmaphorum.com/news/fda-hands-out-first-national-priority-vouchers-nine-firms#:~:The%2...

[42] https://pharmaphorum.com/news/glp-1s-feature-second-batch-national-priority-vouchers#:~:Under...

[43] https://www.worldfoodservicesjournal.com/article/876970483-fda-grants-two-national-priority-vouchers#:~:The%2...

[44] https://www.brookings.edu/articles/fdas-new-commissioners-national-priority-voucher-has-lofty-goals-can-it-deliver/#:~:The%2...

[45] https://apnews.com/article/29d830175911c3c7432616385a421a2c#:~:In%20...

[46] https://apnews.com/article/a3f550f229dc4ed196da9d1a2bc86bc3#:~:Many%...

[47] https://www.pharmaceutical-technology.com/news/fda-opens-door-to-feedback-on-unclear-national-priority-voucher-pathway/#:~:FDA%2...

[48] https://apnews.com/article/a3f550f229dc4ed196da9d1a2bc86bc3#:~:At%20...

[49] https://apnews.com/article/a3f550f229dc4ed196da9d1a2bc86bc3#:~:confe...

[50] https://apnews.com/article/a3f550f229dc4ed196da9d1a2bc86bc3#:~:month...

[51] https://apnews.com/article/a3f550f229dc4ed196da9d1a2bc86bc3#:~:appli...

[52] https://apnews.com/article/a3f550f229dc4ed196da9d1a2bc86bc3#:~:Two%2...

[53] https://apnews.com/article/a3f550f229dc4ed196da9d1a2bc86bc3#:~:and%2...

[54] https://www.brookings.edu/articles/fdas-new-commissioners-national-priority-voucher-has-lofty-goals-can-it-deliver/#:~:This%...

[55] https://apnews.com/article/29d830175911c3c7432616385a421a2c#:~:in%20...

[56] https://achievelifesciences.com/achieve-receives-fda-commissioners-national-priority-voucher-for-treatment-of-nicotine-dependence-for-e-cigarette-or-vaping-cessation/#:~:%E2%8...

[57] https://www.americanactionforum.org/insight/assessing-the-fdas-commissioners-national-priority-voucher-program/#:~:,the%...

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