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IMPORTANT UPDATE

First Awards Announced in the FDA's CNPV Program

Overview

On October 16, 2025, the U.S. Food and Drug Administration (FDA) announced the first nine recipients of the newly established Commissioner's National Priority Voucher (CNPV) pilot program. The initiative, first introduced in June 2025 (read our Issue Brief), is designed to accelerate the review of drug and biologic applications that address major national priorities, including unmet medical needs, public health crises, medication affordability, and domestic manufacturing.

Each FDA drug review division was tasked with nominating one product that aligns with the program's stated national priority goals. Sponsors may also apply directly to their respective review divisions for consideration. The FDA retains discretion to extend review timelines if regulatory concerns arise.

Key Updates

The first nine products selected for the CNPV program reflect a diverse set of therapeutic areas and strategic objectives. The selected products (manufacturers) include:

- **Pergoveris® (EMD Serono)**: an injectable infertility drug aimed at lowering in vitro fertilization costs
- **Teplizumab (Sanofi)**: a treatment for type 1 diabetes
- **Cytisinicline (Achieve Life Sciences)**: a smoking cessation aid targeting nicotine vaping addiction
- **DB-OTO (Regeneron)**: a gene therapy for inherited deafness
- **Cenegermin-bkbj (Dompé)**: a therapy for blindness
- **RMC-6236 (Revolution Medicines):** a targeted therapy for pancreatic cancer
- **Bitopertin (Disc Medicine)**: a treatment for erythropoietic porphyrias
- **Ketamine**: prioritized for domestic manufacturing of the anesthetic
- **Augmentin XR**: prioritized for domestic manufacturing of a widely used antibiotic

FDA Commissioner Marty Makary emphasized the agency's commitment to modernizing the review process and delivering meaningful treatments that address pressing public health needs. The program is expected to reduce regulatory risk for sponsors and accelerate patient access to innovative therapies.

COEUS Insights

The launch of the CNPV program and its first round of awards marks a significant turning point in the FDA's evolving regulatory strategy. As outlined in the July issue brief, the agency is actively reengineering its review infrastructure to better align with national priorities, emphasizing speed, flexibility, and impact with the intent to use regulatory innovation as a lever to address systemic challenges in public health, affordability, and supply chain resilience. As additional awards are made, manufacturers should view the CNPV program not as a one-time pilot, but as a blueprint for future FDA initiatives.

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