Huntington's Disease Society of America

June 16, 2026

Re: National Priority Voucher Pilot Program
Docket No. FDA-2026-N-2366

Kyle Diamantas
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Mr. Diamantas,

The Huntington's Disease Society of America (HDSA) appreciates the opportunity to provide comments regarding the National Priority Voucher Pilot Program.

HDSA is a leading national organization dedicated to the care and cure of Huntington's disease (HD), a rare and fatal hereditary disorder that manifests as a neurological disease with both physical and psychiatric components. If one parent has HD, their children have a 50 percent chance of inheriting HD. Our focus is to promote and support research to find a cure for HD; help people and families affected by the disease; and educate the public and healthcare professionals about HD.

Currently, there is no clinically available pharmacological, biological, or surgical agent or method which slows or stops the progression of HD. HDSA supports continued research to better understand HD, as well as improve access to quality treatment by financially supporting 60 HDSA Centers of Excellence and 9 Clinical Partner Sites covering 37 states plus the District of Columbia. HDSA has a long history of supporting people living with HD and family members through a network of 47 Chapters and Affiliates that provide access to locally-based social workers and support group meetings.

HDSA supports FDA efforts to explore mechanisms that accelerate the review of therapies addressing serious unmet medical needs. The underlying objective of the National Priority Voucher Pilot Program—to bring potentially transformative treatments to patients more quickly—is particularly important for Huntington's disease and rare disease communities facing devastating and relentlessly progressive conditions.

At the same time, accelerated review pathways must be accompanied by clear, transparent, and consistently applied eligibility criteria. Patients, sponsors, and investors need confidence

Huntington's Disease Society of America

that participation decisions are based on objective public-health considerations and scientific merit rather than discretionary or opaque processes. Transparency strengthens trust in both the program and the agency while providing sponsors with greater predictability when making critical development and investment decisions.

As FDA considers the future of the program, HDSA encourages the agency to establish formal guidance that clearly defines eligibility standards, decision-making processes, review timelines, and opportunities for stakeholder engagement. In addition, we recommend that FDA incorporate disease-specific expertise into the evaluation of applications involving Huntington's disease and other rare and complex disorders. Consultation with clinicians, researchers, and patient communities can provide valuable context regarding disease burden, unmet need, and the practical implications of review timelines for affected populations.

HDSA also encourages FDA to ensure that any continuation or expansion of the National Priority Voucher Pilot Program is accompanied by dedicated resources and staffing sufficient to support the additional workload created by expedited reviews. While innovative review pathways may offer important benefits for patients with serious unmet medical needs, they should not come at the expense of existing review programs or divert limited agency resources from other applications and review teams that are already operating under significant capacity constraints. Sustaining both the quality and timeliness of FDA reviews will require clear resource planning, appropriate staffing, and transparent accountability measures to ensure that accelerated pathways enhance, rather than undermine, the agency's broader mission.

For individuals and families living with Huntington's disease, regulatory innovation is not simply about efficiency—it is about ensuring that urgently needed therapies are evaluated as quickly as possible while maintaining the scientific rigor and public trust that are essential to FDA's mission. HDSA stands ready to work with FDA to advance policies that achieve both goals.

Thank you for the opportunity to provide these comments and for your ongoing partnership with the rare disease community.

Sincerely,

Amy Gray
President and Chief Executive Officer
Huntington's Disease Society of America