diaTribe

June 29, 2026

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: The diaTribe Foundation Comments to Docket No. FDA-2026-N-2366: Commissioner's National Priority Voucher (CNPV) Pilot Program; Public Hearing; Request for Comments

To Whom It May Concern:

The diaTribe Foundation (diaTribe) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA or the Agency) on the Commissioner's National Priority Voucher (CNPV) Pilot Program (Pilot Program). diaTribe supports the stated goal of the Pilot Program to expedite approval of select products, including those that represent innovative breakthrough therapies. Accelerating the review of applications for products that address unmet public health needs, if conducted in a transparent manner and without any diminishment of the rigor of review, may offer individuals with diabetes and other serious and life-threatening conditions expedited access to safe and effective medicines. However, we recommend the modification or addition of elements to the Pilot Program to improve program integrity, mitigate unintended negative effects on applications under review outside the Pilot Program, and increase transparency and accountability. We thank you in advance for your consideration of our views and stand ready to partner with you and the Agency to ensure people with diabetes continue to benefit from innovations in care and treatments.

The diaTribe Foundation and the Need for Improved Diabetes Therapies

diaTribe's mission is to help people with diabetes and to advocate for action. diaTribe is dedicated to bringing people with diabetes to the conversation on regulatory issues, connecting the field and the diabetes community, and changing the narrative around diabetes.

An estimated 12% of the U.S. population has diabetes, a staggering 40.1 million people.[1] Over the past decade, FDA approvals of safe and effective drugs and devices have transformed diabetes care, management, and outcomes. People with diabetes now have access to therapies and devices that not only improve glucose levels, but also support weight management, reduce hypoglycemia, and prevent some of the costly and often lethal complications associated with diabetes, including cardiovascular and renal disease. Furthermore, advances in the accuracy and ease of use of continuous glucose monitoring (CGM) technology have improved acceptability among clinicians and people with diabetes who are increasingly reliant on CGM metrics like time in range (TIR) for daily diabetes management. A growing body of evidence shows that TIR has added value in clinical, research, and regulatory settings beyond the currently accepted "gold standard" of hemoglobin A1c (A1c).[2–5] However, despite treatment advances to date, people with diabetes still need improved tools to tackle the daily hurdles and burdens of managing this complex chronic condition.

Improving Pilot Program Integrity

Currently, we understand that a central element of the Pilot Program is the use of a CNPV Review Council (Council). According to FDA's Staff Manual Guide for the Pilot Program SMG 2010.23 - CNPR Program Review Council Charter, the Council, which is comprised of various FDA senior leadership and is chaired by the Commissioner, meets in a "tumor board style" format, in which the primary review team presents the application and offers its recommendation to the Council, which, in turn, votes on a recommendation to send forward to the Center Director, who makes the final approval decision.

According to the Staff Manual Guide, the Council, "shall review relevant materials provided by the primary review team or delegated official in advance of all meetings and engage in thorough discussion of the application and findings presented by the review team. Council members shall review briefing materials—as applicable examining the scientific merit, regulatory appropriateness, and potential public health implications of the application. Council discussion should allow for comprehensive evaluation of complex technical issues and consideration of multiple perspectives. Members will actively participate in deliberations, and members with relevant expertise shall contribute specialized knowledge to address specific aspects of the application."

It is unclear how the use of the Council furthers the Pilot Program's goal of expediting the review and approval of products that address certain national health priorities. It is not evident what value, if any, this new process offers over the long-standing process of the review team providing an action package with a recommendation to the Office or Division Director, who serves as the final decisionmaker on approval. It is also unclear how the factors noted above that the Council is instructed to consider, vary, if at all, from current drug approval standards. At minimum, the insertion of the Council into the approval process for CNPV products creates the perception of undue political influence and pressure on subordinate FDA staff to conform their decision to that of FDA leadership and raises questions about the potential for deviations from existing regulatory standards.

Preserving a predictable, transparent, and consistent decision-making process that is evidence-based and free from either the perception or reality of political influence is essential to maintaining public trust in FDA's drug approval decisions. It has been a long-established practice for approval decision authority to reside with career scientific reviewers, who have extensive experience in resolving difficult scientific questions and in upholding existing regulatory standards, with Agency leadership involvement only in very limited circumstances. Deviating from that practice risks the loss of the public's confidence in FDA's decisions, innovators' interest in investing in the development of new therapies, and payors' willingness to cover new therapies. Thus, we recommend the Council be eliminated as a program element and that review decision-making follow the established process in place for all other drug approvals, with the addition of specific staffing and resources to fulfill the condensed CNPV review timeline.

Preserving Timely Review for Non-CNPV Applications

To best serve patients, FDA's drug review process requires adequate numbers of both reviewers and review support staff. Recent personnel reductions have diminished the Agency's workforce capacity. While the Agency has indicated that it plans to hire additional staff, the loss of experienced staff, continued staff departures, and the time required to fully train new hires means that for the foreseeable future, the Agency's review functions will be under strain. The introduction of the Pilot Program with its ambitious timelines, and without associated additional funding, has the potential to exacerbate existing workforce stress, particularly as the number of products under the Pilot Program expands.

As noted, diaTribe supports accelerated review for innovative products that address unmet health needs. We recognize, however, that review staff time is finite. The pressures to meet the timeframes of Pilot Program reviews could result in slowed or halted development and review of products that are not included in the Pilot Program, but that may still offer meaningful advances for people with diabetes, particularly for review divisions with multiple CNPV products under review.

We recommend that prior to any additional expansion of the Pilot Program, FDA should conduct and make public a study of the additional workload the new initiative creates for review divisions, with an estimate of staffing required to meet the CNPV timelines. We feel strongly that the Pilot Program should not be expanded until sufficient staff are in place in a review division to accommodate a CNPV product review. For current CNPV products, FDA should make public by review division on a quarterly basis the number of CNPV products under review, review timeframes for those products, and review timeframes for non-CNPV products within that division, as well as hirings, staff losses, and staff recusals by review division.

Ensuring Transparency, Accountability, and Inclusion of the Patient Voice

We believe greater transparency about both the selection criteria and the approval process under the Pilot Program would instill greater public confidence in the Pilot Program's outcomes. FDA should consider publishing defined selection criteria in a draft guidance document, with the opportunity for public comment before the guidance is finalized. FDA should also consider making public at the time the award is made the justification for the selection of each product awarded a CNPV and the FDA officials involved in the selection process. Similarly, at the time of approval of a product under the Pilot Program, information should be made public about the deliberations of the Council, if that program element is maintained, or if not, disclosing the involvement of FDA leadership in the review decision.

We would also urge FDA to consider how to solicit the patient voice in both the selection of products for the Pilot Program and in decision-making on CNPV approvals. Public meetings conducted on annual or semi-annual basis with time allotted for patient comments could provide input to FDA on the selection of products that represent the highest priorities for patients. Similarly, to solicit the patient voice on the approval of CNPV products, the Agency could hold Advisory Committees, which allow for patient comment during the open public hearing portion.

Conclusion

Thank you again for the opportunity to submit comments on the Pilot Program. The expertise of career FDA reviewers and the grounding of decision-making in science, rather than politics, is what has made FDA the gold standard for drug approvals globally. We support expediting the development and approval of truly innovative therapies; our concerns lie with the decision-making processes currently in place for the Pilot Program and the added strain on FDA staff already operating under difficult conditions. We appreciate your consideration of our recommendations and welcome the opportunity to work with you and Agency staff on this and other efforts to accelerate the delivery of innovative therapies to individuals with diabetes.

Respectfully,

Jim Carroll
CEO, The diaTribe Foundation

Julie K. Heverly
Vice President, Time in Range Coalition and Patient Advocacy, The diaTribe Foundation

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