



NATIONAL HEALTH COUNCIL

September 19, 2022

The Honorable Chuck Schumer
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Senators Schumer and McConnell, Speaker Pelosi, and Representative McCarthy:

On behalf of the National Health Council (NHC), I am writing to urge you to move swiftly to complete work on reauthorizing the Food and Drug Administration's (FDA's) user fee agreements for fiscal years 2023-2027. Barring action, these important programs will expire September 30, causing disruption to FDA's important role of helping deliver safe and effective medical products to people with chronic diseases and disabilities. We also urge inclusion of additional policies of importance to the patient community.

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, sustainable health care. Made up of more than 145 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

The NHC supports the promise that the negotiated agreements hold for assuring patients have access to new treatments in a timely manner and that the FDA has the resources they need to achieve the common goal of safe, effective treatments for patients. We particularly support the inclusion of several parts of the agreement that will help engage patients. Specifically, we are glad to see the following in the Prescription Drug User Fee Act (PDUFA VII) negotiated agreement:

- Enhancing the incorporation of the patient's voice in drug development and decision-making;
- Enhancing use of digital health technologies to support drug development and review;
- Advancing real-world evidence for use in regulatory decision making; and
- Enhancing FDA's capacity to support development, review, and approval of cell and gene therapy products.

Additional Policies for Inclusion

The NHC fully supports inclusion of several policies that are related to, but not included, in the negotiated agreements. It is important that we use the opportunity to enact policies that will advance the work of FDA. These include policies to improve the diversity of clinical trials and to improve the accelerated approval process.

The House legislation includes provisions to increase clinical trial diversity, requiring sponsors to develop diversity plans that would include goals for enrollment, rationale for the goals, and how they plan to meet the goals. The bill also instructs FDA to issue a report within two years on progress on submitting and meeting diversity plan goals as well as a recommendation on whether FDA needs authority to mandate post approval studies or post market surveillance due to insufficient demographic subgroup data. Finally, it includes several provisions for public meetings and guidance from FDA to seek input into increasing diversity in clinical trials. This clinical trial diversity initiative is in line with recommendations from the NHC report "[Access, Affordability and Quality: A Patient-Focused Blueprint for Real Health Equity.](#)"

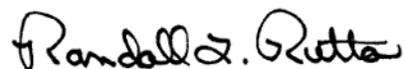
Additionally, both the House bill and the Senate bill passed out of Committee emphasize the FDA's role in assuring transparency and review of drugs approved through an accelerated process. We urge you to include such provisions that will give greater confidence in the accelerated approval pathway.

We urge you to include these two priorities in the final legislation.

Conclusion

The NHC supports reauthorization of the FDA user fee programs and strongly urges Congress to do so as soon as possible. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,



Randall L. Rutta
Chief Executive Officer