Coalition for Clinical Trials Awareness

April 28, 2017

The Honorable Lamar Alexander
Chairman
Senate Health, Education, Labor, and Pensions Committee
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Senate Health, Education, Labor, and Pensions Committee
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Greg Walden
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

RE: Discussion Draft of FDA User Fees Reauthorization

Dear Chairman Alexander, Ranking Member Murray, Chairman Walden, and Ranking Member Pallone:

On behalf of the Coalition for Clinical Trials Awareness, thank you for your bipartisan commitment to reauthorizing the user fee amendments to the FDA Reauthorization Act of 2017. This critical legislation ensures the appropriate review of medical applications by FDA, protecting patient safety and speeding the development of cures.

One important component of this review process is the presentation of robust clinical trial data. Building on the success of the 21st Century Cures Act, we urge you to include in the Prescription Drug User Fee Act reauthorization process a related effort to address a pressing public health challenge: lack of public awareness of the benefits of clinical trials leading to underenrollment.

Since 2013, the 40 patient, professional, and research organizations that comprise CCTA have worked to bring attention to the concerning facts about clinical trials awareness in the United States. For instance, **37% of clinical trial sites do not meet their enrollment goals**. According to the Tufts Center for the Study of Drug Development, **11% of trials fail to enroll even a single patient**.

Low participation can delay drug development and increase discovery costs, hindering patient access

to life-saving treatments. Further, low enrollment of women and minorities in clinical trials makes it difficult to determine the efficacy of a medicine, and can lead to a lack of information about demographic-specific aspects of disease, outcomes, and responses to a therapy.

By working together to raise public awareness, we can improve enrollment and encourage efficient, cost-effective development of vital treatments. Toward that goal, please consider working with your colleagues to implement the following legislative measures as you consider the Prescription Drug User Fee Act reauthorization during this congressional session:

First, form an interagency task force on clinical trials awareness. The Secretary of Health and Human Services would convene a task force with representatives from the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Department of Health and Human Services, as well as patient group representatives, health care professionals, and representatives from the pharmaceutical industry.

Second, **create a roadmap** based on the task force's findings. The roadmap would describe:

- How the government, patient groups, and industry can engage in a public-private partnership to advance clinical trials awareness.
- What additional training is needed for health care professionals so that they would more appropriately inform patients about clinical trials.
- How digital technology and social media platforms can promote clinical trials awareness and participation.

Third, implement an information campaign based upon the roadmap. The Offices of the Assistant Secretary for Health and Assistant Secretary for Public Affairs would conduct an educational campaign to raise awareness of the need for and benefits of clinical trials for both patients and society at large. Demographic groups with historically low levels of clinical trials participation, including women and minorities, would be targeted by the campaign; therefore, the Offices of Women's and Minority Health would play important leadership roles in implementing this initiative. This information campaign would advance the message of clinical trials enrollment through television advertisements, social media, and outreach events for the patient and health care professional communities.

CCTA envisions what such a campaign might look like. We invite you to explore these materials at http://cctawareness.org/CTAW-2016/.

In past years, federally directed task forces, strategic plans, and information campaigns have successfully addressed important public health challenges, including drug shortages, a regulatory

framework for health information technology, and the accessibility of prescription drug container information for Americans with disabilities. CCTA urges members of Congress to use the precedent set by these efforts to launch a similarly structured and equally successful initiative to improve clinical trials awareness and enrollment.

Thank you again for your prioritization of the FDA User Fee Reauthorizations. If we may be of assistance in this matter, please contact us at info@cctawareness.org or 888-507-5675.

Sincerely,

Alliance for Headache Disorders Advocacy

Alliance for Patient Access

Aimed Alliance

Arthritis Foundation

Association of Clinical Research Organizations

Association of Pediatric Hematology/Oncology Nurses

Cholangiocarcinoma Foundation

Conference Forum

Fabry Support & Information Group

FCBVIO

Gerontological Society of America

Global Colon Cancer Association

Lupus and Allied Diseases Association, Inc.

Michael J. Fox Foundation for Parkinson's Research

Pancreatic Cancer Action Network

Susan G. Komen

WomenHeart: The National Coalition for Women with Heart Disease