Latinos Against Alzheimer's Coalition

Convened by the UsAgainstAlzheimer's Network

July 28, 2017

The Honorable Lamar Alexander Chairman 455 Dirksen Senate Office Building United States Senate Washington, D.C. 20510

The Honorable Patty Murray Ranking Minority 145 Russell Senate Office Building United States Senate Washington, D.C. 20510

Dear Senators Alexander and Murray,

On behalf of the diverse patients and communities we represent, we urge you to approve the Food and Drug Administration Reauthorization Act (FDARA) before August recess to ensure the FDA has the resources necessary to approve needed medications and preserve patient access to innovative treatments.

The user fee agreements that FDARA would reauthorize are critical to patient health since they provide resources for the FDA to review and approve medications that patients need. Further, they increase the agency's ability to gather meaningful patient and caregiver input for decision making – a vital innovation that advances patient-centered treatment and care. Since originally authorized in 1992, the agreements have facilitated the approval of more than 1,500 new treatments and medications.

For the more than 5 million individuals touched by Alzheimer's, ensuring the efficient approval of new medications can be a matter of life and death. In fact, a recent analysis¹ by ResearchersAgainstAlzheimer's – a network of UsAgainstAlzheimer's – found that there are 27 Alzheimer's drugs in Phase III clinical trials and eight drugs in Phase II clinical trials that may launch in the next five years. Failing to reauthorize these agreements could slow the

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Our Coalition Members Include

Alzheimer's Greater Los Angeles Dialogue on Diversity El Centro, Inc. Fuerza Contra Alzheimer's Guadalupe Centers Labor Council of Latin American Advancement MAAC Project MANA - A National Latina Organization Mattie Rhodes Center Multicultural Coalition on Aging National Latino Behavioral Health Association (NLBHA) The Hispanic Federation The Latino Alzheimer's & Memories Disorders Alliance (LAMDA) The Latino Coalition The League of United Latin American Citizens (LULAC) The National Association of Hispanic Nurses (NAHN) The National Hispanic Council on Aging (NHCOA) The National Latino Medical Student Association (LMSA) The USC Edward R. Roybal Institute on Aging

www.LatinosAgainstAlzheimers.org

¹ ReseachersAgainstAlzheimer's, http://bit.ly/2tuFgUF

approval of promising treatments and cures for Alzheimer's and other diseases that disproportionately impact communities of color like heart disease, diabetes, and others.

Disruptions to the review and approval of new medications are especially important to the minority populations that we represent. These populations already face disproportionate obstacles to care and treatment. Health experts and researchers have acknowledged the unique needs of communities of color and are working to address them through improved access to care and the development of new and tailored treatments. However, interruptions in the review and approval of medications could stifle the innovation aimed at addressing the needs of these specific communities.

As you know, the Prescription Drug User Fee Act (PDUFA) and the Biosimilar User Fee Act (BsUFA) will expire at the end of September. According to reports by Politico, this package accounts for nearly half of the FDA's budget for regulating medical products. This will create a significant shortfall of resources that must be immediately addressed through cutbacks and closures.

We are grateful to the Senate for its leadership and continued bipartisan support of funding for the National Institutes of Health (NIH) and FDA. Legislators now have another opportunity demonstrate their commitment to patients by approving FDARA. To prevent any disruptions to the approval and availability of medications that can change the lives of our patients, we urge you to reauthorize the user fee agreements as they stand before August recess.

Sincerely,

Asian & Pacific Islander American Health Forum

Lisette P. Carbajal, Community Integration Coordinator at Virginia Department for Aging and Rehabilitative Services (DARS)*

Dialogue on Diversity

Fuerza Contra Alzheimer's

Guadalupe Centers

Hispanic Health Network

Labor Council For Latin American Advancement, LCLAA

The LatinosAgainstAlzheimer's Network

League of United Latin American Citizens

Ambassador Carmen Lomellin*

National Council of Asian Pacific Islander Physicians

National Hispanic Council on Aging (NHCOA)

National Hispanic Medical Association

The National Puerto Rican Chamber of Commerce

Carmen Pastor, Alzheimer's Caregiver*

CiCi Rojas, President, Tico Productions*

Mary Theresa Vasquez, RN, Alzheimer's Caregiver *

* Affiliations of individual researchers are for identification purposes only and do not necessarily represent the endorsement of affiliated institutions.