

September 15, 2022

OFFICERS Susan Dentzer, Chair The Hon. Michael N. Castle, Chair Emeritus The Hon. Bart Gordon, Vice Chair Mary Woolley, President E. Albert Reece, MD, PhD, MBA, Secretary Amy Comstock Rick, JD, Treasurer

BOARD MEMBERS Tenley E. Albright, MD Georges C. Benjamin, MD Nancy Brown The Hon. Charlie Dent Mikael Dolsten, MD, PhD Victor J. Dzau, MD Kafui Dzirasa, MD, PhD Arthur C. Evans Jr., PhD Dario Gil, PhD William N. Hait, MD, PhD Mary J.C. Hendrix, PhD The Hon. Rush D. Holt, PhD James L. Madara, MD Mark McClellan, MD, PhD Michelle McMurry-Heath, MD, PhD Jessica L. Mega, MD, MPH Herbert Pardes, MD Sudip S. Parikh, PhD Harold L. Paz, MD, MS Guillermo Prado, PhD Derek Rapp Laing Rogers Lewis G. Sandy, MD, FACP The Hon. Donna Shalala Larry J. Shapiro, MD Deborah Trautman, PhD, RN, FAAN M. Roy Wilson, MD Cynthia Zagieboylo

241 18th Street South Suite 501 Arlington, VA 22202 P 703.739.2577 F 703.739.2372 E info@researchamerica.org The Honorable Joseph Biden The White House 1600 Pennsylvania Avenue, NW Washington, DC

The Honorable Nancy Pelosi Speaker of the House United States Capitol Washington, DC 20515 The Honorable Charles Schumer Senate Senate Majority Leader 322 Hart Senate Office Building Washington, DC 20510

The Honorable Mitch McConnell Senate Minority Leader 317 Russell Senate Office Building Washington, DC 20510

The Honorable Kevin McCarthy House House Minority Leader 2468 Rayburn House Office Building Washington, DC 20515

Dear President Biden, Speaker Pelosi, Senate Majority Leader Schumer, Leader McConnell, and Leader McCarthy:

On behalf of Research!America, thank you for your extraordinary leadership and for your respective roles in accelerating the pace of medical progress and access to its benefits. In that context, we urge you to reauthorize the Food and Drug Administration user fee programs before September 30, 2022.

Your individual and collaborative efforts have contributed to unprecedented strides in the treatment and cure of deadly and debilitating health threats. By ensuring timely passage of FDA user fee legislation in past Congresses, you have also played a profoundly important role in equipping the Food and Drug Administration (FDA) to modernize and increase the time- and cost-efficiency of regulatory decision-making.

In that context, we urge you to act swiftly to reauthorize FDA User Fee programs before they expire on September 30, 2022. Failure to reauthorize these programs by that date will compromise FDA's ability to sustain hard-won advances in regulatory rigor and efficiency that increase the societal returns of science. These societal returns compound over time. With each day that passes, more individuals lose hope, quality of life, or their very lives to health threats for which potential solutions have been developed. The faster we isolate and enable access to safe and effective medical advances, the greater the total number of people who benefit in profoundly important ways. The user fee programs will expire in a matter of weeks absent congressional and presidential action. Please do not allow that possibility to turn into a reality.

Thank you again, President Biden, Speaker Pelosi, Leader Schumer, Leader McConnell, and Leader McCarthy, for your service to our nation, and please extend our thanks to your respective teams for their hard work and commitment.

Respectfully,

Maryloolley

Mary Woolley President and CEO