September 3, 2019

The Honorable Donald J. Trump President The White House 1600 Pennsylvania Avenue, N.W. Washington, D.C. 20500

The Honorable Alex M. Azar II Secretary U.S. Department of Health & Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Mr. President and Secretary Azar;

The undersigned former Commissioners of the U.S. Food and Drug Administration (FDA), spanning both Republican and Democratic Administrations, write to respectfully ask that you urgently nominate a permanent commissioner to lead the FDA. With the agency regulating a quarter of the value of the product consumption of the U.S. economy, including life-saving therapies, and the nation's food supply, it is imperative that FDA have a permanent leader.

We appreciate the Administration's dedication to patients and science, as reflected in the appointment of Dr. Norman E. Sharpless to serve as acting Commissioner of the FDA. During his time in the acting Commissioner role, he has shown the ability to execute the critical and complex work of the agency. He has gained the respect of the agency staff and a broad spectrum of the public in support the FDA's mission. Dr. Sharpless is an outstanding candidate to be nominated and confirmed as the next Commissioner.

FDA is a unique federal agency with many multifaceted roles that are critical to the health of the public. The agency is in the midst of many important initiatives begun under former Commissioner Gottlieb, and Dr. Sharpless' expertise will enable new activities in such key areas as cancer treatment and prevention, and precision medicine. Having a Presidentially appointed and Senate confirmed Commissioner will not only provide more secure governance for the agency at a time when there is so much to do, but will also create needed momentum and support for the thousands of public servants who serve to protect and promote the health of the American public.

We thank you for your commitment to science, innovation, patients, and the mission of the FDA. We hope you will continue this commitment by swiftly nominating Dr. Sharpless to become the permanent FDA Commissioner.

Sincerely,

Robert M. Califf, M.D., MACC

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FDA Commissioner 2016-2017

Margaret Hamburg, M.D.

FDA Commissioner 2009-2015

Andrew C. von Eschenbach, M.D.

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FDA Commissioner 2006-2009 ! Melille

Mark McClellan, M.D., Ph.D FDA Commissioner, 2002-2004