May 17, 2017

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

The Honorable Frank Pallone
Ranking Member
House Committee on Energy and Commerce
237 Cannon House Office Building
Washington, D.C. 20515

The Honorable Michael Burgess, M.D.
Chairman
Subcommittee on Health
2336 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
2470 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Walden, Chairman Burgess, Ranking Member Pallone, and Ranking Member Green,

On behalf of our nation's venture capital investors and the entrepreneurs they support, thank you for calling a markup on the *Food and Drug Administration (FDA) Reauthorization Act of 2017*, an important piece of legislation that reauthorizes the FDA user fee agreements for new prescription drugs and medical devices. We welcome the opportunity to share our perspective of the investors and startups advancing medical innovation and the challenges they face.

Venture capital investors are critical in spurring significant growth in the medical field, working with startups, scientists, universities, and entrepreneurs to develop life changing therapies and cures. In 2016, $11.7 billion was invested into life science companies, accounting for 17% of the overall venture activity last year. Venture-backed life science companies have made strides in a variety of areas, ranging from biotechnology research and production, the development of new drugs, and manufacturing of new medical devices and equipment. Notable investments into life science companies include Human Longevity, a developer of genomics and cell therapy-based diagnostic and therapeutic technology; CVRx, a developer of implantable technology for treatment of high blood pressure and heart failure; and Deciphera, a developer of kinase-inhibiting drugs designed to treat cancer and immunological diseases.

Life science companies and investors have helped to cultivate some of our country's most groundbreaking medical products, but it is important to understand there are considerable challenges that come with the development of new drugs and medical devices. A stable regulatory environment is a critical component to driving future innovation, and the FDA user fee agreements with the biopharmaceutical and medical device industries are essential to that stability. The user fee programs

authorize the FDA to collect application fees from the industry, which provide the resources for a more efficient approval process within the agency and greater predictability for the broader medical ecosystem. NVCA is pleased to see the Committee consider legislation that would reauthorize the user fee programs, which are currently set to expire on September 30, 2017. Any delay or failure to act would result in disruption and loss of resources at the FDA and have harmful effects to future medical advancements and investment. The venture community supports the timely passage of the *FDA Reauthorization Act of 2017*, legislation that will provide the agency with the resources needed to encourage future investment and continue to enhance our nation's vibrant medical innovation ecosystem.

The entrepreneurial ecosystem thanks you for bringing this legislation under consideration. Your work to advance a timely reauthorization of the agreements ensures continued medical advancement and innovation. We stand ready to assist the Committee as you further examine this important matter.

Sincerely,

Bobby Franklin
President and CEO