



June 23, 2014

The Honorable Fred Upton
Chairman, Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Henry A. Waxman
Ranking Member, Energy & Commerce
Committee
United States House of Representatives
Washington, DC 20515

The Honorable Joe Pitts
Chairman, Health Subcommittee
Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member, Health Subcommittee
Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

Dear Chairman Upton, Ranking Member Waxman, Chairman Pitts, and Ranking Member Pallone,

Thank you for the Energy and Commerce Committee's bi-partisan call to action to ensure that the U.S. life sciences industry is best equipped to maintain its position as a global leader in medical innovation and develop medical cures and treatments that provide value to U.S. patients and our overall healthcare system.

The successful development of new medical innovations is dependent on policies that support the entire life sciences ecosystem, from the lab to the patient. NVCA and our members look forward to working with the Committee to help define the appropriate policies that drive the next generation of medical innovations forward in the U.S.

One issue that NVCA would like to bring to your attention is the importance of the Food and Drug Administration's (FDA) Special Protocol Assessment (SPA) process. Since its creation in the Food and Drug Administration Modernization Act of 1997, the SPA process has provided biomedical innovators with clarity and predictability in the FDA approval process. The process also provides the venture capital industry with an important degree of certainty as investors make critical investment decisions to advance drug development.

As you are aware, the House Appropriations Committee recently included language in the FY 2015 House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations bill highlighting the importance of the SPA process. NVCA supports

the provisions in the House Appropriations Committee report that directs FDA to treat drug sponsors fairly and abide by congressional standards for rescinding SPA agreements. We also welcome the Appropriations Committee's direction to require FDA to revise and re-issue its existing guidance concerning SPA agreements in order to clarify the agency's interpretation of the statutory standard governing the treatment of such agreements. We urge you as the leaders of the authorizing committee to oversee this process.

For NVCA members, biomedical investment involves significant risks both outside and within the regulatory process. The SPA program has long provided venture capital investors with a degree of transparency and predictability that has aided in mitigating the risks associated with new product development, thus helping to attract needed investment capital. In particular, some of the most innovative product development concepts with the greatest potential for improving patient care rely most heavily on the SPA program. Without confidence in this imperative regulatory risk mitigation program, the development of many new medicines will be stifled.

Again, thank you for your leadership and focus on the 21st Century Cure Call to Action. We look forward to working with you on this critical issue and urge your continued review of the FDA to ensure the Agency's compliance with existing SPA program standards.

Sincerely,

A handwritten signature in cursive script that reads "Bobby Franklin".

Bobby Franklin
President & CEO