



May 10, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
United States Senate
Washington, DC 20515

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
United States Senate
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman,

The National Venture Capital Association's Medical Innovation and Competitiveness (MedIC) Coalition applauds you and your colleagues on the House Energy and Commerce Committee for securing full Committee passage of the H.R. 5651, "the Food and Drug Administration Act of 2012" with strong bipartisan support. We believe the legislation approved today by the Committee represents a positive step forward and will help provide greater certainty in the Food and Drug Administration's (FDA) regulatory process and help to reinvigorate venture capital investment in innovative, life-saving medical products.

In particular, we are very pleased following provisions are included in H.R. 5651:

- expanding the accelerated approval process to new medical treatments;
- providing a new pathway for breakthrough therapies;
- providing incentives for antibiotic development;
- improving the FDA's advisory committee conflict of interest rules;
- clarifying the least burdensome standards for medical devices; and
- modifying the De Novo application process.

However, we would like to work with you to get language included in the final package that would establish a risk-benefit framework for the drug and medical device approval process and provide a consistent and balanced approach to FDA's decisionmaking of the benefit and risks of new drugs and medical devices.

As the legislation moves to the House floor, we look forward to working with you and your colleagues to ensure that these important improvements are retained and that the risk-benefit framework can be further strengthened.

Sincerely,

A handwritten signature in black ink that reads "Kelly Slone".

Kelly Slone
Vice President, Federal Life Sciences Policy

CC: Speaker John A. Boehner
Minority Leader Nancy Pelosi