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NVCA Members Testify at Congressional Hearing on Incentives to Advance Medical Research and Development

Venture capital investors offer solutions to reduce regulatory complexity and encourage investment into innovative medical companies

ARLINGTON, VA – At a hearing today before the House Energy and Commerce Subcommittee on Health, National Venture Capital Association (NVCA) members Mike Carusi, General Partner at Advanced Technology Ventures, and Alexis Borisy, Partner at Third Rock Ventures and NVCA Board Member, testified on the state of investment for medical technology and research and the role that regulatory and economic incentives can play to advance treatments and cures for patients.

During testimony, Carusi discussed the ways that regulatory challenges are impacting venture investment activity in the medical technology industry, resulting in the lowest level of initial funding for medical device technology in more than two decades.

“As you know, the path to FDA approval in the U.S. has become increasingly difficult and unpredictable,” said Carusi in his prepared remarks. “Regulatory delays increase the time and capital required to bring products to market. A recent NVCA survey found that 42 percent of health care investors decreased their investment in medical devices due to the longer time frames to regulatory approval.”

Carusi went on to describe the ways in which reimbursement challenges are also creating roadblocks for the development of new innovative medical technologies.

“Obtaining coverage and reimbursement for innovative products has become an increasingly difficult process that can add another three to five years to the development of a new product,” said Carusi. “As with FDA in the past, we are forced to navigate a path with government and private payors that lacks transparency, predictability, and consistency.”

In agreement with Carusi that regulatory barriers are impeding early-stage investment, Borisy offered some solutions to address the problem. Specifically, Borisy suggested that recent

reforms at the FDA to work with companies to develop more effective clinical development programs for rare diseases could serve as a model.

“The modern approach to regulation that exists now for cancer and rare diseases attracts investment for three reasons,” said Borisy in his prepared remarks. “First, the regulatory process is more interactive, flexible, and reflective of the disease and patient being treated. Second, the amount of investment required to fund a company through ‘proof of concept’ is better understood. And, third, the larger companies and public investors feel more confident about the development and approval process for these drugs.”

As Borisy pointed out, because of this flexibility to regulation, capital has flowed towards companies developing solutions to address rare diseases, with oncology remaining one of the hottest investment areas. Unfortunately, the same cannot be said for chronic diseases where the regulatory requirements are much greater. Without improving these processes, Borisy said early-stage investment will continue to struggle.

“We must ask ourselves how we can learn from rare diseases and oncology and work to improve how we treat conditions like obesity, diabetes, and Alzheimer’s – which have a dramatic impact on our long-term health care costs,” said Borisy. “We must advance to a system that critically determines whether information required is actually informative as to the potential success of the drug in the real world. Creating approval pathways that enable the development of drugs for subpopulations of patients could be a game-changer.”

A copy of Carusi’s testimony can be downloaded [here](#) and a copy of Borisy’s testimony can be downloaded [here](#).

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