



July 6, 2018

VIA ELECTRONIC FILING

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

Re: *Request for Information (RFI) Regarding Facilitation of Public-Private Dialogue to Increase Innovation and Investment in the Healthcare Sector*

Dear Secretary Azar:

On behalf of our nation’s venture capital investors and the entrepreneurs they support, thank you for requesting feedback on a public-private workgroup between the Department of Health and Human Services (HHS) leadership and stakeholders focused on innovating and investing in the healthcare industry.¹ We welcome the opportunity to share the perspective of investors and startups advancing medical innovation, and provide comments on why our industry can be a valuable partner to HHS as it develops this important initiative.

Introduction to venture capital and its economic contribution

The venture capital industry raises capital from a broad range of limited partners (LPs), such as endowments, foundations, pension plans, family offices, and fund-of-funds. That capital is then invested in great entrepreneurs with breakthrough ideas. Venture capitalists invest anywhere from the very early stage, where the startup has little more than an idea and a couple of people, to growth-stage startups, where there is some revenue coming in and the focus is on effectively scaling the business. Generally, a company leaves the venture ecosystem via an initial public offering (IPO), a merger or acquisition, or bankruptcy. There is often a misconception that venture capitalists are like other investment fund managers in that they find

¹ U.S. Department of Health and Human Services, *Facilitation of Public-Private Dialogue to Increase Innovation and Investment in the Healthcare Sector*, 83 FR 26485, (June 2018) (hereinafter “HHS Facilitation of Public-Private Dialogue”).

promising investments and write checks. But writing the check is simply the beginning of venture engagement; the hard work begins when a venture capitalist works closely with startups to help entrepreneurs turn their ideas into successful companies. The reality is that successful venture capitalists—whether in healthcare or other areas of the economy—do not just pick winners. They work actively with startups to help them throughout the company-building lifecycle over a long period of time.

Venture investors often support a portfolio company with multiple investment rounds generally spanning five to ten years, or longer as is frequently the case in healthcare. Venture capitalists commonly serve on the boards of portfolio companies, provide strategic advice, open contact lists, and generally do whatever needs to be done to help a company succeed. The hope of a venture capitalist is that all their startups succeed against huge risks and grow into successful companies, but the reality is that the majority fail.

Entrepreneurship is inherently a risky endeavor but it is absolutely essential to the American economy. Successful venture-backed companies have had an outsized positive impact on the U.S. economy. According to a 2015 study by Ilya Strebulaev of Stanford University and Will Gornall of the University of British Columbia, 42 percent of all U.S. company IPOs since 1974 were venture-backed.² Collectively, those venture-backed companies have invested \$115 billion in research and development (R&D), accounting for 85 percent of all R&D spending, and created \$4.3 trillion dollars in market capitalization, 63 percent of the total market capitalization of public companies formed since 1974.³ Specific to the impact on the American workforce, a 2010 study from the Kauffman Foundation found that young startups, most venture-backed, were responsible for *almost all* the 25 million net jobs created since 1977.⁴

It is quite clear that the American economy is dependent on the economic activity that comes from young firms scaling into successful companies. The rapid hiring, innovative product development, increasing sales and distribution needs, and the downstream effects all serve to push the U.S. economy forward. The American economy needs more of this activity to help deal with many of the challenges we see today. Historically, the United States has done an excellent job encouraging risk-taking and entrepreneurship, but it is imperative that policymakers, entrepreneurs, and venture capitalists work together to encourage entrepreneurship in our country.

Significance of venture capital in the healthcare startup ecosystem

Venture capital investors are critical in spurring significant growth in healthcare, working shoulder-to-shoulder with startups, scientists, universities, and entrepreneurs to develop life changing therapies and cures. The historical contribution of venture capital to medical

² “The Economic Impact of Venture Capital: Evidence from Public Companies,” Stanford University Graduate School of Business Research Paper No. 15-55, *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2681841.

³ *Id.*

⁴ “The Importance of Startups in Job Creation and Job Destruction,” Kauffmann Foundation Research Series: Firm Foundation and Economic Growth, (July 2010), *available at* http://www.kauffman.org/~media/kauffman_org/research%20reports%20and%20covers/2010/07/firm_formation_importance_of_startups.pdf.

advancement is immense, having backed impactful companies like Amgen, Genentech, Stryker, and many more. In 2017, 1,071 life science companies nationwide attracted \$18 billion in venture investment.⁵ This includes \$12.93 billion in pharmaceutical and biotechnology companies and \$4.85 billion in healthcare device and supply companies.⁶ Life science investment overall has steadily increased in recent years, accounting for 21% of overall venture capital dollars invested last year and 14% of overall venture deals completed.⁷ 2017 also experienced a notable uptick in the biotechnology, diagnostic equipment, and drug discovery sectors, contributing to a 12-year high in terms of venture capital investment.⁸ In fact, two life science companies – cancer screening company Grail and drug therapy company Intarcia Therapeutics—ranked in the six largest venture capital investments of the year.

Goals for establishment of innovation workgroup

In convening a workgroup to facilitate dialogue on innovation and investing in the healthcare industry, it is imperative HHS bring together voices from across the innovation ecosystem. We appreciate HHS’s recognition in its RFI that among those participants ought to be “healthcare-focused venture capital firms.”⁹ Venture capitalists with a healthcare focus can play a unique and indispensable role in the workgroup. For example, venture investors can provide HHS with insight into key scientific and technological trends occurring in the marketplace; what factors help inform a decision to invest in a healthcare startup; and how government policy can help or hinder investment in promising, young technologies.

We also commend your inclusion of “healthcare innovation-focused companies [and] healthcare startup incubators and accelerators” in the workgroup and agree it is important the workgroup is “diverse across the subsectors of the healthcare industry and the investment and innovation lifecycles...”¹⁰ Representation from the discovery, development, and delivery stages of a life science company is crucial to understanding the complexity of the medical technology innovation ecosystem. Each of these ecosystem participants plays a critical role in healthcare advancement. In addition, we believe inclusion of serial healthcare entrepreneurs is vital to understanding innovation in the marketplace.

As HHS pursues this initiative, we also encourage the agency to convene and solicit feedback from startup communities throughout the United States. We believe it would benefit HHS to engage in dialogue sessions in healthcare innovation hubs to understand where common challenges exist that can be addressed, but also where discrete issues reside that are holding innovation back. In choosing where to engage, it is important to understand the venture and healthcare startup industry is bringing economic benefits to cities and regions beyond the traditional venture capital hubs. To provide illustrative examples:

⁵ Pitchbook – NVCA data.

⁶ Id.

⁷ Id.

⁸ Id.

⁹ HHS Facilitation of Public-Private Dialogue.

¹⁰ Id. An example of an incubator in the medical device space that would provide valuable perspective to the workgroup is Exploramed, which is a “venture-backed medical device incubator dedicated to the identification, creation, and development of novel solutions to meet the unmet health needs of patients around the world.” See <https://www.exploramed.com/>.

- The Minneapolis-St. Paul, MN MSA attracted \$1.18 billion in venture investment in 142 companies from 2013-2017, with therapeutic devices garnering the most venture dollars;
- The Durham, NC MSA attracted \$1.119 billion in venture investment in 96 companies from 2013-2017, with biotechnology garnering the most venture dollars;
- The Cleveland, OH MSA attracted \$501 million in venture investment in 58 companies from 2013-2017, with drug discovery garnering the most venture dollars;
- The Pittsburgh, PA MSA attracted \$343 million in venture investment in 60 companies from 2013-2017, with therapeutic devices garnering the most venture dollars;
- The Ann Arbor, MI MSA attracted \$287 million in 34 companies from 2013-2017, with biotechnology garnering the most venture dollars;
- The Raleigh-Cary, NC MSA attracted \$267 million in venture investment in 28 companies from 2013-2017, with therapeutic devices garnering the most venture dollars; and
- The Indianapolis-Carmel, IN MSA attracted \$73 million in venture investment in 31 companies from 2013-2017, with biotechnology garnering the most venture dollars.

We believe including ecosystems like these in the workgroup and/or its outreach will help HHS understand how they have achieved success to date; what needs they perceive in the future; and how emerging startup ecosystems in the healthcare space can be spread to other pockets of the United States in need of economic development.

Policy issues for the workgroup to address

HHS seeks comment on “[s]pecific areas of inquiry or focus for the workgroup.”¹¹ Three possible areas for examination by the workgroup include:

- How reimbursement policy can be reformed to provide for provision coverage for innovative technologies following Food and Drug Administration approval while the manufacturer collects additional data on the technology;¹²
- How drug pricing reforms can be enacted in a way that does not provide disincentives for venture capital investment in new drug discovery and innovation;¹³ and

¹¹ HHS Facilitation of Public-Private Dialogue.

¹² The *Expedited Coverage of Innovative Technology* (ExCITe) proposal was withdrawn on January 10, 2018, though the venture industry remains committed to furthering this policy with the administration. See <https://reginfo.gov/public/Forward?SearchTarget=RegReview&textfield=ExCITe>.

¹³ NVCA intends to provide comments in the separate proceeding on *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, RIN 0991-ZA49.

- How FDA clinical trials can be improved to facilitate greater innovation in healthcare.

The entrepreneurial ecosystem thanks you for recognizing the need to address the complex challenges facing the healthcare industry today. Establishing an open dialogue and increased engagement among all participants of the healthcare ecosystem will help ensure access to innovative new treatments and cures, and help to strengthen U.S. leadership in medical innovation.

Sincerely,

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

Bobby Franklin
President & CEO