July 16, 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: *Policy Statement; Request for information on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*

Dear Secretary Azar:

On behalf of our nation's venture capital investors and the entrepreneurs they support, we greatly appreciate the opportunity to provide comments on administration efforts to reduce drug prices while promoting innovation and U.S. leadership.[1] As investors in early-stage healthcare startups, venture capitalists have a unique and valuable perspective on this topic. We share the concern of the administration that bad actors in the healthcare system must be dealt with appropriately. In working toward that goal, the venture capital industry encourages the administration to be cognizant of how reforms impact early-stage investment in new medicine discovery and, in particular, the message changes send to long-term investors in new medicine. The risk capital provided by the venture industry is not replaceable by other types of investors or the government, and decreases in capital deployed in medicine development will have a significant and lasting impact on the health of all Americans.

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,

[1] Department of Health and Human Services, "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," RIN 0991-ZA49.

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 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.

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[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.

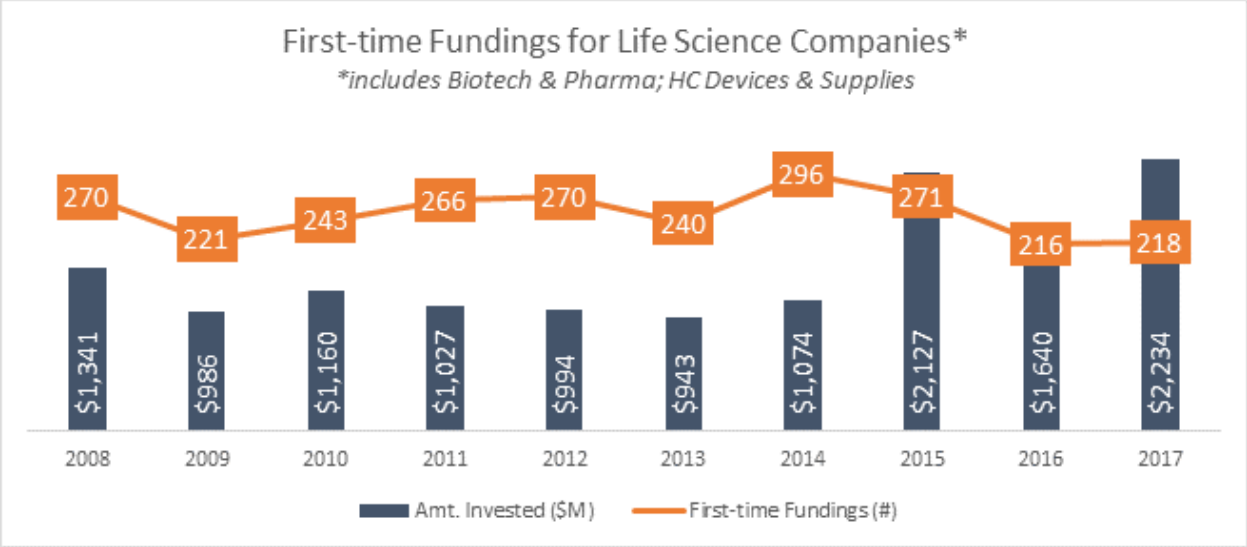
[4] "The Importance of Startups in Job Creation and Job Destruction," Kauffmann Foundation Research Series: Firm Foundation and Economic Growth, (July 2010), *available at* http://www.kauffman.org/~/media/kauffman_org/research%20reports%20and%20covers/2010/07/firm_formation_importance_of_startups.pdf.

Significance of venture capital in the healthcare startup ecosystem

Venture capital investors are critical in healthcare innovation, 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 advancement is immense, having backed impactful companies like Amgen, Genentech, Stryker, and many more.

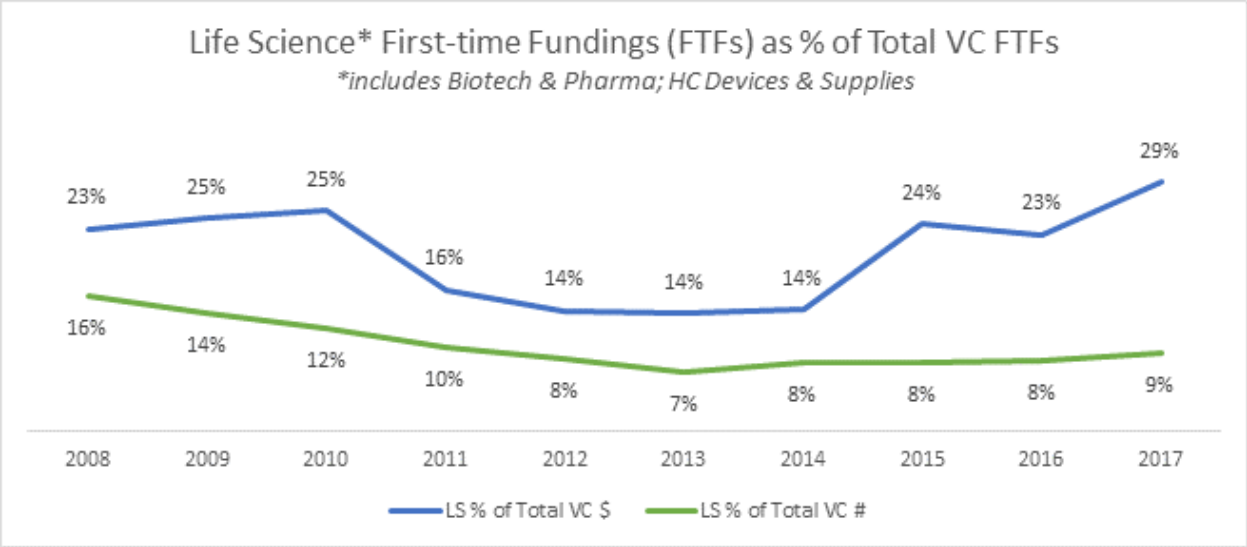
In 2017, 1,071 life science companies nationwide attracted $18 billion in venture investment.[5] This includes $12.93 billion in pharmaceutical and biotechnology companies and $4.85 billion in healthcare device and supply companies.[6] Life science investment overall has steadily increased in recent 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.

Venture capital is partnering with entrepreneurs in solving our nation's most pressing healthcare challenges. For example, the "number of oncology exits is double that of any other indication over the last five years," with venture investment of $3.41 billion in 2016-2017. Other notable areas of significant venture investment over 2016-2017 include: orphan/rare disease ($734 million); neuro ($664 million); anti-infective ($649 million); and auto-immune ($541 million).[9]



Source: Pitchbook-NVCA data

[5] Pitchbook – NVCA data.
[6] Id.
[7] Id.
[8] Id.
[9] "Trends in Healthcare Investments and Exits 2018: Investments and Fundraising Reach All-Time Highs, Focus Grows on Early-Stage M&A," Silicon Valley Bank (Annual Report 2018), *available at* https://www.svb.com/uploadedFiles/Content/Trends_and_Insights/Reports/Healthcare_Investments_and_Exits_Report/healthcare-report-2018.pdf.



Source: Pitchbook-NVCA data

Drug pricing reforms must not curtail investment in new medicine

The venture industry commends the administration's attention to how Americans are impacted by drug prices and its work thus far in finding solutions. Prescription drug costs have been under the microscope in recent years due, in part, to price gouging by bad actors. These actions prey on the vulnerable and should be condemned. Bad actors who buy up the rights to prescription drugs and raise prices simply because they can create no value for patients.

In addressing this reprehensible model, it must be distinguished from the new company formation and innovation (described above) that is achieved through venture investment. Far from raising prices on the vulnerable, venture capitalists only benefit when a company succeeds in creating an innovative therapy, cure, or treatment. Venture-backed healthcare startups create true value for patients, competition in the marketplace, and ensure the U.S. remains the global home for scientific advancement. Patient, long-term investment by venture investors in life-saving medicine is essential to creating new cures and treatments from which we all gain, as no government entity or large corporation is willing to take the same level of risk throughout the drug development process.

In most cases, a truly transformational drug is the result of early investment by venture capitalists in small startups with a big idea on how to revolutionize health. By the time a pill is in Americans medicine cabinets it might be branded by a recognizable drug company, but the product was probably developed by a young company driven by a bold idea and the support of investors. In 2017, 76% of new molecular entities approved "originated from smaller or mid-sized biopharma firms. . .Only 6 new drugs approved in 2017 were discovered by the top 10 pharma companies."[10]

[10] "Trends in US New Drug Approvals: 2017 FDA New Drug Approvals (and Multi-Year Trends)," HBM Partners (January 2018), *available at* http://www.hbmpartners.com/media/docs/industry-reports/HBM-Partners-Report-Trends-in-FDA-New-Drug-Approvals-2008-2017.pdf. A 2017 *FDA Voice piece* stated: "We may think of the

Achieving new drug discovery is incredibly challenging, and only happens when brilliant scientists, doctors, and researchers are married with significant financial investment in a high-risk quest to discover cures. Development is very expensive, with the cost of creating a single prescription drug that gains approval pegged at $2.6 billion.[11] Venture capitalists invest in these startups knowing that it will take ten to fifteen years for a new drug to make its way through the complex maze of the government approval process, and even if it does emerge, the odds of success are extremely low. In fact, less than 12 percent of drugs entering clinical trials receive approval after a process that generally lasts more than a decade.[12]

In a small percentage of cases, a drug is a true breakthrough and brought to market, resulting in better care for patients and, yes, a financial return for the investor and company founders. Home run medical discoveries offset significant losses from other unsuccessful pursuits and are a reality of new medicine discovery. This win-win formula has led to groundbreaking advancements against the world's most deadly and costly diseases. It is imperative the administration not disrupt this model as it considers changes to the healthcare system.

Investment patters react to policy shifts

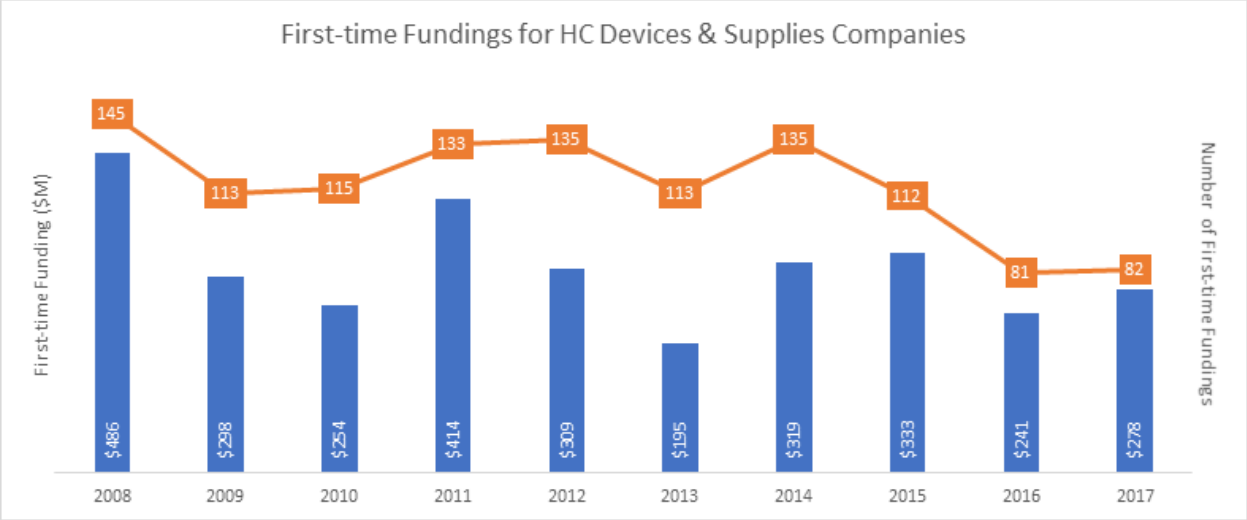
The administration should be especially sensitive to how drug pricing reforms affect the investment decisions of venture capitalists because investors can react strongly to policy decisions, even if these policies are designed to cure an ill later in the drug development process. Furthermore, if changes deter venture investment in new drugs, that capital is not replaceable as no large corporation or government entity will withstand the risk and long-term nature of the investment as VCs do.

The unfortunate decline in venture investment is a cautionary tale for the administration as it considers drug pricing reforms. Many investors cite misguided reimbursement policy as challenging the economics of medical device investing. As a result, the below charts demonstrate the decline in medical device companies receiving their first round of venture funding. The U.S. will see capital investment flow away from drug discovery in the same way it has from medical device companies if shortsighted policy is enacted. This would be a disaster for medical innovation, to say nothing of the health of our citizens.

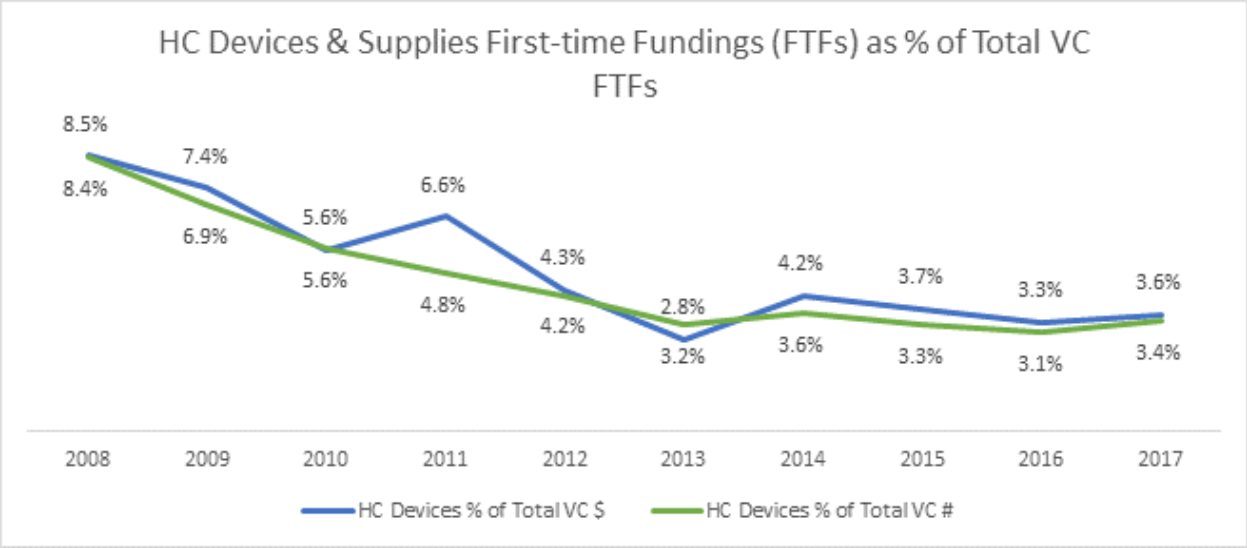
pharmaceutical industry in terms of giant corporations, but the fact is that there are hundreds of small firms—with very few employees—that are developing many of the important drugs that we use every day. . .Industry sources indicate that, over the past decade or so, more than half of the novel drugs [] developed in this country and approved by FDA, have been developed by small companies." *See* "FDA: Helping Small Businesses Get Big Results," *available at* https://blogs.fda.gov/fdavoice/index.php/2017/03/fda-helping-small-businesses-get-big-results/.

[11] "Biopharmaceutical Research Industry: 2016 Profile," PhRMA, *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf.

[12] Id.



Source: Pitchbook-NVCA data



Source: Pitchbook-NVCA data

In addition, the comparative medical innovation in other parts of the world tell an important tale of how investment capital and innovation react to public policy. From 2000 to 2010, the U.S. was responsible for 57 percent of new drugs, whereas France, Germany, Japan, and the United Kingdom—nations with moderate to strict price controls—were collectively responsible for just 29 percent of new drugs developed.[13] The United States should avoid such blunt instruments that will curtail investment in medical innovation by devastating the economics of bringing new medicine to life.

[13] "Why Life-Sciences Innovation Is Politically 'Purple'—and How Partisans Get it Wrong," Robert D. Atkinson, Information Technology & Innovation Foundation (February 2016), *available at* http://www2.itif.org/2016-life-sciences-purple.pdf.

Conclusion

The administration is right to work towards solutions to make drugs affordable for all Americans. But it must recognize that medical innovation is a national treasure that affects all of us and must be promoted, not stifled. The U.S. is the world leader in life-saving drug development because of the correct balance of policies that encourages innovation. We should embrace, and not retreat from that position.

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,

Bobby Franklin
President & CEO