



February 7, 2024

The Honorable Bernie Sanders
Chairman
U.S. Senate Committee on Health,
Education, Labor and Pensions Committee
Dirksen Senate Office Building
SD-428
Washington, DC 20510

The Honorable Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health,
Education, Labor and Pensions Committee
Dirksen Senate Office Building
SD-428
Washington, DC 20510

Dear Chairman Sanders and Ranking Member Cassidy,

Thank you for the consideration of these views, submitted to the Senate Committee on Health, Education, Labor, and Pensions (HELP), in advance of its hearing: *Why Does the United States Pay, By Far, The Highest Prices In The World For Prescription Drugs?*

Incubate is an international coalition of life science venture capitalists committed to educating policymakers on the role of venture capital in bringing promising, innovative treatments to patients in need.

The driver of this hearing, as we understand it, is ongoing concern from policymakers about the broken healthcare payer system in the United States that continues to force patients to face high out-of-pocket costs at the pharmacy counter. We are aligned with the Committee that addressing systemic issues of access and affordability should be a top priority for this Congress.

From our view, however, a better title for the hearing might be *Why Are We Letting Our Broken Healthcare System Drive Higher Healthcare Costs?* The reason being that we cannot unpack prescription drug pricing in a vacuum—instead, it must be considered in as part of a holistic value chain beginning with an entrepreneur and investors ultimately ending with the patient.

Venture capitalists fund effectively all early-stage drug development at the start of that journey. We are financiers with a high tolerance of risk -- far higher than any other actors like banks or other private capital. No one else -- in government or the private sector -- is interested in funding the early days of translating academic discoveries to real-world drugs.

That is why we are unbelievably frustrated by the growing universe of middlemen wielding enormous power and injecting perverse incentives into the purchase of prescription drugs in the United States. Similarly, with the rise of high-deductible health plans, insurance seems to no longer function as insurance – meaning patients are often on the financial hook for the medicines they need.

European governments don't have to navigate this incredibly complex web – and are willing at times to say no to a treatment that can change and save lives. We hope the Committee will discuss these issues at the hearing, which could also be dubbed *Are We Willing to Pay for the World's Medicine Cabinet?*

For many medicines, though not all, the United States is the largest market for innovative medicines. Why? The same reason we are the largest market for any expensive good: America is a wealthy country with resources to pay for life-changing or life-extending medicines.

But without the U.S. market, there simply would not be the capital required to fund early-stage drug development. A survey of our international venture capital network indicated that investors in the E.U. and Asia simply could not justify investments into new medicines with a U.S. market like the one we have today. That is why so many spoke out against the price control mechanisms in the Inflation Reduction Act. The brightest scientists and the investors that back them are laser-focused on the American patient. That is the tradeoff this Committee must discuss.

But it'd be myopic to focus solely on the price of drugs, without also looking at patients' access in each country to those medicines or the research ecosystem in the U.S. that fosters their development. As one example, consider the different approaches that the United States and Europe take towards orphan drugs that treat rare diseases. Because these medicines are costly to develop and by definition treat a relatively small number of patients, the price per course of treatment tends to be quite substantial.

Roughly 500 rare diseases have approved treatments in the United States -- nearly four times the number of such diseases with approved treatments in the EU. That disparity is the result of a more favorable policy environment in the United States when it comes to drug development.¹

In the EU, biotech companies must jump through more regulatory hurdles to even receive an orphan drug designation and the market exclusivity that comes with it. Those incentives are also more likely to be overturned with the introduction of competitor drugs or increased disease prevalence.²

Policy that encourages investments in drugs that treat rare diseases is not only beneficial to the millions who collectively suffer from rare diseases, but for patients everywhere as follow-on indications can lead to treatments for more common diseases. Twenty percent of FDA-approved orphan drugs since 1990 have also been approved to treat a common disease.³

Furthermore, the European pricing model does not honor the economic tenet of supply and demand. Lopsided price-volume agreements and faulty reference pricing systems too often cap the quantity of drugs available to be sold at lower prices, without proportionately increased prices for those drugs that sell in smaller quantities.⁴ Capping the available supply for high-demand drugs deters biotech companies from developing, or even launching, drugs in the European market.

It is true that the American market is the largest in the world for medicines. And it's also true that Americans have more access to medicines than their foreign counterparts. As the financiers for the next generation of medicines, we urge this Committee – and this Congress – to tackle the broken healthcare payer system in the United States without going down the path that deprives patients of breakthroughs. We would welcome the opportunity to provide more information for your hearing or at any other time.

¹<https://www.raps.org/News-and-Articles/News-Articles/2023/6/Market-exclusivity-for-orphan-drugs-in-the-US-and> (MATH: 500 in U.S. vs 130 in EU (4*130=520))

² <https://www.raps.org/News-and-Articles/News-Articles/2023/6/Market-exclusivity-for-orphan-drugs-in-the-US-and>

³ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00219>

⁴ <https://ec.europa.eu/docsroom/documents/7605/attachments/1/translations/en/renditions/pdf> (p. 28-32, 83)



Sincerely,

John Stanford
Executive Director, Incubate Coalition