incubate Policy Lab
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SIGNAL WATCHING

How Life Science Venture Capital Perceives Medicare Part D Reforms

Table of Contents

About incubate Policy Lab

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Incubate is a 501(c)(4) organization of venture capital organizations representing the patient, corporate, and investment communities whose aim is to educate policymakers on the role of venture in bringing promising ideas to patients in need. The advocacy organization recently launched its research arm, Incubate Policy Lab, which explores various policy initiatives and potential effects on the biopharmaceutical industry.

The 117th Congress is discussing a wide variety of policy proposals related to health care, including potential changes to the Medicare Part D program. Incubate published this report to examine proposed changes to Part D from the lens of the early-stage life science research ecosystem, including implications for future access to innovative medicines. Thank you to our members for their insights and contributions to this report.

Introduction

With its robust research and development ecosystem, America produces more innovative medicines than any other country in the world. This ecosystem is composed of academic, government, and private industry researchers who all contribute to a body of basic science research that lays the foundation for the extensive investment and development required to translate that research into new medicines. As health care in the United States continues to be a focus of policymakers, the early-stage life science research ecosystem has increased its efforts to educate stakeholders about the complexity, risk, and timing of the dynamic period between basic and translational research, and clinical trials, manufacturing and commercialization of new medicines.

Engaging in debate over reimbursement policies, especially those affecting government payer programs, has not historically been a priority for entrepreneurs and their venture capital investors; however, there is increasing awareness that we represent a key stakeholder in the policy realm. It is increasingly apparent that *drug investment, development, approval and access are points along a continuum that are inextricably linked*. That linkage, however, is not always fully understood by policymakers.

The rapid scientific response in the development of COVID-19 vaccines and treatments is a signal to the world that the American system of innovation is working.[1] This innovation, arguably a modern-day scientific miracle, is just one example of the life-changing medicines the industry is delivering for millions of Americans with chronic conditions, cancer, rare diseases, and other conditions.

Policies that would significantly alter the U.S. market for prescription drugs should therefore be evaluated in terms of how they could impact this high-functioning ecosystem — from discovery in a lab, to clinical trials, to manufacturing, to delivery to a patient. It is important that incentives be provided to drive innovation, and that science and unmet patient needs guide research efforts.

For these reasons, the investor community is closely watching how Congress and the Administration propose to reform and regulate the Medicare Part D program, which provides prescription drug coverage to seniors and people with disabilities.

For the many early-stage investors and scientists, it is important that reforms to major programs like Medicare Part D do not disincentivize certain types of research and commercialization. Proposals that simultaneously support continued investment in innovative treatments that target rare diseases and unmet medical needs while also encouraging advancement of traditional, but sorely needed, medicines represent the proper path forward, from the view of the early-stage ecosystem.

This paper examines three elements of the investor's perspective on reforms to the Medicare Part D program, leading to the following conclusions:

1. Coverage and reimbursement policies send signals to investors, who are paying increased attention to proposals that would affect the market for innovative medicines

2. The drug development ecosystem has made many important scientific advances, yet unmet medical needs remain, requiring new treatment modalities and innovation

3. Reforms should ensure that medicines are more affordable and accessible to all patients.

Coverage and Reimbursement Policies Send Signals to Investors

Investors in even the earliest-stage pharmaceutical and biotechnology companies evaluate a drug's future market potential as part of their investment decision. As RA Capital Managing Partner Peter Kolchinsky notes, the investor considers three elements in weighing whether to invest: the amount of capital required today, the scientific likelihood of success, and the expected market for a successful product.[2]

Given that government health care programs are significant markets for biopharmaceuticals—the Congressional Budget Office projects Part D spending will total $96 billion in 2021 policy—changes that affect how prescription medicines are covered and reimbursed by these programs will impact some elements of the investor calculation.[3]

While this paper focuses on Medicare Part D, many proposed reforms would have a far-reaching impact on other health care programs and sectors, including Medicare Part B and even commercial markets.

Unmet Needs Meet Incredible Science

Patients need the next generation of medical innovation. Seniors in particular face conditions where new treatments and possible cures could have life-changing impacts, including heart disease, cancer, neurological disease, chronic obstructive pulmonary disease (COPD), cerebrovascular disease, diabetes, pneumonia and influenza, nephritis, and septicemia.

Academic, government, and industry scientists are rising to meet the challenges posed by unmet medical needs. Whether through entirely new modalities, like mRNA, or the ever-growing improvements of existing medicines, the prognosis for many of these ailments is improving. Emerging innovation is a clear product of the cycle of basic research, private investment, translational research, and drug development.

The entire cycle, in turn, is a by-product of synergistic partnerships in research and development (R&D) between industry, academia, government agencies, and others all facilitated by a pro-innovation policy framework including intellectual property protections. As industry R&D budgets have increased, the output (measured in new drugs, new indications, new modalities, etc.) has risen. The ability to meet patient needs is a clear function of the incentives in our system paired with the scientific capability to take the necessary risks in early-, middle-, and late-stage development. From the perspective of the early-stage investment community, the scientific ability to address these diseases is only limited by investment—and the downstream ability to recoup these investments. This is why policies that would threaten the free flow of capital or reduce the incentives to invest would be so harmful.

Ensuring this flow of early-stage private capital, often from venture capitalists, is critical. The success rate of drug development in the early stage is extremely low, and the initial costs to get into clinical trials can require investments of hundreds of millions of dollars.[4] Therefore, partnerships between the early-stage researchers and private venture capitalists or larger biotech firms is critical to making ideas viable by bringing concepts through clinical trials and to market.

It's also worth noting that the disease burden in America and throughout the world may grow due to the coronavirus (COVID-19) pandemic. While much remains unknown about the long-term implications of COVID-19, including its many variants, it is possible that an entire generation of Americans may face increased risk of complications and chronic diseases. Moreover, the last year has seen a sharp decrease in routine use of health care, including the delay of screenings and treatments. The consequences could be significant, leading to increased health care needs in the United States and beyond.

To counter this challenge, the entire life sciences ecosystem requires a commitment that returns on early-stage investments can be realized. A critical element to protecting the health of this life science ecosystem is ensuring that intellectual property incentives, and coverage and access policies for innovative medicines, is both transparent and predictable.

Improving Access for Patients

A common frustration among life sciences investors and the entrepreneurs they support is that their collective innovation does not always reach patients. We believe that drug coverage and reimbursement policy changes, which may impose additional financial liabilities on the pharmaceutical industry, must directly benefit patients.

There is overwhelming agreement among life sciences venture capitalists that the growth of out-of-pocket (OOP) costs is a major impediment to patients accessing medicines. Many stakeholder voices have embraced constructive policies to address patient OOP burden. For example, the Lupus Foundation of America, an Incubate member, convened the Medicare Access for Patients Rx (MAPRx) coalition, bringing together Medicare Part D patients, family caregivers, and health professional organizations that focus on chronic diseases and disabilities.

MAPRx has recommended specific changes that align with Incubate's mission to expand access to medicines, including:

1. Requiring robust formularies and providing coverage for a variety of medications in each drug class or category.
2. Preserving required coverage within Medicare Part D's six protected classes of drugs and any additional classes where restricted access to medicines would have significant health consequences.
3. Requiring plans to provide clarity and transparency on coverage and patient out of-pocket costs.
4. Ensuring that notice of non-coverage, appeals, and exceptions processes be simple and understandable.
5. Establishing rigorous oversight of medication utilization management tools (such as medication substitution, step therapy, or quantity limits) to help ensure patients' timely access to prescription drugs.[5]

MAPRx and other patient organizations also have embraced establishing a cap on OOP costs in Part D to limit the amount beneficiaries have to pay for covered prescription drugs each year and policies that would allow beneficiaries to spread their cost sharing throughout the year (instead of having to pay the entire annual cost sharing amount in the first month or two of the plan year). Such approaches would offer financial protections and predictability for patients battling multiple chronic diseases or those facing serious new diagnoses such as cancer.

Taken together, such policy solutions would help Medicare Part D keep pace with medical science — providing patients with the access they need and giving early-stage investors the confidence of knowing that a strong and reliable intellectual property protection and reimbursement framework exists.

Part D Reform Must Avoid "Picking Winners"

From the perspective of early-stage investors, public policy proposals — even well-intentioned ones — that disrupt the efficient and effective drug development ecosystem we have today are untenable. When it comes to Medicare Part D reforms, life sciences venture capitalists believe it is imperative that changes do not tip the scales toward one approach to science over another.

Part D reforms must not inadvertently disincentivize certain types of research and commercialization.

Some proposals seek an approach that simultaneously supports innovative treatment modalities that can address unmet need and myriad rare diseases while also encouraging advancement of traditional, but sorely needed, medicines. The system should equitably encourage innovation across disease states, including rare diseases. From the view of the early-stage ecosystem, this is the proper path forward.

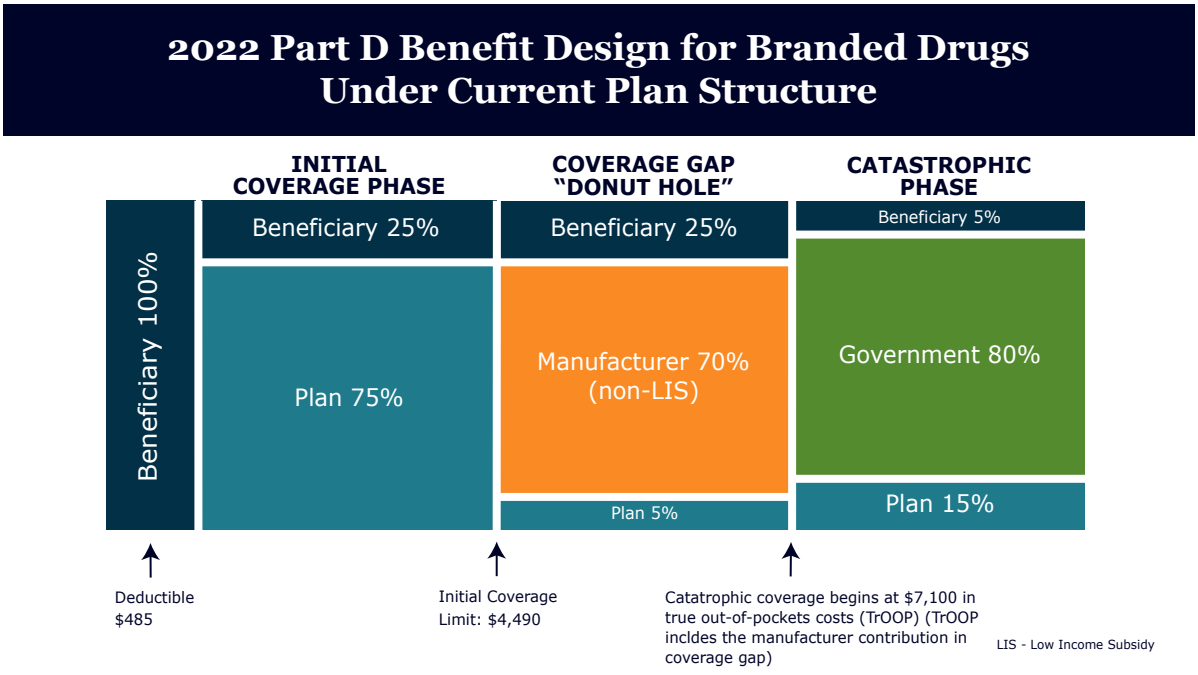
Proposals to allow the government to set prices by repealing or creating an exception to the non-interference provision will send worrisome signals to the investor community and could harm vulnerable patients by significantly reducing access to existing medications. Other proposals that, for example, vary the size of the manufacturer contribution depending on whether a patient is in the initial coverage

phase or the catastrophic portion of the Part D benefit are the *wrong* path forward, as they would result in inconsistent treatment of traditional medicines and specialty medicines and could disincentivize future investment in breakthrough medicines. Policymakers should instead pursue reforms that apply manufacturer liability consistently throughout the benefit, which leaves investors and researchers to pursue where the science leads.

Changes to the Part D program must also address affordability challenges for beneficiaries. Recent Part D redesign proposals would move from the current four-phased model (annual deductible, initial coverage phase, coverage gap, and catastrophic) to a three-phase design that eliminates the coverage gap (or "donut hole"). Under all the reform proposals, an annual out-of-pocket cap on patient costs would be implemented after the initial coverage phase, with the government, insurers, and manufacturers responsible for different percentages of coverage in the catastrophic phase.

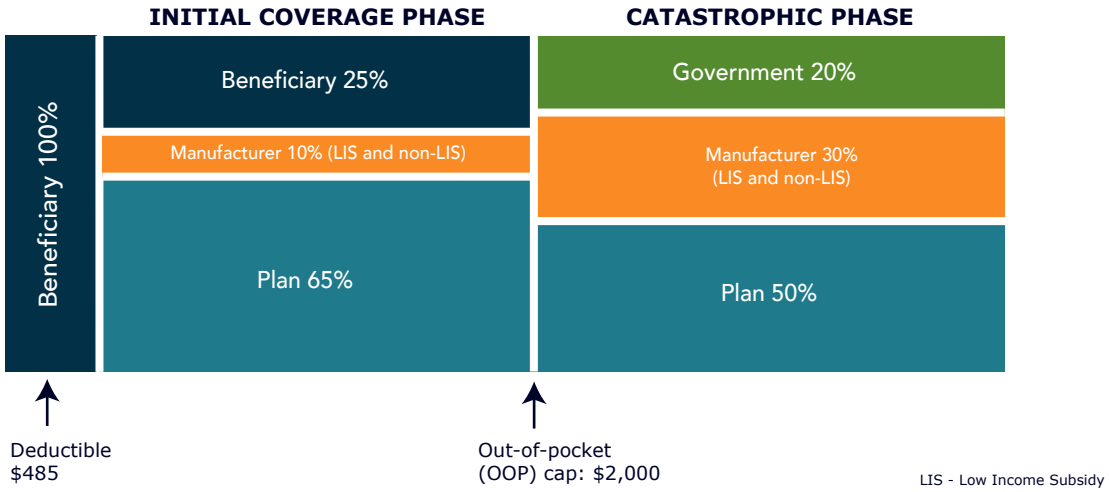
From an early-stage investor's perspective, establishing an annual OOP limit within Part D is a positive step for beneficiaries that will help address affordability challenges. However, differing approaches to assigning liability in the catastrophic phase illustrate the importance of a balanced approach to reform.

The following graphs illustrate the structure of Part D under current law and two competing proposals: the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3), which applies significant manufacturer liability, and the Lower Costs, More Cures Act of 2021 (H.R. 19), which applies balanced manufacturer liability throughout the benefit.



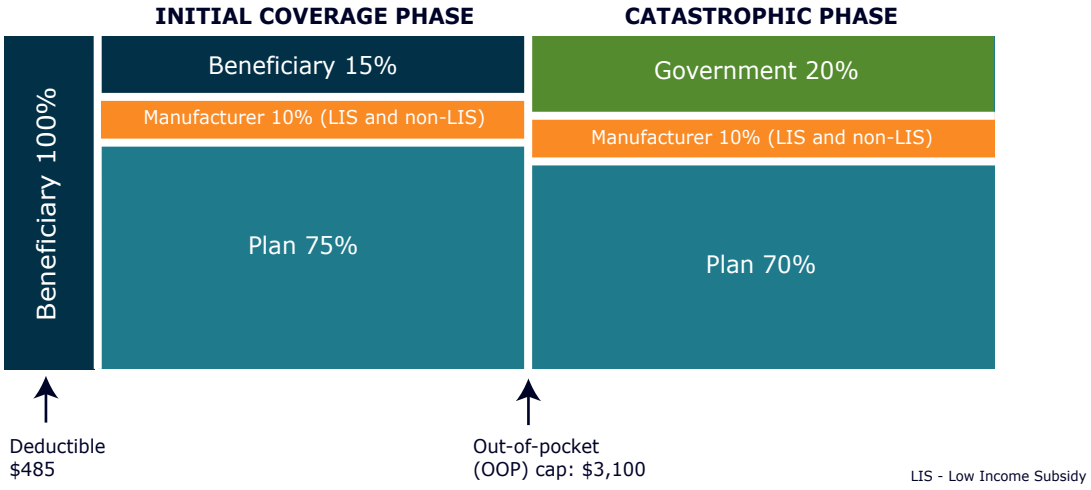
As currently designed, Part D has no limit on total beneficiary OOP expenses. Current proposed reforms create an annual OOP cap on beneficiary drug costs.

Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3): Branded Drugs



H.R. 3 proposes an extreme imbalance between manufacturers' liability in the initial and catastrophic phases. Under this plan, the manufacturer contribution in the initial coverage phase is 10%, rising steeply to 30% in the catastrophic phase. Imposing significantly higher liability in the catastrophic phase of the benefit substantially limits appeal for investing in potential specialty medicines to treat complex and rare diseases, essentially impacting a disproportionate share of innovative therapies.

Lower Costs, More Cures Act of 2021 (H.R. 19): Branded Drugs



Conversely, H.R. 19 achieves similar reforms to Part D but applies the manufacturer liability consistently at 10% in both the initial coverage phase and catastrophic phase.

The dramatic imbalance in H.R. 3 (10% in the initial coverage phase vs. 30% in the catastrophic phase) would implicitly incentivize one type of drug over another—expressly counter to the open-market preference of the early-stage ecosystem. Investment and R&D into higher-cost and more complex specialty medicines for rare diseases, cancers, and other areas of unmet need, would be disincentivized.

On the other hand, the approach outlined in H.R. 19 would increase manufacturer responsibility but not interfere to tip the scales in favor of one type of science over another. In addition to taking a consistent approach preferred by the investor community, H.R. 19 would also directly benefit patients by lowering OOP costs earlier in the benefit and capping annual out-of-pocket costs.

Research from the Council for Affordable Health Coverage shows that equitable proposals, like H.R. 19, would be more effective than H.R. 3 for lowering patient OOP costs across many treatment areas.[6] For example a patient with COPD would see 8% in OOP savings under the Part D redesign approach in H.R. 3 vs. 31% savings under the Part D redesign approach in H.R. 19.

Similarly, consistent and predictable approaches like those envisioned in H.R. 19 carry particular importance for the rare disease population. With so few patients, rare diseases are especially reliant on market incentives for investment. The approval of these medicines has increased significantly in recent years as both advancement in science and predictable reimbursement policies have spurred further research and development.

This robust period of development occurred in part because disincentives to the development of rare disease drugs did not materialize. Misguided reforms of a significant program like Part D could create the exact barriers and negative consequences that would chill investment into rare diseases. Indeed, investment and R&D focused on rare diseases and specialty medicines to treat other complex conditions have strong support from patient advocates, who frequently advocate for removing barriers to innovation and access.

Impact of Other Proposals

Neither policymaking nor scientific development happen in a vacuum. The principles outlined in this paper have parallels to other policy proposals in Washington.

International Reference Pricing
Proposals that would incorporate price controls through foreign reference pricing schemes send a clear signal to the investor community that recouping investment may be prevented by government action.[7] A version of international reference pricing is incorporated into H.R. 3, which would effectively tie the price of certain drugs in the United States to the prices set by governments in other countries. This proposal would significantly weaken the investment thesis for the early-stage ecosystem, leading to a dramatic decrease in funding and development of novel therapies and medicines.

Non-interference clause
Some policymakers have advocated for repeal of the Medicare Part D non-interference clause, which prohibits the Secretary of the Department of Health & Human Services (HHS) from interfering in the negotiations that Part D plans or pharmacy benefit managers, manufacturers, and pharmacies engage in to effectively achieve drug cost savings. Repealing the non-interference clause to allow the Secretary to negotiate would dramatically shift Part D away from its existing (and successful) competitive market-based structure without achieving budgetary savings and—worst of all—could restrict access for Part D patients. The non-interference clause protects patients by prohibiting a specific formulary, which would limit access to lifesaving medicines.

Actual Part D spending has come in under early budget projections in part due to marketplace-based competition, and we strongly urge Congress to reinforce policies that support this competition. As mentioned above, it is critically important that investors have a sense of certainty for the products made by the companies they invest in. The addition of the HHS Secretary into the already existing – and complicated – payer system would further limit predictability, increasing the cost of capital and potentially medicines.

Conclusion

Early-stage investors recognize that improved patient affordability should be a top priority for modernizing the Medicare Part D program. However, as outlined above, coverage and reimbursement policies can have a direct impact on early investment decisions that will have a downstream effect on the development and availability of future treatments and cures for areas of unmet medical need. Policymakers must ensure that changes to Medicare Part D will promote incentives for investment, creativity, and R&D across different avenues of medical science.

Endnotes

[1] https://www.washingtonpost.com/opinions/the-drug-development-system-isnt-broken-covid-19-shows-it-has-never-worked-better/2020/11/10/259b7a00-2396-11eb-a688-5298ad5d580a_story.html

[2] For a deeper discussion on investor considerations, visit Incubate's YouTube channel to see the "Investor's Paradox" Video featuring Peter Kolchinsky. Video permanently available at https://www.youtube.com/watch?v=LOv6gPfAtgU&t=31s

[3] https://www.cbo.gov/system/files/2020-03/51302-2020-03-medicare.pdf

[4] "Adventure Forward." Video permanently available at: https://vid-cdn.multiscreensite.com/ed3d73ef/videos/0R3m47J4TBQz0JUFiwua_Incubate_AdventureForward_MGFX_SG_V02a-v.mp4

[5] More information can be found on the MAPRx website: https://maprx.info/home/aboutmaprx/

[6] https://static1.squarespace.com/static/58bf2243d482e99321a69178/t/5e5956fbc57f9f5105aeb4e9/1582913283570/XCENDA+Part+D+Patient+Profiles+Update+HOUSE++Feb+20+XD+%281%29.pdf

[7] https://www.globenewswire.com/news-release/2020/07/31/2071350/0/en/INCUBATE-RAISES-CONCERN-ABUT-PRESIDENT-TRUMP-S-EXECUTIVE-ORDER-ON-DRUG-PRICING.html

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