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DRUG PRICE CONTROLS IN THE U.S.

A ROUNDTABLE DISCUSSION WITH EXPERTS

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. Thank you to our members for their insights and contributions to this report.

Background

The United States is the world leader in innovative drug development, supporting patients and health systems globally by advancing the creation of new cures and treatments. World class universities and academic institutions, strong and reliable intellectual property rights, and a robust entrepreneurial environment have contributed to the success of the U.S. pharmaceutical and biotech industry.

Arguably, the main difference between the U.S. and other developed markets such as the European Union and Japan is the system for pricing prescription drugs. In the U.S. market-based system, drug companies negotiate with health insurers for formulary placement, which results in faster and more open access to medicine; in other developed countries the government often decides what will be available and delays or restricts access to new therapies through centralized pricing and approval processes.

However, one consequence of the U.S. competitive market system for drug pricing is that drug prices are often higher than in other countries that impose some form of price control. This has contributed to a growing debate in the U.S. on whether federal government intervention should be used to reduce drug prices, which has been furthered by executive orders issued by the Trump administration and more recently, by price control proposals by the Biden administration and Congress. Most recently, in early September 2021, U.S. Health and Human Services (HHS) published its "Comprehensive Plan for Addressing High Drug Prices" in response to President Biden's Executive Order on Promoting Competition in the American Economy.[i] The Plan proposes three pillars through which drug pricing would be reformed: direct price negotiations between Medicare and drug manufacturers; increasing price competition by promoting generics and biosimilars via market changes; and advancing innovation and promoting new drug discovery by "bolstering government investment in research" and "aligning incentives" with drug manufacturers.[ii]

Previous to that report, in December 2019, the U.S. House of Representatives passed the Elijah E. Cummings Lower Drug Costs Now Act (also known as H.R.3). As the name suggests, the Act is intended to lower the cost of prescription drugs and reduce drug spending for both private and public health insurers. Title I of H.R.3 calls for the Secretary of HHS to negotiate lower drug prices for several products, specifically targeting single-source drugs that do not face generic competition and drugs that account for the greatest national or Medicare spending.[iii]

Government price setting on a broad scale as considered in the legislation or administration proposals would represent a significant departure from today's U.S. biopharmaceutical market, where prices are typically negotiated between private payers and biopharmaceutical companies for most people with insurance, and price intervention by the federal government is limited to high need groups such as lower income and disabled populations insured through Medicaid, people receiving care

through certain hospitals the government identifies as high need (340B), and to defined groups such as individuals insured via the Department of Veterans Affairs.

The Congressional Budget Office (CBO) has published its assessment of the effects of H.R.3 on the U.S. pharmaceutical drug market.[iv] The CBO estimates that H.R.3 will cause an overall reduction in global sales of pharmaceuticals and that fewer new drug products will come to market over the coming decades as a result. Academics and private entities studying the CBO analysis have evaluated the underlying evidence and assumptions made by the CBO and conclude that the CBO underestimates the true impact of H.R.3 on future innovation. In particular, the CBO undervalues the importance of the U.S. market as the largest source of industry revenue; ignores how H.R.3 will disproportionately affect certain patient populations; underestimates the impact of reduced revenue on R&D; and ignores the complexity and mobility of the investor market.[v] These arguments have been advanced by several experts, including economists Tomas J. Philipson and Troy Durie (University of Chicago),[vi] the Commonwealth Fund,[vii] and the USC-Brookings Schaeffer Initiative for Health Policy.[viii]

To better understand the potential effect of price-setting policies such as H.R.3 on pharmaceutical innovation, Charles River Associates (CRA) with the support of Incubate, convened a roundtable of diverse industry experts in July 2021.[1] Participants in the discussion included economists, venture capitalists and representatives of the investor community, current and former pharmaceutical and biotech executives, a former CBO official, and a selection of the academic researchers who authored the studies used by the CBO in their analysis of the H.R.3 impact. The session was conducted according to the Chatham House Rule. Therefore, we summarize the overall discussion from the meeting below without attributing specific comments.

Specifically, participants discussed the assumptions and sources of evidence used in the CBO's analyses and how H.R.3's impact on innovation might disproportionately affect certain therapeutic areas and patient groups. Insights from this event suggest that the reduction in pharmaceutical innovation could have far-reaching effects not only on drugs coming to market but on public health, academic institutions, and the labor market.

[1] The conclusions set forth herein are based on independent research and publicly available material. The views expressed herein are the views and opinions of the authors and do not reflect or represent the views of Charles River Associates or any of the organizations with which the authors are affiliated. Any opinion expressed herein shall not amount to any form of guarantee that the authors or Charles River Associates has determined or predicted future events or circumstances, and no such reliance may be inferred or implied. The authors and Charles River Associates accept no duty of care or liability of any kind whatsoever to any party, and no responsibility for damages, if any, suffered by any party as a result of decisions made, or not made, or actions taken, or not taken, based on this paper. Detailed information about Charles River Associates, a tradename of CRA International, Inc., is available at www.crai.com.

Expert Consensus

Price control will have an unprecedented impact on the nature of innovation and affect patients disproportionately

H.R.3 specifically targets drugs that "are among either the 125 drugs that account for the greatest national spending or the 125 drugs that account for the greatest spending under the Medicare prescription drug benefit and Medicare Advantage."[ix] Lowering the prices that manufacturers are allowed to charge for these products will lower revenues earned on these drugs and, as is true for every private sector industry, research and development in the industry will decline as pharmaceutical companies will only invest when the risk is expected to be rewarded – i.e., when the high cost of R&D can be compensated by expected returns.

Roundtable participants agreed that by lowering drug prices and expected returns, federal price controls like those proposed in H.R.3. would reduce the incentives to invest in innovation in specific therapeutic areas, shifting innovation away from cutting-edge (high-risk, high reward) drugs towards more conservative incremental improvements on existing medicine. One participant put it simply that pharmaceutical companies would rather undertake smaller, less expensive clinical studies than bear the risk of launching a breakthrough drug only to have its price tightly controlled, unable to balance product revenue against the capital spent to get it to market.
Participants agreed that the shift in innovation resulting from H.R.3 or a similar type of policy will have a disproportionate impact on certain patient groups, including those who are most in need of new, innovative treatments. There was roundtable consensus that the wide-reaching effects of reduced innovation in both the rarest and most common therapy areas is a double-edged sword: disproportionately burdening the most vulnerable while simultaneously affecting the many.

Transformational innovation would decline, impacting innovative medicines for rare and oncological diseases

In recent years, pharmaceutical R&D has been more focused on the development of rare disease and specialty medicines. In 2020, thirty-one of the fifty-five new active substances that were approved and launched in the U.S. were granted orphan drug designation.[x] Oncology and rare diseases are two therapy areas with the highest number of clinical trials.[xi]

The roundtable participants highlighted that investment and innovation in immune-oncology and gene and cell therapies is driven by the prospect of the potential return on investment (specialty medicines account for 53 percent of net manufacturer revenues).[xii] Price premiums for new products in rare and oncological diseases aim to generate a return on the value provided by the innovative new medicines developed and the financial risk undertaken by developers working on newer, less-tested therapeutic approaches and targets.

Conversely, the roundtable group provided examples of therapeutic areas such as women's health or infectious diseases, where, as a result of high financial risk and low potential for returns, it is increasingly difficult to raise capital. As such, the development of new treatments is slow in these therapy areas despite significant unmet need to improve human health. The roundtable group highlighted that, all else equal, revenue potential is the biggest driver for investment. Lower prices diminish the potential return on value, resulting in less investment in high-risk therapy areas and stagnant innovation, with minimal progress towards major improvements in treatment options. As has been the case in women's health and infectious diseases, under federal price controls such as those proposed in H.R.3, there may be a shift away from transformative innovation such as rare diseases and oncology.

A shift to reliance on incremental innovation

Roundtable representatives from pharmaceutical companies highlighted three aspects that must be balanced when making drug development decisions: 1) the amount of capital that needs to be invested during development, 2) the scientific likelihood of clinical success, and 3) the likelihood of long-run commercial success. The price controls outlined in H.R.3 or a similar policy will affect the likelihood of commercial success in the long run by lowering a drug's price and revenue potential, forcing investors to rebalance the other two aspects of uncertainty when making investment decisions. Federal price controls, such as those proposed in H.R.3, would reduce the level of scientific uncertainty a pharma company is willing to accept to balance the reduction in expected returns. In order for pharma to still raise sufficient capital in an environment with price controls, their scientific endeavors must bear a relatively lower risk profile. This is because investors will generally be less willing to tolerate risk in the scientific likelihood of success when expected returns are lower, causing a fundamental shift in R&D towards less risky scientific undertakings. On the other hand, when thinking about capital needed early in the development process, reducing the value of long-term success lessens investors' willingness to invest more capital upfront. This new dynamic will result in more budget constraints for R&D, shifting pharma towards less expensive endeavors.

Working in tandem, a reduction in upfront capital and lowered scientific risk tolerance will force innovators to be more cautious when making R&D decisions, leading to smaller, less risky clinical trials focused on incremental innovation. The roundtable experts agreed that under H.R.3, we could expect to see fewer breakthrough and novel drugs discovered, since these require extensive capital investment and are very risky from a scientific perspective. The shift towards incremental innovation could lead to the U.S. falling behind as a leader in pharmaceutical innovation.

Drug price controls will make the U.S. a less appealing hub for innovation

An area of clear consensus among the roundtable participants was that innovation and access to new medicines will be reduced by federal price controls such as those proposed in H.R.3 and the impact will be far greater than estimated by the CBO. The experts also

highlighted a major consideration outside the scope of CBO's analysis: The decline in the U.S. pharmaceutical market size could cause the U.S to lose its attractiveness as a hub for innovation and the U.S. may no longer be seen as a world leader in the development of transformational medicines.

As described above, federal price controls like those proposed in H.R.3, will reduce expected revenue for pharma companies. As a result, companies may choose to downsize, putting at risk bio-scientific research and engineering jobs. Experts agreed that drug price controls could lead to the bioscience sector being perceived as a less compelling sector to work if there is less investment in transformational science, leading to a reduction in the number of students pursuing Ph.D. programs in scientific fields and resulting in funding reductions for academic research institutions and labs. If the focus of new medicine development shifts away from transformational innovation, the U.S. will likely lose its status as a hub for cutting-edge innovation and entrepreneurialism, causing unprecedented effects across the scientific community well beyond the immediate impact to the private sector biopharmaceutical companies.

Conclusion

In addition to concerns that price controls would have a chilling impact on innovation and reduce the number of new medicines brought to market, roundtable participants highlighted that price controls such as those proposed in H.R.3 would have far-reaching consequences for public health, academic institutions, and the labor market. The following impacts were not fully considered in the CBO's analysis of H.R.3.

- Federal drug price controls will harm certain types of patients disproportionately. The types of medicines that will be lost to society will affect patients with rare diseases and cancer, many of whom lack any treatment options.
- The role of the U.S. as a world leader in the development of new, transformational medicines will deteriorate.
- There will likely be a significant loss to the U.S. scientific community and jobs.

Endnotes

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