# PRESCRIPTION DRUG SPENDING REFORM WILL NOT HARM INNOVATION AND WILL BENEFIT THE AMERICAN PUBLIC

**Statement of Rena Conti, Ph.D.**

Associate Professor

Department of Markets, Public Policy and Law

Questrom School of Business

Boston University

Senate Finance Committee Hearing

*Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare*

Wednesday, March 16, 2022 - 10:00am

## SUMMARY OF REMARKS

There is an urgent need for Congress to reform how Medicare pays for prescription drugs. Proposals to reduce drug prices, such as proposed in the recently passed House bill (H.R. 5376), will not harm pharmaceutical innovation and will improve affordability for the American public. I review the strong empirical evidence base supporting these claims.

## MY BACKGROUND AND EXPERTISE

I am Rena M. Conti, Ph.D., Associate Professor of Markets, Public Policy and Law in the Questrom School of Business, and co-director of the Technology Policy and Research Institute, a joint program of Boston University's Business and Law Schools. Between 2006 and 2018, I was faculty at the University of Chicago. I am a graduate of Harvard University's Interfaculty Initiative in Health Policy, concentration economics.

My research interests are in the economics of the pharmaceutical industry. I have published over 100 peer reviewed articles, many in top economics, policy and medical journals. I have taught health economics and strategy in the pharmaceutical industry for two decades.

My research work is supported by grants, including from the National Cancer Institute, the Leukemia and Lymphoma Society, the American Cancer Society and Arnold Ventures.

## OVERVIEW OF PROPOSED REFORMS AND LIKELY SAVINGS

There is a social compact between the American public and pharmaceutical companies: the industry is supported by taxpayer investments to benefit their health at an affordable price.[1] It does so by supporting all aspects of innovation and competition. Yet, some pharmaceutical companies are breaking the social compact. Pharmaceutical companies set prices of prescription drug which are so high they impose financial toxicity on the American public. 29% of Americans either can't afford their drugs or are rationing their drugs.[2] Instead of seeking the next breakthrough, companies delay competition to maintain exceptional revenue.

[1] Gruber J, Johnson S. **Jump-starting America: how breakthrough science can revive economic growth and the American dream**. NY: Public Affairs, 2019.

[2] Kirzinger A, Lopes L, Wu Bryan, Brodie M. *KFF Health Tracking Poll – February 2019: Prescription Drugs.* March 2019.

***Reform provisions address these challenges in several ways***.[3]

First, by imposing penalties on pharmaceutical companies to ensure that prices do not increase greater than inflation. These changes will reduce the number of prescriptions Americans don't fill or currently ration due to their expense.

Second, by extending new authority for the federal government to negotiate Medicare prices for selected drugs.[4] Negotiation will only target of drugs that have frequently manipulated the FDA rules and patent policy to extend exclusivity far beyond the intent of the legislation that created our patent system.

Third, by redesigning seniors' pharmacy coverage to cap out of pocket costs.

***Reforms will generate significant savings for the American public over the next decade***.[5]

For example, reform proposals aim to cap seniors' out of pocket costs for insulin at $35 dollars per prescription. For the 2.27 million seniors who use insulin daily, this will result in measurable savings.[6] American workers will also benefit from this change.

With access improvements, better health will likely follow.[7]

Reform will benefit the American public in other ways. Reform will benefit taxpayers. One government estimate suggests reform will generate $160 billion in savings over the next decade.

**REFORM WILL NOT HARM INNOVATION**

***What these proposals will not do is harm pharmaceutical innovation***.

---

[3] Conti RM, Frank RG, Gruber J. *Regulating Drug Prices while Increasing Innovation*. New England Journal of Medicine. 385(21): 1921-1923. November 2021.

[4] U.S. House of Representatives. *Drug Price Investigation. Lost Savings: How Prohibiting Medicare Negotiation Has Cost Taxpayers*. Staff Report Committee on Oversight and Reform. September 2021.

[5] Congressional Budget Office. *CBO's Simulation Model of New Drug Development*. Working Paper Series 2021-09. August 2021.

[6] Turner A, Conti RM, Hughes-Cromwick P. *Strategies to Advance Insulin Affordability in The United States*. Altarum's Center for Value in Health Care. September 2020.

[7] Chandra A, Flack E, Obermeyer Z. *The Health Costs of Cost Sharing*. National Bureau of Economic Research Working Paper 28439. February 2021.

Prior debates on how to make drugs more affordable have been weighed down by concerns about how reducing any drug prices will reduce the number of new 'cures'. A particularly colorful version of this claim include the head of PhRMA, the industry lobby group, threatening reform would cause a 'nuclear winter' for innovation.[8]

Those claims are not empirically based.

***First, CBO reports that the proposed legislation would have very little impact on the number of new drugs produced.***

The non-partisan Congressional Budget Office's report suggests that an earlier version of the latest House proposal would not result in material reductions in innovation in the next decade and would have small effects over 30 years – 1 less drug over the next decade and 4 less drugs over the subsequent decade.

Even then, the CBO report may have overstated reform's impact on innovation. CBO's estimate does not account for the coincident increases in profits the pharmaceutical industry has realized in the past two years and is expected to increase in the next 5 years.[9] CBO assumes pre-COVID-19 growth in revenues derived from pharmaceutical sales. It does not account for the expected effects of pharmaceutical company revenue increases from COVID-19 therapeutics and vaccine sales, and outsized revenues from new product launches in oncology and immunology.

***Second, new drugs are not the same as new 'cures.'***

In the context of reform, the key policy question for assessing the trade-off is not how many new drugs maybe lost (i.e. absolute quantity of new drugs), but what is the likely impact on breakthrough treatments by reducing prices for a limited number of older high-cost drugs (i.e quality of new drugs)?

Most of the evidence on which all sides base their claims come from the same "natural experiment", the expansion of Medicare to include the drug benefit or Medicare Part D

[8] U.S. House of Representatives, Committee on Oversight and Reform. *Drug Pricing Investigation: Majority Staff Report*. December 2021.

[9] IQVIA. *Global Medicine Spending and Usage Trends: Outlook to 2025.* April 2021.

implemented in 2006.[10] The research consistently showed that the number of new drugs grows as the market increased.

Yet, on the question of quality, the story is different. Research by Dranove and colleagues shows that the new launches following Part D implementation were almost entirely in areas where there were already existing therapies (5 or more, rather than 2 or fewer).[11] They also found that few were truly innovative. *Figure 1* from the paper highlights this point clearly.

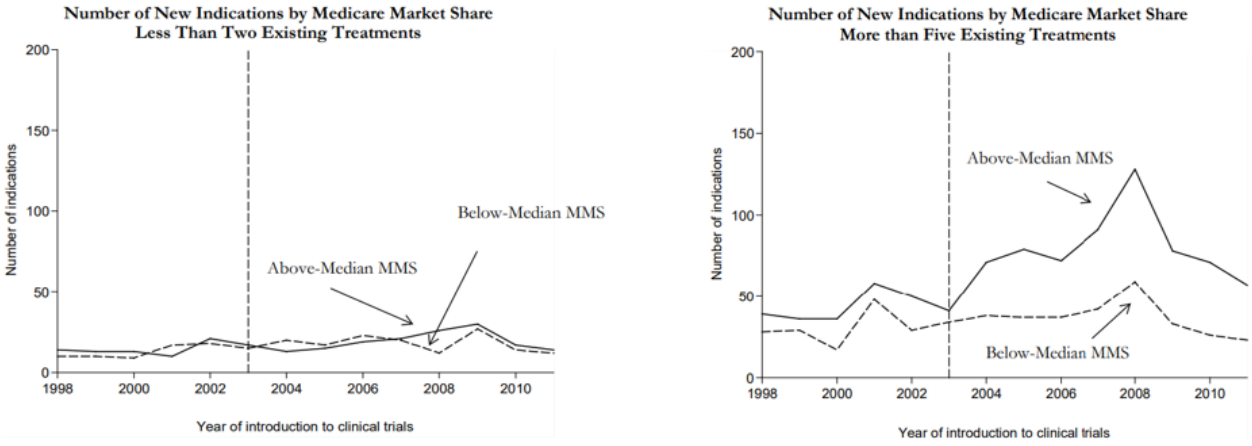


***Figure 1.*** *Number of New Indications by Medicare Market Share Less Than or More than Five Existing Treatments*

Research by Amy Finkelstein[12] provides some insight into the possible mechanisms behind this. Her work argues that the companies took existing products that were "on the shelf" but not sufficiently profitable with the smaller market and launched them as the market grew.

[10] Blume-Kohout ME, Sood N. *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*. Journal of Public Economics. 97: 327-336. January 2013.

[11] Dranove D, Garthwaite C, Hermosilla M. *Pharmaceutical Profits and the Social Value of Innovation.* NBER Working Paper 20212. June 2014.

[12] Finkelstein A. *Static and Dynamic Effects of Health Policy: Evidence From The Vaccine Industry.* The Quarterly Journal of Economics. 119(2): 527-564. May 2004.

Research by Byrski and colleagues extends this line of analysis.[13] They examine the same data on the impact of the creation of Part D and then looked at the impact of the market expansion on new drugs, new patents, and new published science. What they found was that they could replicate the increase in new drugs found by prior studies and there was no overall evidence of increases in patenting or new published science.

In addition, most of the new pharmaceutical products (excluding generics) approved by the U.S. FDA are not new drugs at all. Data on FDA approvals from 2011 through 2021 show that of all brand name drug products approved only 32% were new molecular entities. The rest represent new version of old drugs. This is reflected in industry SEC filings and public testimony showing large R&D investments in new formulations for existing blockbuster drugs.

- Bristol-Myers spent a large part of its 2018-19 R&D dollars for line extensions for Opdivo and Yervoy existing blockbusters.
- Sanofi testified in the Senate that only 33 of its 81 R&D projects were for new chemical entities.

***Third, new breakthrough treatments come from new science.***

Drug innovation that is truly transformative for human health often emerges in large part from taxpayer supported research and development, even though this is rarely reflected in the pricing of the resulting drugs, nor in commensurate "payback" to the funding agencies that made them possible.

While the industry often plays an important role in bringing new drugs to market, all drugs brought to market in the U.S. can trace their discovery back to NIH-supported basic and translational science.[14]

Current reforms will not alter the American public's support for these investments.

[13] Byrski D, Gaessler F, Higgins MJ. *Market Size and Research: Evidence from the Pharmaceutical Industry*. National Bureau of Economics Research Working Paper 28858. May 2021.

[14] Kesselheim AS, Tan YT, Avorn J. *The Roles of Academia, Rare Diseases, and Repurposing in the Development of the Most Transformative Drugs.* Health Affairs (Millwood). 34(2):286-93. February 2015.

Therefore, as long as Congress continues funding the National Institutes of Health and university-based scientists, then we can be assured that the next generation of important new treatments will be in the pipeline.

***Fourth, additional drivers of innovation will not be altered by reform.***

The pharmaceutical industry wouldn't exist without the support of the American public in many additional ways. These include:

- Patents and other types of intellectual property protections offer the potential for economic rewards to invention of new treatments.[15]
- Public support is also linked to the later-stage development of many transformative drugs at university labs or spin-off small companies before being acquired by large manufacturers.[16] For example, the public supports private sector investments into orphan diseases, antibiotics, COVID-19 therapeutics and vaccines.[17]
- Robust financial markets which affect both the existence and pace of innovation.[18]

The American public also supports policies that protect consumers from companies taking advantage of this support. For example, the U.S. Food and Drug Administration establishes the level of testing for safety and efficacy that pharmaceutical companies must conduct to avoid patient harm. Policies such as The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, support innovation and competition.

***Finally, proposed reforms are further targeted to mitigate potential harms to innovation.***

Empirical evidence suggests even many of the most expensive drugs make in revenue the full costs of research and development within 5 years post-launch.[19] Under currently discussed

---

[15] Lerner J. *150 Years of Patent Protection*. American Economic Review. 92(2): 221-225. May 2002.

[16] Nayak RK, Avorn J, Kesselheim AS. *Public sector financial support for late stage discovery of new drugs in the United States: cohort study.* BMJ. 367(l5766). September 2019.

[17] Congressional Research Service. *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials.* March 2021.

[18] Hall B, Lerner J. *The Financing of R&D and Innovation*. Chapter 14 in **Handbook of the Economics of Innovation**, vol. 1: pp. 609-639. 2010.

[19] United States Government Accountability Office. *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*. GAO-18-40. November 2017.

reforms, drugs are only eligible for Medicare price negotiation after being on the U.S. market for more than a decade. Therefore, the proposed reforms give manufacturers plenty of time to make profits on new drugs while reducing the incentives companies currently face to forestall competition. Reform's focus on older drugs a decade or more post-launch for negotiation obviates another extreme argument the industry propounded earlier in the debate, that companies will refrain from launching their products in the U.S. if they are subject to negotiation.

## THERE IS A STRONG EVIDENCE BASE FOR THE REFORMS CURRENTLY PROPOSED

### *U.S. pharmaceutical spending levels and trends*

There were 6.3 billion prescription dispensed in the U.S. market in 2020. Older Americans use most dispensed prescription drugs and polypharmacy is common. Nearly 7 in 10 adults aged 40–79 used at least 1 prescription drug in the past 30 days in the United States (69.0%) and around 1 in 5 used at least 5 prescription drugs (22.4%).[20]

U.S. pharmaceutical spending currently represents approximately 14% of overall healthcare spending,[21] including 4% of spending in non-retail outpatient clinics and hospital settings. Spending on pharmaceuticals has risen by 20% over the past 10 years; an average of 2% per year.[22]

U.S. spending on pharmaceuticals is forecast to grow 0–3% CAGR over the next 5 years. To put these figures in broader context, industry reports expect global medicine spending through 2025 to amount to about $1.6 trillion. Projected global spending on pharmaceuticals by IQVIA, the industry gold standard, is $88 billion higher than their pre-COVID outlook.

Two types of on patent 'branded' pharmaceuticals contribute substantively to drug spending growth: new drugs and the expanded use of existing drugs. Also notable is that specialty drugs, including those in the protected Part D categories of oncology and immunology, have been

[20] Hales CM, Servais J, Martin CB, Kohen D. *Prescription drug use among adults aged 40–79 in the United States and Canada.* NCHS (National Center for Health Statistics) Data Brief. 347. August 2019.

[21] Conti RM, Turner A, Hughes-Cromwick P. *Projections of US Prescription Drug Spending and Key Policy Implications.* JAMA Health Forum. 2(1): e201613. January 2021.

[22] IQVIA Institute. *The Use of Medicines in the United States*. May 2021.

increasing as a share of spending. In 2020, specialty drugs comprised 47% of spending, up from 24% 10 years earlier. Specialty drug spending is expected to increase to 60% of total pharmaceutical spending in the U.S. by 2025.

According to a recent analysis by the Kaiser Family Foundation, half of all Part D covered drugs (50% of 3,343 drugs) and nearly half of all Part B covered drugs (48% of 568 drugs) had price increases greater than inflation between July 2019 and July 2020, which was 1.0.[23] Moreover, 23 of the top 25 Part D drugs and 16 of the top 25 Part B drugs had price increases above inflation between 2019 and 2020.[24] See Figure 2 for details.

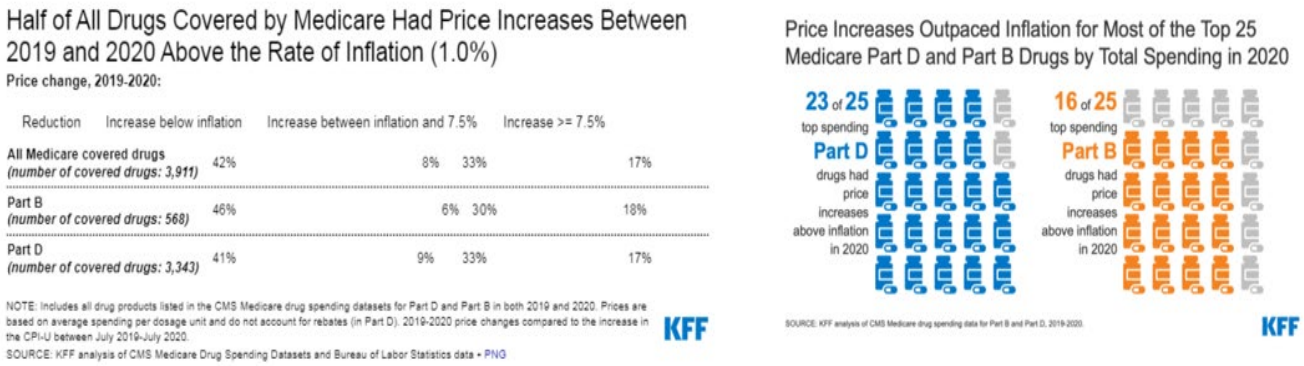


***Figure 2**: Price Trends Paid by Medicare Beneficiaries Outpace Inflation.*

***High pharmaceutical prices and price inflation is a result of pharmaceutical companies breaking the social compact with the American public.***

Paying high prices for new pharmaceuticals is one way among many the American public encourages innovation. The counterweight to paying high prices is competition. Our system relies on competition after patents and other exclusivities expire on pharmaceuticals to bring

[23] Cubanski J, Neumann T. *Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020*. KFF Issue Brief. February 2022.

[24] Annual price increases are also inconsistent with the notion that prices are optimized for profit maximization at launch and appear unrelated to approval of supplemental indications, additional information about the benefits associated with treatment, and potential increases in manufacturing costs. See Bennette CS, Richards C, Sullivan SD, Ramsey SD. *Steady Increase in Prices for Oral Anticancer Drugs after Market Launch Suggests a Lack of Competitive Pressure*. Health Affairs (Millwood). 35(5):805-12. May 2016.

down prices and reduce spending. We expect companies to move onto innovate the next opportunities.

Yet, there is mounting empirical evidence that this social contract has been violated by some pharmaceutical companies.[25] New reports released by the U.S. House of Representatives' Oversight Committee details drug companies egregious and widespread manipulation of our system to delay competition from lower-priced generics and biosimilars of such drugs a decade or more after launch.

Price inflation is the direct result of pharmaceutical companies ensuring their profitability in drugs by delaying competition.[26] The House Oversight's recent report on Copaxone, an MS drug, suggests Teva played many games to forestall competition, while raising prices.[27] Celgene and Bristol Myers Squibb's Revlimid,[28] a drug that treats blood cancers launched in the U.S. in 2005, and Abbvie's Humira, a drug that treats arthritis and other inflammatory diseases launched into the U.S. market in 2002 has only recently faced competition. The pricing of these drugs in the U.S. has also increased since launch. A one-month supply of Revlimid pills now costs approximately $23,000 and a one-month supply of Humira injections costs approximately $10,000.

Moreover, the significant revenues reaped from these activities by the pharmaceutical companies are not primarily directed into research and development efforts. Instead, high prices, price

[25] For an explanation and summary of activities, see Statement by Michael A. Carrier to House Judiciary Committee (Subcommittee on Antitrust, Commercial and Administrative Law). House Subcommittee of House Judiciary Committee hearing. April 27, 2021.

[26] See for example, U.S. House of Representatives. *Drug Pricing Investigation AbbVie—Humira and Imbruvica*. Staff Report Committee on Oversight and Reform. May 2021.

The report states "New documents show that these settlements allowed AbbVie to delay competition far beyond what its own internal assessments of the strength of its patent portfolio predicted. In 2014, AbbVie's executives estimated that three to five biosimilar competitors would enter the market by the first quarter of 2017. AbbVie ultimately entered into settlement agreements with four of these competitors, delaying their entry into the market until 2023."

[27] U.S. House of Representatives. *Drug Pricing Investigation Teva—Copaxone*. Staff Report Committee on Oversight and Reform. September 2020.

[28] U.S. House of Representatives. *Drug Pricing Investigation Celgene and Bristol Myers Squibb—Revlimid*. Staff Report Committee on Oversight and Reform. September 2020.

increases and significant profits lead to higher executive compensation, dividend payments to stockholders and stock buybacks.[29]

***Why should Americans always have to pay the highest prices for pharmaceuticals?***

The U.S. is the largest market for prescription drugs in the world.[30] Approximately 40% of all prescription drug sales is in the U.S. market.[31] Corporate profits off the sale of prescription drugs are expected to reach over $1.3 trillion in 2021 and the top pharmaceutical companies are more profitable than those in non-pharmaceutical industries, including the technology giants Apple and Amazon.[32]

Pharmaceutical companies strongly prefer to launch new drugs in the U.S. where they fetch the highest prices.[33] Unlike other OECD countries, U.S. payers place no limits on the prices pharmaceutical companies can charge for drugs while they are protected from competition by patents and market exclusivities. These features lead drug companies to set high prices well above standard measures of clinical and economic benefit and pursue price increases that greatly exceed the general rate of inflation.[34] In fact, evidence suggests pharmaceutical companies target U.S. payers for drug price increases, while at the same time decreasing prices in other countries. Celgene's Revlimid and Teva's Copaxone took significant price increases to increase revenue in the U.S. at the same time as cutting prices in other countries. In a new study of cancer drugs, pharmaceutical companies are observed to increase prices in the U.S. that exceed inflation, while

[29] U.S. House of Representatives. *Industry Spending on Buybacks, Dividends, and Executive Compensation*. Staff Report Committee on Oversight and Reform. July 2021.

[30] International Federation of Pharmaceutical Manufacturers & Associations. *The Pharmaceutical Industry and Global Health. Facts and Figures 2021.* April 2021.

[31] United States Government Accountability Office. *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*. GAO-18-40. November 2017.

[32] Ledley FD, McCoy SS, Vaughan G, Cleary EG. *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*. JAMA. 323(9): 834-843. March 2020.

[33] National Academies of Sciences, Engineering, and Medicine. **Making Medicines Affordable: a National Imperative**. Washington, DC: National Academies Press. 2018.

[34] Schondelmeyer SW, Purvis L. *Rx Price Watch*: *Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2019*. AARP Public Policy Institute. November 2019.

at the same time prices stayed stable or declined in Germany and Switzerland.[35] When Abbvie pursued price increases on Humira, it claimed it did so because it was being 'forced' to reduce prices in other countries. While it may make common sense for firm to offset 'losses' with gains, this pricing behavior by pharmaceutical companies controverts the companies' own statements to Congress suggesting the prices of prescription drugs in the U.S. are untethered to those in other countries.[36]

While many expensive biologics remain without competition in the U.S., inexpensive biosimilars have been available since 2006 within Europe. In 2021, biologics represented 34% of spending in Europe on pharmaceuticals.[37] Despite 2020 being impacted by the COVID-19 pandemic, the volume of biosimilar prescribing in the EU is estimated to have generated a record high in savings from biosimilar competition, of €5.7 billion (about $6.8 billion USD) in savings versus the pre-biosimilar cost of the originator by 2020.

When reforms reduce the option for companies to pursue such behavior, pharmaceutical companies will move onto seek revenue by investing in innovative treatments. When the Supreme Court ruled that companies could no longer pay to delay generic entry, the companies that were doing that instead started to pour money into research and development.[38]

***American public 'financial toxicity' related to high and growing pharmaceutical prices.***

Expanded pharmaceutical insurance coverage has benefited many. Yet, too many seniors are locked out of the promise of pharmaceuticals currently available. The prices of some drugs seniors need to stay alive – such as Tysabri and Rebif for MS and Revlimid and Imbruvica for cancer - are now so high that they exceed the costs of a private university education. A recent survey suggests 18 million Americans

[35] Vokinger KN, Hwang TJ, Carl DL, Laube Y, Ludwig W-D, Naci H, Kesselheim AS. *Price changes and within-class competition of cancer drugs in the USA and Europe: a comparative analysis*. The Lancet Oncology. March 2022.

[36] Pharmaceutical company executives have dismissed this as a possibility, stating repeatedly that there is no direct relationship between U.S. drug prices and foreign prices. See U.S. House of Representatives. *Drug Pricing Investigation AbbVie—Humira and Imbruvica*. Staff Report Committee on Oversight and Reform. May 2021; and PhRMA. Complaint, in Litigation Challenging Legality of the Administration's Most Favored Nation Rule. December 4, 2020.

[37] IQVIA. *The Impact of Biosimilar Competition in Europe*. December 2021.

[38] Li X, Lo AW, Thakor RT. *Paying Off The Competition: Market Power And Innovation Incentives*. NBER Working Paper 28964. June 2021.

can't pay for the drugs they need.[39] The substantial costs of cancer care on patients are now so common they are termed 'financial' toxicity, a play on the commonly encountered medical toxicities patients experience with chemotherapy.[40]

My own work on this topic focuses on the blood cancers, multiple myeloma (MM) and chronic lymphocytic leukemia (CLL), which represent a small percentage of all cancers, but for which treatment costs are among the highest. Treatment advances in both cancer types have resulted in greater survivorship and improved quality of life for patients. Nevertheless, my research group has found that close to half of the blood cancer patients we surveyed report financial difficulties associated with cancer treatment. Reports of financial burden commonly include an inability to pay for basic necessities such as food and utility bills, the presence of medical debt and high out of pocket burdens relative to income.

There is also underuse. In my study, reports of financial burden are associated with worrisome deficits in care - medication non-adherence including skipping medication, taking less medication or not filling recommended prescriptions at all. In other work, while new drugs have transformed calls for the elimination of HIV[41] and the hepatitis C virus by 2030[42] into tangible goals, these drugs remain underused.

The status quo also imposes costs on taxpayers. Finally, these behaviors harm workers in the form of higher health insurance premiums and lower wages.

**CONCLUSIONS**

In summary, the consequences of continued Congressional inaction on pharmaceutical prices are simply untenable. Currently, 29% of Americans either can't afford their drugs or are rationing their drugs. Proposed reforms will not harm innovation. Proposed reforms will not alter the

---

[39] Witters D. *In U.S., an Estimated 18 Million Can't Pay for Needed Drugs*. Gallup. September 21, 2021.

[40] National Institutes of Health, National Cancer Institute. *Financial Toxicity Associated with Cancer Care – Background and Prevalence.*

[41] U.S. Department of Health and Human Services. *HIV National Strategic Plan: A Roadmap to End the Epidemic for the United States 2021-2025*. 2021.

[42] Hofmeister MG, et al. *Estimating Prevalence of Hepatitis C Virus Infection in the United States, 2013-2016*. Hepatology. 69: 1020-1031. November 2018; Centers for Disease Control and Prevention. *CDC Estimates Nearly 2.4 Million Americans Living with Hepatitis C.* Press Release. November 2018.

American public's substantial support for basic science, product development, strong universities, nor a highly favorable funding environment. Proposed reforms will not alter patents or market exclusivities pharmaceutical companies selling their products to American consumers currently enjoy nor reduce insurance coverage for these products.

After reform, the U.S. will remain the largest market for pharmaceuticals in the world. After reform, the U.S. pharmaceutical industry will remain the most profitable sector in our economy. After reform, the U.S. economy will remain the most highly supportive of innovation activity globally. Consequently, pharmaceutical companies will continue to invest in innovative products and investors will remain invested in this sector.

What these reforms do represent is a modest step towards limiting the economic burden placed on Americans from pharmaceutical companies' manipulations of our system. In doing so, they help restore the social compact between pharmaceutical companies and the American public.