THE IMPACT OF HR 5376 ON ANTIVIRAL INNOVATION AND PATIENT HEALTH

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Issue Brief:
The Impact of HR 5376 on Antiviral Innovation and Patient Health*

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Executive Summary

This issue brief reviews the evidence-base to assess the impact HR 5376 on innovation into antivirals and patient health. A large academic literature estimates the effect of future drug revenues on R&D spending and finds that on average that a 1 percent reduction in revenue leads to a 1.5 percent reduction in R&D activity. We find that HR5376 will reduce revenues by 15 percent through 2039 and therefore that the evidence base predicts that R&D spending on antivirals will fall about 23.1 percent, amounting to $165 billion. We find that this cut in R&D activity leads to 21 to 43 fewer new antivirals, dependent on methodologies used to estimate new drugs from R&D spending. This drop in new antiviral drugs is predicted to generate a loss of 82.4 million life years, about 7.7 times as large as the life years lost from COVID-19 in the US to date. For HIV, the largest antiviral class, we find 4 to 9 fewer new drug approvals during that period with 2.5 to 5.1 million lost life years for HIV patients, about 24 to 48 percent of COVID-19 losses in the US to date. These estimated effects on new number of drugs are about 37 to 68 times larger than projected by CBO which finds that only about 5 fewer total drugs will be lost until 2039, equaling a 0.63 percent reduction. In addition, we find that the changes in the catastrophic phase of Medicare Part D will add additional negative impact on antivirals as they are often for chronic conditions such as HIV that involve large annual spending. The incentives for the rapid response in antivirals we saw in response to the COVID-19 pandemic would be greatly reduced under HR 5376.

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Section 1: Introduction

A national debate has emerged again about the effect of price controls on pharmaceutical innovation. Many proponents of price controls for pharmaceutical drugs argue that they have negligible effects on innovation while opponents argue they will lead to a significant number of fewer new drugs delaying treatment for millions of Americans. This issue brief attempts to provide insight into the quantitative effects of the most recent price control proposal in HR 5376 on antiviral innovation and patient health by analyzing how the implications of it can be informed by basic economics and the prevailing empirical evidence base on innovation.

Section 2: Evidence Base on Revenue Effects on Innovation

Biopharmaceutical companies routinely project future market size and profits for their products to determine the rate of return on investment (ROI) that drives R&D funding. A large body of evidence suggests that these market practices translate into a predictable positive relationship between realized revenues and R&D spending in the economy in general, and for biomedical innovation in particular.

A set of papers looks at the expansion of the Medicare prescription drug benefit, Medicare Part D, which provides the most relevant evidence for assessing the revenue effects of Medicare policy changes. They find that companies recognized this expansion and increased innovation in drugs treating diseases prevalent in the elderly population more so than innovation in non-elderly diseases (Blume-Kohout and Sood 2013). Quantifying that relationship, a 1 percent increase in market size due to Medicare Part D leads to a 2.8 percent increase in new drug approvals.[1] Another often cited paper finds a 1 percent increase in potential market size leads to a 4-6 percent increase in the entry of new drugs (Acemoglu and Linn 2004) in the US. Other studies show that a 1 percent increase in price leads to a 0.22-1.33 percent increase in innovation.[2]

We synthesized the evidence base by computing the average R&D elasticity with respect to revenue estimated from 10 different studies looking at the effect of a price change, expected market, and overall revenue on R&D. Table 1 illustrates the elasticities used from each paper, and the average elasticity across these 10 studies is 1.54.

Table 1. Elasticities used from the 10 Papers Identified

Paper	Elasticity
Acemoglu and Linn (2004)	5
Dubois et al (2015)	0.23
Finkelstein (2004)	2.75
Blume-Kohout and Sood (2013)	2.8
Filson (2012)	1
Lichtenberg (2005)	1.3

[1] Finkelstein (2004) finds a similar effect of a 1 percent increase in the utilization of preexisting vaccines through public policy increases new clinical trials for new vaccines by 2.5-2.75 percent.

[2] Dubois et al (2015) uses a multi-country sample to look at expected market size innovation. Giacotto, Santerre, and Vernon (2005) look at drug prices and R&D spending, Vernon (2005) look at potential cash flow and R&D spending, Civan and Maloney (2009) look at entry price and drugs in the pipeline, and Abbott and Vernon (2007) look at price and R&D projects undertaken.

Vernon (2005)	0.22
Giacotto, Santerre, and Vernon (2005)	0.58
Civan and Maloney (2009)	0.5
Abbott and Vernon (2007)	1
Mean	1.54

Note: Acemoglu and Linn (2004) find an elasticity range of 4-6 based on if all approved including generics are included or not. We take the midpoint of this range. Abbott and Vernon (2007) find a price cut of 40 to 50 percent lowers R&D by 30 to 60 percent. Taking the midpoint of these numbers gives a 45 percent price cut leads to a 45 percent decrease in R&D, or an elasticity of 1.

To assess the impact on the number of new drugs from reductions in R&D spending, a common approach is to divide the reduction in R&D spending by an estimate of the costs of bringing a drug to market. This is a useful approach and implies a proportional reduction in new drugs to the reduction in R&D spending regardless of the cost-per-drug. In other words, using this methodology, a 10 percent reduction in R&D spending leads to 10 percent fewer drugs regardless of the cost per drug estimate used. The elasticity of R&D spending with respect to revenue in this case therefore also represents the elasticity of new drugs to revenue.

Section 3: The Impact of the Drug Pricing Provisions in HR 5376

On November 19, the House of Representatives passed HR 5376. The drug pricing section of this bill has three main provisions: 1. allows Medicare to negotiate drug prices after a certain number of years of initial exclusivity, 2. drug rebates to make sure drug prices do not increase more than the rate of inflation, and 3. redesign Part D coverage capping patient out-of-pocket costs. In particular, certain single-source brand drugs are priced for Medicare beneficiaries by requiring drug manufacturers to "negotiate" drug prices with the Secretary of Health and Human Services. A prohibitive excise tax of 65 to 95 percent will be applied to a company's annual gross sales if they refuse to negotiate, making the requirement largely equivalent to mandatory price controls. In the Appendix we have a discussion noting the differences between HR3 and HR 5376.

We estimate these changes will have substantial innovation effects. We find that revenues will fall to generate a 23 percent reduction in innovation, $165 billion, through 2039 leading to 21 fewer new antivirals. Estimating the impact on new drugs from using the approach of using cost estimates of bringing a drug to market, the $165 billion in lost R&D spending could lead to as many as 43 fewer new antiviral approvals. We find that this leads to a loss of 82.4 million life years, more than 7 times as large as the 10.7 million life years lost from COVID-19 in the US to date. For HIV, the largest antiviral class, we find 4 to 9 fewer new drug approvals during that period with 2.5 to 5.1 million lost life years for HIV patients, about 24 to 48 percent as large as COVID-19 in the US to date.

3. 1 The Impact of the HR 5376 on Antiviral Innovation

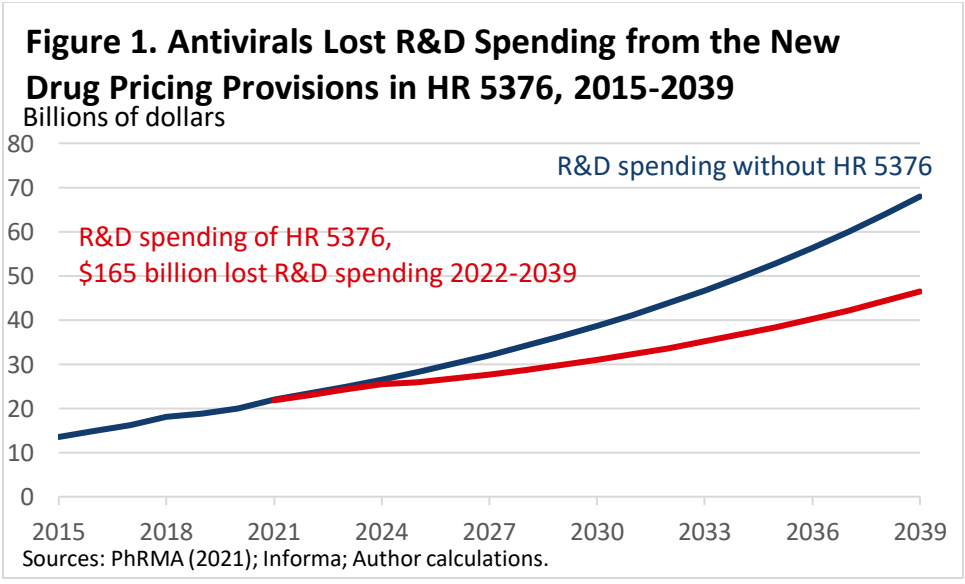
We find that revenues will fall 15 percent under HR 5376 and using the average elasticity of R&D to revenues discussed applied to antivirals, this would mean $165 billion in lost R&D spending, a 23.1 percent drop,

resulting in 21 fewer antiviral drugs approved through 2039 with a proportionate impact on new drugs. As in CEA (2019), we assume every $2,000 in lost R&D spending leads to 1 loss of life year, so losing $165 billion in R&D spending on antivirals leads to 82.4 million lost life years. This is 7.7 times as large as the estimated lost life years from COVID-19. These estimated effects are about 37 times larger than the corresponding effects of CBO (2021) and differ because we find larger revenue effects and we use the scientific evidence base on the impact of those revenue effects on R&D.

This is our preferred estimate, but an alternative way to calculate the lost new antiviral drugs is dividing the lost R&D spending by the cost of making the drug. This methodology possibly accounts for the loss in expected revenue from the shortened market life as well since it is factoring in the cost of development. DiMasi et al (2016) find a $2.9 billion (adjusted to 2020 dollars) cost to bring a drug to market. We assume this increases 2 percent due to inflation every year through 2039. Applying this growing cost to the timeseries in the drop in R&D spending in the below paragraph shows 43 fewer antiviral drug approvals for an upper bound effect on antivirals.

We create antiviral R&D spending over time by taking a time series from PhRMA's 2021 Membership Survey showing pharmaceutical R&D spending from 2000-2019 and calculated the compound annual growth rate to get a trend for expected R&D spending through 2039. Infectious diseases are estimated to make up about 22.7 percent of the pharmaceutical pipeline (Access to Medicine 2018) and assume new drug approvals for antivirals will be affected proportionally. We scale PhRMA's R&D spending timeseries down by the share of antivirals in the pipeline to get the level of R&D spending on antivirals for prevention and therapeutics. We then applied the impact on R&D to each year and summed these values to calculate lost R&D spending through 2039. R&D spending for antivirals will fall immediately due to HR 5376 and lead to a $165 billion drop through 2039 (Figure 1). Put another way, R&D spending under the amended HR 5376 will lag R&D spending without HR 5376 by up to 6 years meaning new drug treatments that would become available without HR 5376 will now be delayed 6 years.

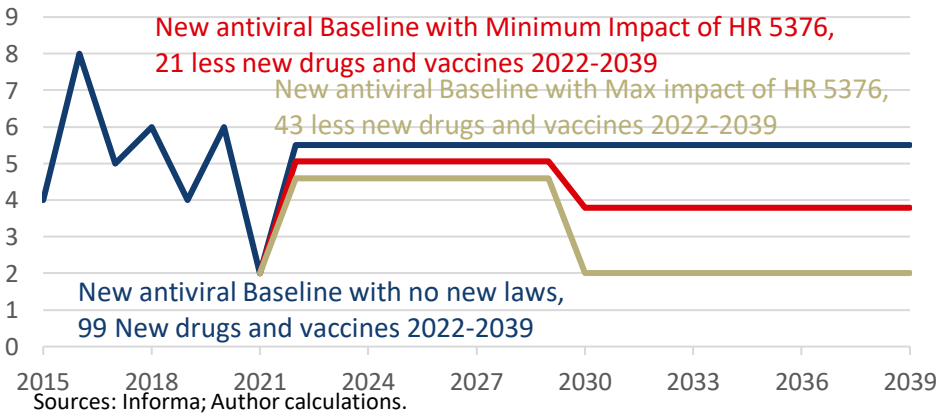
Figure 1. Antivirals Lost R&D Spending from the New Drug Pricing Provisions in HR 5376, 2015-2039



Sources: PhRMA (2021); Informa; Author calculations.

This drop in R&D spending will lead to a resulting decline in antiviral new drug approvals. We created a baseline estimate of annual antiviral new drug approvals using Informa data during 2015-20 which finds that there were about 6 new drug approvals annually for antivirals during that period. Using that level of new approvals as the status quo in absence of HR 5376, we find that the 23.1 reduction in innovation from HR 5376 leads to 21 fewer new drug approvals through 2039 with most of the decline occurring from 2030 to 2039 due to long drug development processes (Figure 2). We find the maximum impact of HR 5376 could be as high as 43 fewer new antiviral drug approvals by dividing the lost R&D spending per year by the $2.9 billion cost of developing a new drug from DiMasi et al (2016) and increase this annually by expected inflation of 2 percent.[3] CBO (2019) points out that lower R&D spending will take time to be reflected in new drug approvals due to long development process.[4] In other words, if R&D spending falls today most current projects will still be completed, but most likely with some sort of delay making new drug approvals pushed back. Additionally, new drug development projects will be foregone today and in the future leading to less new drug approvals in the future. They show 18.9 percent of their total estimate will occur through 2029 and 81.1 percent of their total estimate from 2030 to 2039. Through 2029, new drug approvals of antivirals will only be about 1 drug lower annually, but this grows to 2 to 3 fewer drugs annually by 2030.

Figure 2. Antiviral New Drug Approvals Lost from the New Drug Pricing Provision in HR 5376, 2015-2039



Sources: Informa; Author calculations.
Note: 2021 is only with approved drugs through September.

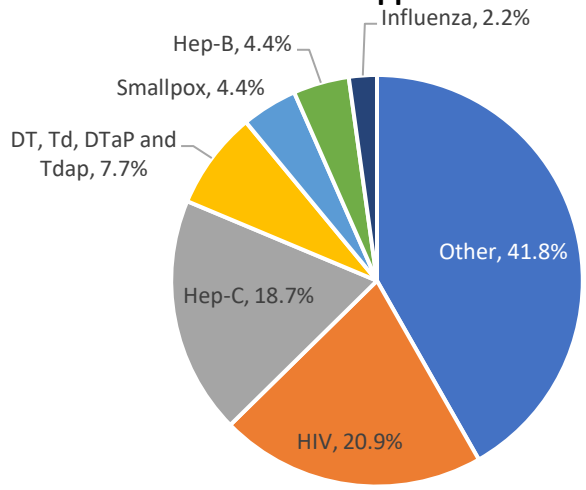
[3] Dubois et al (2015) show the needed revenue for one new antiviral (as part of the group "Anti-infectives for systemic use") is higher, $3.0 billion, than the average drug, $2.5 billion, illustrating how this disease group will be impacted disproportionately as it is more responsive to changes in market conditions.

[4] Blume-Kahoot and Sood (2013) also discuss this phenomenon through a changing elasticity overtime. Basically, in the short-run, revenue effects have lower impact which increases overtime.

3.2 Innovation and Health Effects on the largest antiviral class of HIV

The FDA has approved 91 drugs for 33 different diseases treated by an antiviral from 2000 to 2019. Figure 3 shows the breakdown of the number of drugs approved across all the diseases. HIV and Hep-C preventions and treatments account for 39.6 percent of all antivirals approved this century.

Figure 3. Disease Share of FDA Approved Antivirals, 2000-2019



Sources:Informa; Author calculations.

To consider the impact on an important antiviral class, we consider the innovation and patient health outcomes effects for HIV, the disease with the most approvals. We use data from Informa to calculate the number of new drugs approvals to prevent and treat HIV by the FDA since 1995. We take the average number of new HIV drugs from 2013-2019 to obtain a baseline of an expected 1.1 new HIV drugs approved annually through 2039.[5] Applying the same R&D reduction methodology as above to this baseline implies 4 to 9 fewer new HIV drug approvals will occur through 2039. Assuming CBO's (2019) estimated lag between loss of R&D spending and new drug approvals, new drug approvals will fall by 1 to 2 approvals during the entire period 2022 to 2029 and 3 to 7 approvals during the entire period 2030 to 2039 as seen in Table 2.

Table 2. Impact of Price Controls on R&D for HIV Drugs, 2022-2039

	Lower End of Range	Upper End of Range
Impact on R&D (%)	-23.1%	-42.5%
Impact on New Drug Approvals	-4	-9
2022-2029	-1	-2
2030-2039	-3	-7
Life Years Lost through 2039	2.5	5.1

[5] Informa data shows over 20 clinical trials are ongoing and one drug is under review at the FDA for HIV.

(millions)		
Share of Life Years Lost to COVID (%)	23.7%	47.7%

Sources: CBO (2019); CDC; Papers cited in table 1; Author calculations.
Note: The 42.5 percent drop in R&D comes from the lost new drug approvals using the cost of developing a drug methodology outlined in section 3.1.

These significant drops in new drug approvals will lead to delays in needed drug therapies, resulting in worse health outcomes for patients. Table 2 also summarizes our findings on the health impact of price controls on the HIV Class alone. We find that losing 4 to 9 new drug approvals through 2039 would imply a loss in 2.5 to 5.1 million life years. Updating the COVID-19 life years lost from Philipson and Durie (2021), we calculated COVID-19 has resulted in 10.7 million life years lost through November 17, 2021. This implies that the life years lost from price controls for HIV patients would be about 23.7 to 47.7 percent as large as COVID-19. These results can be applied to similar price control policy proposals that have similar global revenue impacts. Price controls will have a negative impact on innovation that would delay breakthrough treatments for millions of Americans. Further, as the United States provides the bulk of returns to innovation, these delays in treatments will have global effects and raise development times for national and global pandemic response initiatives.

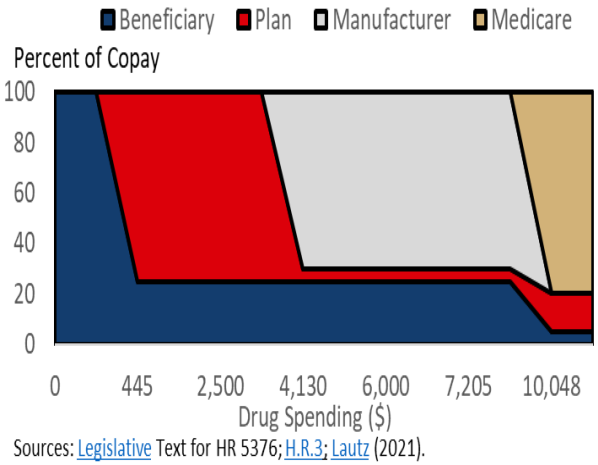
The health findings of Table 2 are calculated as follows. We calculated the life years gained per HIV drug approved from 1995 to 2019 and applied this to the lost number of new HIV drug approvals to get the overall life-years lost. We estimated a lower bound on the life years gained from new HIV drugs by finding the change in life expectancy from 1996, the year HAART was marketed, and 2019. We calculated how much longer people lived in 2019 compared to 1996, based on CDC's estimates, and applied that to the average age of infection based on CDC's age distribution of new infections in 2019.[6] The difference between these 2 numbers gives us a 14.9 year change in life expectancy between new infections in 1996 and 2019.[7] With 1.2 million people currently living with HIV in the US, according to the CDC, we multiply this by the increase in life expectancy to get the number of life years gained. This is a lower bound on life years gained as some individuals today are still living due to the new innovations since 1996. We use Informa data to find 30 new HIV drug approvals occurred from 1995-2019 indicating about 594,118 life years gained per new drug approval. Multiplying this by the number of new drug approvals lost from HR 5376 gives us our final loss in life years due to this bill.

[6] Life expectancy for an HIV patient in 1996, the year before new life-saving treatment was FDA approved, was 4 years (39.5 – 35.5 years) and 18.8 years in 2019 (54.4 – 35.5), based on our methodology.
[7] This estimate is consistent with Lichtenberg (2006) HIV patients' life expectancy increased 13.4 years due to drug innovation from 1993-2001. Samji et al (2013) also show life expectancy for HIV positive patients in the United States and Canada increased 15.3 years from 2000 to 2007 due to drug innovation. Murrell (2020), Forsythe et al (2019) and Nakagawa et al (2013) cite other research and perform their own analysis showing the value of new HIV treatment finding even higher estimates of life expectancy for HIV patients receiving treatment, as much as 31 years.

3.3 Impact on Antivirals from Restructuring Copays in Medicare Part D

Another large aspect of the HR 5376 is the redesign of Medicare Part D. Figure 4 illustrates the changing shares of copays by stakeholders for brand name drugs for patients not eligible for the low-income subsidy. HR 5376 would put a $2,000 out-of-pocket cap on drug spending for beneficiaries. HR 5376 eliminates the coverage gap (doughnut hole) and takes away the beneficiary's contributions in the catastrophic phase. The catastrophic phase is reallocated away from government reinsurance and beneficiaries towards companies and plans. The uncapped and increased company share hits innovation into antivirals disproportionally serving chronic disease patients such as e.g., those with HIV falling into the larger spending categories.

Figure 4. Share of Brand Drug Copays by Payer under Current Law



Sources: Legislative Text for HR 5376; H.R.3; Lautz (2021).

Share of Brand Drug Copays by Payer under HR 5376

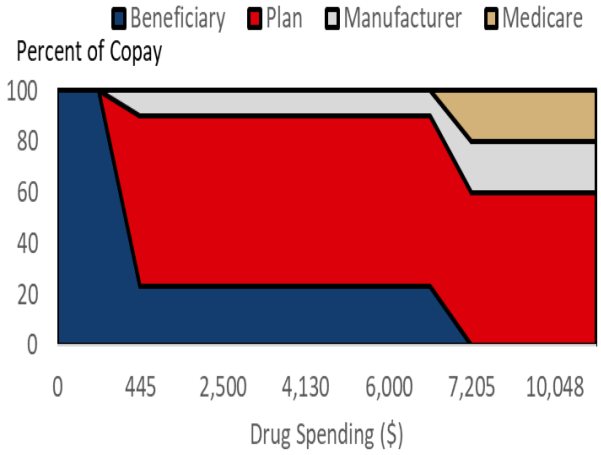
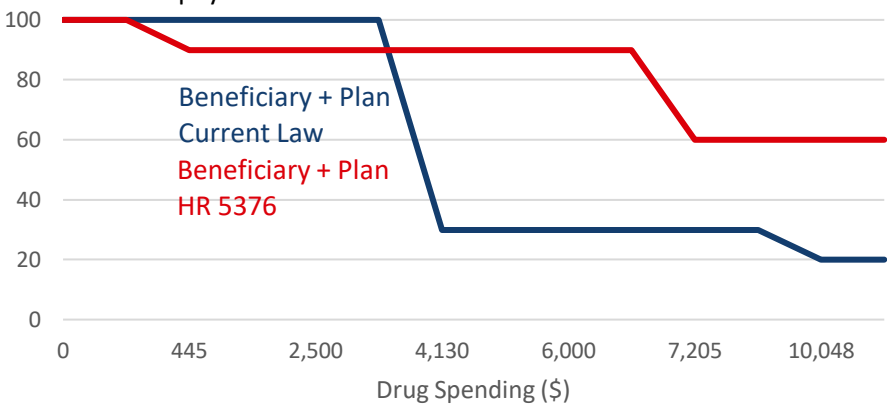


Figure 5 illustrates the dramatic changes on high expenses covered by patients, either through copay shares directly or through premiums through the plan shares. The figure depicts the share of spending covered by patients or plans under the status quo and HR 5376 for non-low-income subsidy individuals. The Medicare reinsurance share of the catastrophic phase changes from 80 percent under current law to 20 percent for brand name drugs.

Figure 5. Beneficiary and Plan Share of Copays for Brand Drugs under Current Law and HR 5376



Sources: Legislative Text for HR 5376; H.R.3; Lautz (2021).

In 2017, the catastrophic phase accounted for about 40 percent of total Part D spending, $59 billion, and growing for non-low-income subsidy eligible patients (Sen et al 2020). Assuming only brand drugs reach the catastrophic phase, if the new design was law in 2017, Medicare's reinsurance cost burden would have been $35.4 billion lower, going from $47.2 billion down to $11.8 billion. The plan's cost burden just in the catastrophic phase would increase from $8.9 billion to $38.4 billion. The rest of the catastrophic phase, 20 percent, would be paid by the manufacturer as they go from paying nothing to $11.8 billion in this example. With the higher cost burden on plans, this will lead to higher premiums for beneficiaries reducing savings from the new lower cap and the elimination of the coverage gap. It is unclear whether the small increases in proposed premium subsidies will cover the additional spending induced by the larger plan costs and lower patient copays.

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Appendix: Notable Differences Between HR3 and HR 5376

HR 5376 is different from another bill House Leadership previously proposed for inclusion in BBBA, HR3, the Lower Drug Costs Now Act. HR 5376 and the original HR3 bill have similar features with different crucial details for drug price negotiations and the inflation cap. Table 3 illustrates these differences. A key difference is in HR3 the negotiated price for Medicare would be applied to commercial plans, while under the HR 5376, the negotiated price still has impacts on non-negotiated drugs through several channels. One is competing drugs to those negotiated whose price face downward price pressure, another is through Medicaid best price rules, and a third is through discounts in the 340B to providers. Another key difference for the drug price negotiations is changing the criteria of what drugs can be negotiated and when they are negotiated. In HR 5376, only drugs that are single-sourced and have passed certain exclusivity thresholds are included, independent of patent and data exclusivity status.

Small molecule drugs must have had at least 9 years of exclusivity and biologics at least 13 years. Most antivirals are small molecule drugs, so they will be disproportionally affected which may prioritize innovation into biologic drugs over small molecule drugs due to the 13-year market life for biologics. We examine the patent life and data exclusivity of the top 20 drugs by total Medicare Part B and D spending finding the plan would shorten their market life by 2-4 years on average.

Another aspect of HR 5376 is the speed at which drug prices can be negotiated. Under HR3, the Secretary of HHS could negotiate the price of 25 drugs in year 1 and 50 new drugs annually going forward versus 10 in the first year of HR 5376 rising to 20 new drugs annually after 2 more years. This means under HR3, as many as 225 drugs could be negotiated in the first 5 years versus under HR 5376, which would take 12 years to reach the same number of drugs. This will slow down the pace of revenue losses caused by the price setting provisions in HR 5376, but still yield significant revenue losses.

Table 3. Differences Between HR3 and HR 5376

	HR3	HR 5376
Which drugs can be negotiated?	Single-Source and brand name drugs. Must be either in the top 125 drugs of either national health spending or Medicare spending	Single-Source drugs. Small molecule drugs: must be at least 9 years since the start of the exclusivity period. Biologic drugs: must be at 13 years since the start of the exclusivity period. Drugs with highest total spending for Parts B and D, contributing more than $200 million
What is the Price Cap?	Markup 20% of the average price in 6 foreign countries.	If small molecule and 9-12 years past exclusivity: 75% of 2020 non-federal AMP 13-16 years past exclusivity: 65% of 2020 non-federal AMP

		16+ years past exclusivity: 40% of 2020 non-federal AMP
How many drugs can be negotiated per year?	25 in 2024, 50 annually starting in 2025	10 in 2025, 15 in 2026, 15 in 2027, and 20 annually starting in 2028
What is the Excise Tax on drug revenue due to failure in agreeing to a price?	Up to 95%	Up to 95%
Who are Small Biotech carve-outs for and what are they?	None.	Companies with 80% or more of Medicare revenue coming from one drug with less than 1% of total Medicare spending. These companies do not have to undergo negotiations from 2025-2027. A 2-year phase in period when they do negotiate
Does this proposal limit price increases to inflation, and does it have a "look back" provision?	Yes, and Yes.	Yes, and no.
Part D Redesign	Increases manufacturer cost share in Initial Coverage Phase to 10%. Eliminates the Coverage Gap (donut hole). Eliminates beneficiary share of copay in Catastrophic phase. Increases plan (50%) and manufacturer (30%) share. Decreases Medicare Share (20%).	Increases manufacturer cost share in Initial Coverage Phase for brands to 10%. Eliminates the Coverage Gap (donut hole). Eliminates beneficiary share of copay in Catastrophic phase. Increases plan (60%) and manufacturer (20%) share for brands. Decreases Medicare reinsurance share (20%) for brands.