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Limits on H.R. 3's Ability to Protect Americans from Price Spikes

Many prescription drug corporations rely on increasing prices on existing products to boost revenues. For example, for the 45 top-selling drugs, more than half of all sales growth in the past three years was due to price increases.¹ H.R. 3 requires manufacturers to pay Medicare Part B and Part D rebates based on how much the average sales price (ASP) or the average manufacturer price (AMP) in the entire market, respectively, exceeds the inflation-adjusted benchmark price, multiplied by the volume sold to Medicare.²

$$(New\ ASP\ or\ AMP - Benchmark\ Price\ Inflation-Adjusted) \times Medicare\ Volume$$

This is an important feature, but it largely does not protect patients outside of Medicare. The effect of the rebate depends on the relative volume sold to Medicare. When Medicare does not represent a substantial segment of the market, the rebates will only apply to a limited set of sales, and not restrain private sector price spikes. When Medicare represents a substantial segment of the market, the rebates will apply to a larger set of sales and may reduce the incentive for some price increases, but still fail to constrain others.

H.R.3 would not constrain private sector price spikes when Medicare is not a dominant purchaser.

- Truvada, a medicine used to prevent and treat HIV, provides a salient example. From 2017 to 2018, Gilead Sciences increased the net price of Truvada by 23%. According to the Institute for Clinical and Economic Review, Truvada's price increase was "unsupported by new clinical evidence" and resulted in an additional \$550 million in drug spending.³
- Medicare accounts for 18 percent of U.S. Truvada sales.⁴ If Gilead increased its price by a similar amount under the H.R. 3 system, it would be required to pay a rebate only on a *small fraction* of its sales. Even if it paid this limited penalty, Gilead would likely still make more than \$400 million from its price increases.⁵

Even in cases where Medicare is a dominant purchaser, the bill may not constrain private sector price spikes.

- Consider a simplified hypothetical below for an average new cancer drug, which costs \$150,000. Suppose Medicare accounts for 70 percent of sales, and Medicare price increases occur at the level of inflation at 2% while private sector prices increase by 10% annually:

¹ BioPharma Dive (2018), <https://tinyurl.com/y2tyos5o>

² The baseline price for prescription drugs already on the market is the price from 2016. Part D rebates are based on the average manufacturer price (AMP) and Part B rebates are based on a figure derived from the average sales price (ASP). AMP and ASP are statutorily defined. AMP refers to the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. ASP refers to the average of all non-Federal sales to wholesalers net of discounts and rebates. 42 U.S.C. §1395w-3a and §1396r-8.

³ <https://icer-review.org/announcements/icer-identifies-costliest-us-drug-price-hikes-that-are-not-supported-by-new-clinical-evidence/>

⁴ This figure likely overestimates Medicare market share. In 2017, U.S. Truvada sales reached \$2.26 billion. Medicare, *before* rebates, spent \$417 million on the drug that year. <https://www.gilead.com/news-and-press/press-room/press-releases/2018/2/gilead-sciences-announces-fourth-quarter-and-full-year-2017-financial-results> and Medicare Part D Spending Dashboard.

⁵ This calculation is based on simplified assumptions about the relationship between list price, net price, average manufacturer price, and the inflation-adjusted price.

Table 1—Hypothetical Sales for a Cancer Drug, where Medicare is a Dominant Purchaser

Year	Private Price	Medicare Price	Private Units	Medicare Units	ASP	Required Rebate	Gross Revenue (Private)	Net Revenue (Private)	Expected Inflation-Adjusted Revenue (Private)	Excess Revenue Growth Beyond Inflation
1	150	150	3	7	150	-	450	450	-	-
2	165	153	3	7	156.6	25.2	495	469.8	459	10.8(2.4%)
3	181.5	156.1	3	7	163.7	53.4	544.5	491.1	468.2	22.9(4.9%)

- In this scenario, companies would profit less from price spiking, but they would still continue to benefit. Even after paying the Medicare rebate, a 10 percent price spike would increase net private sector revenue by 2.4%, relative to only increasing the price by the level of inflation. A second year of price increases would net an additional 4.9% in revenue beyond what the company would have made by limiting its private sector price increases to the level of inflation.
- In other words, a company would retain approximately 30% of its expected private sector revenues by spiking the price beyond the level of inflation in just two years
- When Medicare is a dominant purchaser, H.R.3 could reduce the incentive for some price increases. But it would not eliminate them, as illustrated above. The Congressional Budget Office noted that analogous inflation-rebate provisions in the Prescription Drug Pricing Reduction Act may have some impact on the private market, possibly referring to these effects.

H.R.3 price spike measurements may be susceptible to gaming.

H.R. 3 measures Part B price spikes using the average sales price (ASP), which reflects the *net price* after rebates. Companies could avoid paying H.R. 3 rebates by offsetting higher list prices through higher private rebates. While this would decrease costs for some patients, it would increase costs for patients facing high list prices, such as the uninsured and those who pay coinsurance.

Conversely, H.R. 3 measures Medicare Part D price spikes through changes in the average manufacturer price (AMP), which does not reflect rebates. Pharmaceutical companies could manipulate the system to avoid future Part D rebates by developing a “high-price high-rebate” launch model. New drugs could be introduced at the same net price by setting higher launch prices, offset by significant rebates. Over time, the companies could *decrease* the rebate, leading to a spike in the net price but not the AMP.

Proposed Amendment: Include protections against price spikes outside of Medicare.

While other federal health programs are protected against price increases that outpace inflation, H.R. 3 could be strengthened by expanding the inflationary rebate to sales in the private market, and by measuring Part B and Part D price spikes through both list prices and net prices. H.R. 3 could also incorporate an excise tax like the one articulated in H.R. 1093/S. 378, the *Stop Price Gouging Act*,⁶ in which revenues obtained through unjustified price increases in excess of inflation face a tax penalty beginning at 50% and reaching as high as 100%.

⁶ <https://www.congress.gov/bill/116th-congress/senate-bill/378>