Building on H.R. 3 to Provide More Relief to Patients

Issue: H.R. 3 provides limited leverage to reduce launch prices, which are increasing every year.

The plan requires the Secretary to select for negotiation drugs that lack competition with the greatest total cost to Medicare and the U.S. health system. These costs would accrue only after a product has been on market for some time. Ultimately, a drug that comes on the market in 2020 would not be required to be sold at a negotiated price until 2023, its fourth year of sales. However, a drug may be subject to negotiations sooner if upon its launch the Secretary determines that it is likely to generate high costs in the subsequent year, which would then deem it negotiation-eligible, and its launch price is higher than the median household income.

Launch prices are increasing in the United States and other wealthy countries every year. For example, Novartis recently launched a new gene therapy targeting a rare disorder for $2.1 million. The average price of new cancer medicines is $149,000. High launch prices are likely to influence the starting point of subsequent negotiations and thereby limit the plan's ultimate ability to reduce prices.

The clawback mechanism included in H.R. 3 requires manufacturers to pay back to the U.S. treasury revenues attributable to the extent by which U.S. prices are in excess of 200% of the first international reference price. The clawback does not effectively constrain launch prices for three reasons. First, the clawback would only apply to a limited set of sales, beginning in the year that the drug is selected for negotiation. Before the drug is selected, manufacturers may be able to charge any price they deem appropriate without restraint. Second, after the clawback is applied, drug corporations will have been

able to have price gouged U.S. consumers up to 200% of a price in other countries without penalty prior to the negotiated price being established. Finally, since the clawback is based on the first international price available, manufacturers could minimize exposure by launching products at higher prices in the first reference country.

Proposed amendment: Strengthen the revenue clawback mechanism to better address unreasonable pricing prior to negotiations.

To protect against price gouging in the years after a drug is introduced but before a negotiated price is finalized, the clawback should be strengthened to require pharmaceutical companies to pay back any excess revenues obtained, beginning at its *launch*.

Further, the clawback should apply to all eligible drugs when international reference price information becomes available, rather than only those that are selected for negotiation; and recoup all revenues to the extent they are above the 120% Average International Market price ceiling, rather than only those above 200%.

Finally, the clawback should be revised upward if new international pricing information becomes available that would result in a higher clawback subsequent to a clawback based on information from fewer than three reference countries.

Issue: Under H.R. 3, some exorbitantly priced medicines would not be eligible for negotiations.

H.R. 3 limits which drugs would be eligible for negotiation to the 125 single-source, covered Part D drugs that account for the greatest spending under that program, the 125 single-source drugs that account for the greatest spending in the United States, and all insulin products. Additionally, drugs that the Secretary determines are likely to generate costs that would qualify them as negotiation-eligible in the subsequent year may be deemed eligible at the time the Secretary makes that determination.

Under these narrow criteria, excessively priced drugs with smaller patient populations – including treatments for rare diseases – that are responsible for a lower share of health care system costs may be unlikely to qualify for negotiation under the plan. For example, although Martin Shkreli raised the price of Daraprim by 5000 percent, the drug would not be eligible for negotiation under this plan because it is only used by 2000 Americans and thus does not represent a high-share of drug spending.[1]

In addition, with the exception of insulin products, H.R. 3 does not allow negotiations for drugs that have any competitors. Once a drug that has undergone negotiations has two or more competitors on the market, the negotiated maximum fair price is also no longer enforced.

For example, EpiPen would not be eligible for negotiation because of the recent introduction of a competing product. Meaningful price decreases resulting from generic or biosimilar competition typically do not occur, however, until there are at least three competitors. One competitor may often be

[1] See Appendix for examples of prescription drugs that have very high prices, but may not be ineligible for negotiation because aggregate spending may not place them in the top 125 of Part D or the U.S. market at large.

insufficient for market forces to lower prices to a fair level. The EpiPen generic is listed at a price of $300.[2]

Proposed amendment: Expand the scope of negotiation-eligible drugs and, separately, automatically apply the International Price Index to all patented drugs.

H.R.3 should also expand the scope of negotiation-eligible drugs. It should remove spending requirements from negotiation eligibility and allow all drugs with limited or no competition to be eligible for negotiations. H.R. 3 should also eventually require negotiations for all new drugs with government-granted patent or exclusivity protections, or all such drugs that are listed at a price greater than $50,000 per year or course of treatment.

Applying the International Pricing Index does not require negotiation. It could be applied immediately to all patented drugs on the market, generating billions in savings. This could be enforced through the bill's existing mechanisms for enforcing compliance with negotiated prices.

Issue: H.R. 3 may not sufficiently reduce prices when there is not international pricing information available or when international prices are excessive.

In negotiations for a drug that lacks international pricing information, if a manufacturer offers a price that is 20% lower than the average manufacturer price (AMP), H.R. 3 requires the Secretary to accept that price.

Further, if a manufacturer offers to the Secretary the lowest average price of one of the international reference countries, then the Secretary is required to accept that offer, in effect creating a price floor.

Prescription drug prices in other countries are often times excessive, and a fair price – based on research and development costs, federal support for drug development, therapeutic value, and other factors enumerated in H.R. 3 – may be significantly below the lowest average price of one of the reference countries.

Proposed Amendment: Remove the 80% AMP and lowest average international price "target price" floors.

"Target price" language that requires the Secretary to arbitrarily accept a price should be removed. Removing these pricing floors would better enable the Secretary to establish prices consistent with the factors enumerated in the bill. This could be particularly important for prescription drugs that have been on the market for many years and have already recouped and made a reasonable return on risk-adjusted research and development costs many times over.

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[2] See Appendix for examples of prescription drugs that currently face limited competition and thus would be ineligible under H.R. 3 as currently drafted, even though they have high prices.

Issue: Price spike protections outside of Medicare are conditioned on yet to be developed rebate models.

Many prescription drug corporations rely on increasing prices on existing products to boost revenues rather than innovating new therapeutic advances that meet health needs. 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. The inclusion in H.R. 3 of an inflationary rebate that requires companies to pay back excess revenues resulting from price increases outpacing inflation under Medicare is an important feature. It was strengthened in the legislative process by inclusion of provisions requiring development and implementation of a model to provide similar inflation-based rebates to group health plans and health insurance issuers. However, these protections could be simplified and expanded to reduce administrative burdens and be made universal, regardless of insurance status.

Proposed Amendment: Replace the inflationary rebate provisions with a price spike excise tax.

By incorporating an excise tax like the one articulated in H.R. 1093/S. 378, the *Stop Price Gouging Act*, in which revenues obtained through unjustified price increases in excess of inflation face a tax penalty as high as 100%, H.R. 3 could help ensure regardless of purchaser or insurance status, no one in the United States faces sharp price spikes. Academic pharmaceutical pricing experts highlight that the burden of a price spike tax would be "borne by those companies that rely disproportionately on price increases, rather than innovation, to drive returns."[3]

Issue: Prices negotiated under H.R. 3 extend to commercial insurance, but they do not protect the uninsured or people who have insurance that does not cover negotiated drugs from excessive prices.

H.R. 3 only requires negotiated prices to be available to "fair price eligible" individuals and insurers providing coverage to such individuals. These eligible individuals include people enrolled in a prescription drug plan under Medicare Part D or Medicare Part C, Medicare Part A and Medicare Part B beneficiaries, and people enrolled in commercial health insurance plans which have entered into an agreement with the Secretary to receive the negotiated price.

People that do not have insurance or whose insurance plan does not cover the negotiated drug may not have access to a drug at the negotiated price.

Proposed Amendment: Make negotiated prices available to the uninsured and people whose insurance does not cover drugs negotiated by the Secretary.

The definition of "Fair Price Eligible Individual" should be expanded to include people who do not have insurance or whose insurance does not cover a drug the Secretary has negotiated. Existing penalties for failing to offer a product at or below a maximum fair price would also apply to sales to these individuals. Additionally, the bill could put in place an ombudsman to which consumers could report excessive prices, to help ensure manufacturer compliance.

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[3] https://www.healthaffairs.org/do/10.1377/hblog20170512.060041/full/

Issue: The plan does not strike the noninterference clause.

Rather than striking the noninterference clause, which prohibits the government from directly negotiating prices with drug manufacturers for Medicare Part D, H.R. 3 creates an exception to the clause for negotiations that take place under system the bill would put into place.

This means that it would still be illegal for the Secretary to negotiate prices for drugs that are not eligible under H.R. 3 like EpiPen.[4]

Proposed amendment: Strike the noninterference clause.

Striking the noninterference clause would remove an important roadblock to lower prices and should be included alongside other improvements outlined in this document, such as making more drugs eligible and covering more people.

Issue: The plan accepts manufacturer monopoly power.

By relying on a tax penalty without targeting patent monopolies through competitive licensing, the plan accepts and leaves unaddressed the core problem of high drug prices: the standard business model of abusing monopolies to extract unconscionable profits over new medicines. As countries around the world struggle with high drug prices, H.R 3 seeks to limit high prices by looking at the prices charged in other countries. Manufacturers may be able to keep setting and potentially increasing high launch prices by delaying entry of their product in foreign markets, and by raising foreign prices.

Proposed amendment: Make available competitive licensing of patents as a failsafe and as a deterrent for abuse.

Competitive licensing should be made available if:

1) A company refuses to sell a drug that has undergone negotiations to any fair price eligible individual or any provider or supplier of the drug to fair price eligible individuals;
2) A company launches three or more products in the U.S. at levels that exceed their respective average international reference prices;
3) One year after imposing the noncompliance penalty, a company still refuses to negotiate or sell the drug at the negotiated price; or
4) The Secretary determines that a company has attempted to abuse or avoid the drug pricing system.

[4] See Appendix for more about these and other examples of drugs that would not be eligible under H.R. 3 if it was in effect today.

Appendix

Drugs which may not be eligible because of insufficient aggregate spending

1. Daraprim—Martin Shkreli raised the price of Daraprim by 5000 percent, from $13.50 a pill to its current price of $750. But H.R. 3 will not target its price: the drug is used by 2000 Americans per year, so it will not make the list of highest-spending drugs.

2. Zolgensma—Novartis launched a new gene therapy targeting a rare disorder at $2.1 million. Insurers have begun restricting access. If enough of the seven hundred people who need the treatment are able to get access, Zolgensma may be negotiation-eligible given its high total spending. But the lack of control on launch prices means that people will be arbitrarily restricted access to Zolgensma for at least several years until the price is negotiated, if ever.

Drugs which would be ineligible because they are not single-source

Drugs with one generic or biosimilar

3. EpiPen (epinephrine injector)—Originally sold by Mylan. Teva recently introduced a true generic at a list price of $300.

4. Herceptin (trastuzumab)—Originally sold by Roche. Amgen and Allergan jointly launched a biosimilar (Kanjinti) at a list price of only 15% less than originator product. The list price is now $3697.26 per 420-mg multi-dose vial. Top 20 drug by US sales.

5. Avastin (bevacizumab)—Originally sold by Roche. Amgen and Allergan also jointly launched this biosimilar—at only a 15% list discount, for $2709.60 per 400-mg single-dose vial. Top 20 drug by US sales.

6. Advair Diskus (fluticasone propionate and salmeterol)—Originally sold by GSK. Advair is one of the most commonly used asthma inhalers. Although Mylan recently launched a generic for one-third of the originator list price, the nearly $100 U.S. generic price is still far higher than those in other countries.

Drugs with two generic or biosimilars

7. Remicade (infliximab)—Originally sold by J&J. Pfizer and Merck/Samsung have separately introduced biosimilars, with the latter recently introducing it a list price discount of 35%--for a price of $753 per 100 mg dose. In Canada, the drug is available for 493 CAD, or $372 USD. Top 20 drug by US sales.

8. Neulasata (Pegfilgrastim)—Originally sold by Amgen. Mylan and Coherus have separately introduced biosimilars, both at a list price discount of 33%-- for a price of $4175 per syringe.

9. Epogen/Procrit (Epoetin alfa)—Originally sold by Amgen and J&J under a product license agreement. Pfizer launched the first biosimilar to Epogen, at a 33.5% discount—for a list price of $11 per 1000 units/mL. It represents a 57% discount to Procit.