

The Elijah E. Cummings Lower Drug Costs Now Act: How It Would Work, How It Would Affect Prices, and What the Challenges Are

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ABSTRACT

ISSUE: The Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) promises a fundamental shift in efforts to lower the cost of prescription drugs in the United States. A key provision is a requirement for the government to establish prices for selected drugs that have little competition and account for substantial spending. The bill would require a drug's price to be set between the lowest price in six high-income countries and 120 percent of the average price across those countries.

GOALS: Describe how H.R. 3 would change current drug pricing, assess manufacturers' likely responses, and examine challenges of using prices set in other countries.

KEY FINDINGS AND CONCLUSIONS: Drug prices would fall significantly, although the effect on prices would depend on: 1) the specific choices implemented in detailed federal regulations, which could vary significantly based on a presidential administration's policy preferences; 2) the measures instituted by other countries to constrain increases in their prices; and 3) the actions of pharmaceutical manufacturers intended to minimize the reduction in their revenues.

Because constraining drug revenue would lessen expected profitability of new drugs, H.R. 3 is likely to reduce incentives for research and development. A key policy consideration involves weighing the societal trade-off between fewer new drugs coming to market versus the increased affordability of existing drugs. U.S. drug prices could be lowered either by pegging them to prices in other countries — as specified in the legislation — or by instituting a new regulatory process to set prices in the U.S. While utilizing prices in other countries is likely to achieve savings sooner, the approach may be more problematic over the long term due to efforts by other countries to avoid paying higher prices to benefit U.S. consumers. In addition, people in the U.S. may have a lower tolerance for regulation or for policies that limit access to new therapies. Initially pegging U.S. prices to those in other countries could provide a transition period for creating a U.S. regulatory regime to lower drug prices without tying our drug prices directly to those in other countries.

TOPLINES

- ▶ **H.R. 3 represents a fundamentally new approach to lowering the cost of prescription drugs in the U.S., particularly in requiring the government to establish prices for key drugs that have little competition.**
- ▶ **Drug prices could fall significantly under H.R. 3, although the magnitude would depend on several factors.**
- ▶ **Because constraining drug revenue would reduce manufacturers' profitability, H.R. 3 is likely to reduce incentives to fund R&D.**



INTRODUCTION

The [Elijah E. Cummings Lower Drug Costs Now Act \(H.R. 3\)](#), passed largely along party lines in December 2019 by the Democrat-controlled U.S. House of Representatives, represents a fundamental departure from prior initiatives to lower prescription drug costs. Instead of attempting to constrain prices by attempting to increase competition, Title I of the act requires the Department of Health and Human Services (HHS) to negotiate prices for selected drugs that have little competition and account for substantial spending. These prices would apply not only to Medicare but to private insurance and (indirectly) to Medicaid as well.

Negotiations between HHS and drug manufacturers would set prices, which would have to fall between the lowest price in any one of the six high-income countries specified in H.R. 3 and 120 percent of the average price across those six reference countries. Manufacturers' compliance would be enforced through a substantial excise tax.

This issue brief discusses: how H.R. 3 would fundamentally change current drug pricing rules; how prices might vary under different administrations; the potential responses by manufacturers and affected countries to the proposed reform; and the challenges of basing prices in the United States on those in other countries. (While beyond the scope of this brief, the other titles of H.R. 3 contain many other significant changes.¹)

RATIONALE FOR H.R. 3

By Lowering the Cost to Patients, Health Insurance Constrains the Role of High Prices in Limiting Demand

The process by which consumer price sensitivity constrains prices in competitive markets does not work as well for health services. Health insurance plays an important role in both protecting patients from the financial consequences of expensive care and by assuring access to medically necessary treatments. Importantly, because the prices of some drugs are so high, requiring

the patient to pay a large part of the bill is tantamount to denying access, despite federal rules for both employer coverage and individual insurance that require annual limits capping patients' out-of-pocket costs for covered services.

As prescription drugs have become much more expensive, demand constraints have become even less effective in controlling prices. Recognizing the limited effect of high drug prices on demand in the context of insurance, insurers rely on administrative actions to constrain utilization, such as requiring prior authorization or step therapy, which apply to many high-priced drugs.

Lack of Competition

Taken together, the drug patent system and U.S. Food and Drug Administration grants of market exclusivity pose important additional barriers to competition's effectiveness in controlling prices. To foster innovation, manufacturers of newly approved drugs receive a monopoly for their product for a substantial period.² But there is no consensus on how much exclusivity is enough, and concerns have been raised about drug makers' creativity in lengthening the periods of exclusivity beyond what the law contemplated when enacted. For manufacturers of drugs with government-granted market exclusivity and no therapeutic alternatives, high prices cannot be undercut by a competitor unless the FDA approves a new product.

High Social Costs

High drug prices have real social costs. For patients who face high out-of-pocket deductibles and cost-sharing — a situation that is exacerbated when their insurance, such as Medicare, does not include catastrophic protection — high prices can seriously impair access to the most effective treatments. High drug prices raise insurance premiums for individuals and employers, which in turn can lead to lower take-up of health coverage. Governments feel the impact as well, both directly as public insurers and indirectly as subsidizers of private insurance through the tax system.

Government can pass legislation effectively compelling manufacturers to lower drug prices, which is what the sponsors of H.R. 3 propose. Lower prices would lead to some reduction in future investment in new drug development, but the level of change in investment and the productivity of those changes in investments in research and development are highly uncertain. As a result, it is hard to assess whether, at the margin, the level of innovation associated with current rules compared to the level under the lower prices expected under H.R. 3 is large enough to offset the social costs they create.

HOW H.R. 3 WOULD FUNDAMENTALLY CHANGE CURRENT DRUG PRICING RULES

Two federal agencies grant pharmaceutical manufacturers market exclusivity. Patents are awarded by the Patent and Trademark Office, and drugs and biologics are approved to enter the market by the FDA after extensive testing showing safety and efficacy. Despite being a significant regulator of private insurance and directly paying for 35 percent of all health consumption (for example, through Medicare, Medicaid, and other programs), the federal government currently plays a quite limited role in setting drug prices.³

Manufacturers set the list prices of their drugs, but list prices frequently have little bearing on the actual or “net” prices negotiated by manufacturers and payers (such as health insurers), which include discounts and rebates. Negotiated prices reflect the clinical importance of a treatment and the existence or absence of alternative treatments. Market exclusivity conferred by patents and FDA approval creates a meaningful monopoly when therapeutic alternatives do not exist for a drug. The absence of competing alternatives empowers manufacturers to command high prices and undercuts the negotiating power of payers.⁴

Giving Government a Direct Role in Setting Drug Prices Based on Prices in Other Countries

Title I of H.R. 3 would reverse the current “hands off” role of the federal government in setting drug prices. The bill

would impose extensive, detailed requirements intended to lower the prices of single-source drugs and biologics for patients covered by Medicare, Medicaid, fully insured health plans, and self-insured plans (ERISA plans). Its comprehensive reforms would require manufacturers to agree to maximum prices acceptable to the government and direct the HHS Secretary to identify an annually increasing number of drugs with the highest potential for savings.

Two major provisions would give the government strong bargaining power and substantially erode the ability of manufacturers with effective monopolies to command high prices. First, the tax provisions of H.R. 3 would impose prohibitive financial penalties on sales of a specific drug if a manufacturer fails to agree to prices acceptable to the HHS Secretary. Second, the bill sets the maximum or “ceiling” price for a drug at 120 percent of the average of prices in Australia, Canada, France, Germany, Japan, and the United Kingdom (the average international market, or AIM, price). However, the Secretary has the authority to mandate that the U.S. price for a drug equals the lowest price in any of the six countries, which could be substantially below the maximum of 120 percent of the six-nation average.

Manufacturers effectively have to accept the price dictated by the Secretary, which may range between the statutory ceiling and the lowest price in any of the six reference countries — or risk not earning profits on U.S. sales of the specific drug. For these reasons, we characterize such prices as “administered” or “regulated,” notwithstanding H.R. 3 characterizing them as “negotiated.”

HOW MIGHT PRICES UNDER H.R. 3 VARY UNDER DIFFERENT ADMINISTRATIONS?

Drug prices would fall significantly under H.R. 3. However, the extent to which prices would fall could vary under presidential administrations with different policy preferences and approaches to implementation. For example, the HHS Secretary would have considerable leeway in the number of drugs that could be subject to negotiated price ceilings. H.R. 3 requires initially selecting

“at least 50 negotiation-eligible drugs,” but HHS could target up to 125 drugs plus any single-source insulin products not included among those drugs.

Similarly, a Secretary would have discretion to allow prices to equal the statutory maximum of 120 percent of the AIM price or to find acceptable only negotiated prices that were substantially below the ceiling price, which could include the lowest price in any of the six countries. HHS would also retain substantial discretion in assessing how to implement the multiple considerations listed in H.R. 3, such as research and development costs, costs of production, and the comparative therapeutic value of a drug.

H.R. 3 allows the Secretary to determine the required information from manufacturers that “may be needed to carry out the negotiation and renegotiation process,” including the extent to which information used in assessing prices would be net of all price concessions, or whether higher prices that excluded some price concessions would be used. The ability to gather accurate information is likely to depend to some extent on the willingness — and authority — of a Secretary to require detailed reporting about domestic and international prices by companies doing business in the U.S. Furthermore, the willingness to invest in resources and personnel to implement the provisions of H.R. 3 could vary significantly by administration.

COMPETING POLITICAL PRESSURES

One of the most significant variables affecting the aggressiveness with which price cuts are pursued relates to conflicting political pressures from differing stakeholders. Pharmaceutical companies can be expected to vigorously pursue efforts to mitigate the financial impact of H.R. 3, which is likely to include court and other challenges intended to constrain price cuts. Alternatively, consumer groups like AARP and organizations representing employers would be expected to favor policies that maximize price reductions for drugs. Although difficult to disentangle from stakeholder politics, differing views about the innovation-spurring role of higher prices — along with the importance of

robust innovation — could also result in opposing pressures for limiting price reductions versus seeking to maximize price cuts.

CHALLENGES OF USING PRICES FROM SELECTED COUNTRIES

The incentives created by H.R. 3 will likely adversely affect drug prices and access in the six listed countries (as well as potentially others). Affected countries, along with pharmaceutical manufacturers, can be expected to devise approaches to minimize the adverse effects to them associated with tying U.S. prices to international prices. Although minimizing the connection between lower U.S. prices and prices in the six reference countries might somewhat mitigate the adverse effects for other countries, the reduction in U.S. revenues is likely to be a key driver of manufacturer behavior.

Countries with low prices can be expected to facilitate strategies intended to minimize adverse effects or create work-arounds that allow reported (but not actual) prices to rise. As one example, each of the six countries listed in H.R. 3 would have incentives to allow manufacturers to exclude rebates and other price concessions from the (high) prices reported for incorporation into the AIM price. The six countries would each benefit by concealing the much lower net prices they would actually pay. In addition to being in their national interest, such rules also would benefit manufacturers and limit drug savings in the U.S. by increasing reported AIM and target prices. These likely responses will create significant challenges for HHS.

Anticipating Manufacturers' Response

Pharmaceutical manufacturers also can be expected to invest heavily in developing creative legal strategies to organize their businesses and sales to reduce revenue loss. To minimize the impact on U.S. prices, they are likely to raise reported international prices or restrict sales. Lower revenues may not only prompt manufacturers to lower investments in research and development, but H.R. 3 also may cause drug makers to change decisions regarding whether, where, and at what prices to launch new

products, potentially delaying or not entering markets where AIM or target prices would adversely affect U.S. revenues.

Similarly, they may choose to cease selling existing drugs in some or all of the six reference countries to avoid having low prices available for inclusion in the AIM or target prices. Deciding to withdraw products from existing markets would be economically rational where the revenue loss from suspending sales would be less than the reduction in U.S. revenue that would result from having AIM or target prices for the product.

As an alternative to exiting markets entirely, manufacturers would likely seek higher prices abroad, especially in the six reference countries. With limited opportunities for reimportation, manufacturers have been free to set prices in each country according to relative price elasticities. The classic economists' model of price discrimination explains this pattern well. The U.S. has the least resistance to higher prices because of the minimal government role in pricing. For drugs without therapeutic alternatives, the key resistance to higher prices is the affordability of patient cost-sharing. However, requirements for out-of-pocket maximums for individual and employer-based coverage (along with "copay coupons" financed by manufacturers) have sharply reduced this constraint.

In most other advanced countries, the government typically sets price ceilings. Under H.R. 3, manufacturers may be more willing to forgo sales, especially in the six reference countries, in order to achieve a higher price in the U.S. The willingness to withdraw from markets would be greatest in those countries with smaller populations like Australia and Canada, especially if they had low prices. How other countries would address the risk of losing access to new drugs is uncertain. But overall, prices in these countries would likely increase should this legislation be enacted.

Effect on Launch Prices

Launch prices for new drugs introduced into the U.S. would likely be higher than under current law for several

reasons. Title II of the bill would impose new rebates to offset prices that increase faster than inflation. In addition, the bill limits gross prices to 85 percent of average manufacturer price (AMP). A manufacturer's gain from a higher launch price would last at least until the drug is chosen for negotiation and the AIM price is established—which could be many years, especially for drugs that are neither "blockbusters" nor exceptionally high-priced.

U.S. pricing for those drugs in therapeutic classes not selected for negotiation would likely not be changed, because the market forces would generally remain the same and the provisions of H.R. 3 would not incorporate their prices. Over time, additional existing drugs would be identified for negotiation, but there does not appear to be an advantage to raising prices in anticipation of that (and Title II of the bill imposes inflation-related rebates).

Effect on Research and Development

Constraining the profitability of future drugs will reduce resources for research and development. Drug development occurs primarily in the private sector, with private funding accounting for **more than three-quarters** of health research and development. By reducing the expected profits spurred by bringing a new drug to market, lower prices would reduce incentives to invest in development.

The key issues are, first, the size of the reduction in private investment capital and, second, the value of drugs that will not be developed as a result of reduced investment. To the extent that the current availability of investment capital (predicated on current pricing) is viewed as permitting projects of relatively limited value to be funded, constraining the pool of capital might be expected to lead to only limited loss of important new drugs. Alternatively, if one believes either that greater societal investment in drug development is needed or that uncertainty in predicting potential breakthrough drugs undermines a "diminishing marginal return" hypothesis, reducing the pool of investment capital could have significant negative implications. The issue of diminishing returns to additional investment in research and development has

not gotten a lot of attention in the highly charged policy environment.

As a result of this uncertainty, the Congressional Budget Office (CBO) has limited itself to projecting changes in the number of new drugs and has not speculated about their value. CBO has estimated that between eight and 15 fewer drugs would be developed during the next decade if H.R.3 was implemented. Since the development periods for new drugs tend to be very long, arguably the most critical CBO estimate is the long-term percentage reduction in new drugs coming to market, currently estimated at 10 percent, or 30 drugs per decade. A key challenge for policymakers is to weigh this reduction in new drugs against the substantial savings and increased access to drugs that H.R. 3 would achieve.

REGULATING DRUG PRICES WITHOUT USING PRICES IN OTHER COUNTRIES

Compared with establishing a new regulatory process in the U.S., relying on drug prices in other countries would likely lead to savings more quickly. Yet for a nation that is less tolerant of regulation and limits on access to new products than many others are, doing so may not be the best approach over the long term. Still, using prices in other countries might provide a useful transition to a new American approach to regulating drug prices.

Should the U.S. develop its own regulatory mechanism, one likely component would involve comparative effectiveness analysis — an approach to quantifying the benefits of a drug or therapy in terms of improved health. A common measure of comparative effectiveness is the quality-adjusted life year (QALY),⁵ although some analysts have raised both technical and ethical concerns with it. Adopting an approach that incorporates value would allow drugs that are particularly effective to have much higher prices than those with only little effectiveness. This approach is used in countries like the United Kingdom, which sets a maximum on the cost [per QALY](#). In the U.S.,

the Institute for Clinical and Economic Review (ICER) is the best-known independent research organization that conducts this type of analysis, applying it not only to prescription drugs but also to medical tests and procedures.

To date, initiatives to have the federal government use cost-effectiveness analysis have been unsuccessful and strongly opposed by pharmaceutical manufacturers. But pressure to constrain drug prices is much greater now than in 2010 when the Affordable Care Act precluded using cost-effectiveness analysis. Indeed, manufacturers might be more receptive to a U.S. process that weighs effectiveness rather than adopting prices from other countries that assume less cost per QALY. Although the U.S. has no experience in comparing effectiveness and costs in the Medicare program, organizations such as ICER have been honing their analytical methods and strategies to engage stakeholders for many years now. Legislation directing HHS to set a ceiling on what Medicare will pay for a particular prescription drug on the basis of effectiveness analysis could authorize the agency to contract with ICER and other research organizations, create an in-house staff for this analysis, or do both.

CONCLUSION

H.R. 3's provisions on the federal government negotiating prescription drug prices with manufacturers reflects a major change in thinking in this country about how to make drugs affordable to patients and purchasers, although the approach is used in many other countries. The potential to lower spending is substantial but comes at the price of a reduction in spending to develop new drugs of uncertain magnitude and impact on value. Tying prices to those in six other countries might be useful as a transition. But to continue such a policy, the U.S. should develop its own ability to make decisions on the basis of each drug's value, such as through cost-effectiveness analysis.

NOTES

1. These changes include: a redesign of the Medicare Part D drug benefit; the imposition of inflation rebates on certain drugs; requiring drug manufacturers to publicly report detailed information on costs and profits for drugs with high or growing costs; expanding Medicare to cover dental, vision, and hearing services; and other provisions.

2. [“Frequently Asked Questions on Patents and Exclusivity,”](#) U.S. Food and Drug Administration, last updated Feb. 5, 2020.

3. [“Table 3 National Health Expenditures by Source of Funds,”](#) Centers for Medicare and Medicaid Services, last updated Dec. 17, 2019. Calculation by the authors for 2018.

4. Nine out of 10 prescriptions are for generic drugs (totaling 22 percent of spending on outpatient prescriptions). Competing manufacturers offer generics after the FDA approves a drug as being “therapeutically equivalent” to an innovator based on the intellectual property and data submitted for initial FDA approval but only after patent and other intellectual property protections have expired. Single-source innovator drugs, including biologics, account for the remaining 10 percent of prescriptions and 78 percent of outpatient drug spending. See Association for Accessible Medicines, [The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report](#) (AAM, 2019).

5. Peter J. Neumann and Joshua T. Cohen, [“QALYs in 2018 — Advantages and Concerns,”](#) *JAMA* 319, no. 24 (June 26, 2018): 2473–74.

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