

**Hearing on Promoting Competition to Lower Medicare Drug Prices
Before the Committee on Ways and Means**

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Chairman Doggett, Ranking Member Nunes, and distinguished members of the Committee, thank you for the invitation to testify today. My name is Amy Kapczynski, and I am a Professor of Law at Yale Law School, as well as a faculty co-director of both the Collaboration for Research Integrity and Transparency and the Global Health Justice Partnership at Yale University. I teach and write about intellectual property law and innovation policy with a particular focus on the pharmaceutical industry. I am honored to testify before you today. I understand that the committee is interested in broad perspectives on the nature of the drug pricing problem, and on constructive solutions to this problem, and in particular to the challenge of lowering Medicare drug prices. In my testimony, I will emphasize two broad points.

First, the central policy problem in this area is that the government gives exclusive rights over drugs, and these are easily abused. Without policies to contain monopoly pricing power, the drug pricing problem cannot be solved, and indeed is poised to grow.

Second, the most promising solutions are those that permit constraint on prices while also rewarding valuable innovation. The most important such proposals are those that increase the public's negotiating power to ensure fair prices. These powers must be accompanied by clear criteria to ensure that the prices agreed to are fair, and will require important decisions about the backstop that will help ensure negotiations succeed. Although they will likely have less impact, Congress should also implement measures to improve the competitive environment, such as laws to prevent pay-for-delay deals. Finally, Congress should also establish new programs to support R&D, to give us better information about how to use the medicines we have, and to explore new innovation mechanisms that can improve on our current approach to R&D.

I. The Drug Pricing Problem is at its Core a Monopoly Problem

High drug prices today are putting enormous strain on both patients and payors. Retail prescription drug spending, on a per capita basis, has nearly quadrupled since 1990, increasing from \$266 to \$1025.¹ Launch prices are rising, and according to industry analysts, “oncology and orphan drugs can be expected to have median prices well above \$100,000 per year” by

¹ This figure is inflation-adjusted. Peterson-Kaiser Health System Tracker, Recent Trends (2019), available at <https://tinyurl.com/yy8nb3md>.

2023.² Price increases are also a persistent and significant problem: For the 45 top-selling drugs, more than half of all sales growth in the past three years was due to price hikes.³

Consider the case of Humira (adalimumab), a treatment for rheumatoid arthritis and some other inflammatory conditions. Humira is the best-selling drug in America. Its producer, Abbvie, has exploited its market dominance, increasing the price of the product by 18% per year between 2012 and 2016. In that same time period, Medicare’s average spending per person per year for Humira has more than doubled, from \$16,000 to nearly \$33,000.⁴ Humira is not an isolated example.

Rising drug prices impose an extraordinary burden on taxpayers. Medicare Part D, for example, spent \$100.1 billion on prescription drugs in 2017.⁵ By 2027, this is expected to nearly double to \$194.7 billion.⁶ These amounts do not include the billions spent annually by beneficiaries through Part D premiums and out-of-pocket payments.⁷ Evidence shows that high drug prices are also harming patients. One in four Americans surveyed say that they or a family member do not fill prescriptions because of cost, and one in five report skipping doses or cutting pills in half.⁸ My colleagues at Yale have shown that one in four patients at the Yale Diabetes Center are skipping or stretching doses because they cannot afford their insulin – actions that can be extraordinarily dangerous, and even deadly.⁹

Why are prices so high, and rising? The core of the problem is quite simple: originator drug companies enjoy monopoly rights that permit them to set high launch prices and to increase prices with few constraints. These rights are granted by the government, in the form of patents (20 year rights to exclude others from making, using, importing or selling covered inventions), and other forms of market exclusivity (such as the exclusivities offered to companies via the FDA). Although the pharmaceutical industry has historically argued that exclusive rights and high prices are needed to compensate for R&D, there is growing recognition that prices are not set in relation to R&D.¹⁰ Rather, prices are set in relation to what market can bear, and that turns not on R&D costs but on the amount of market power a company can exercise.

² IQVIA, Global Use of Medicine in 2019 and Outlook to 2023 (2019), available at <https://tinyurl.com/yxptt9c9>.

³ Between 2014 and 2017, U.S. sales for 45 leading products increased by about \$23 billion. \$14 billion of that increase was attributable to price increases. Ned Pagliarulo, Price increases on top drugs drove majority of recent growth, analysis finds, BioPharma Dive (2018), available at <https://tinyurl.com/y2tyos5o>.

⁴ I-MAK, Overpatented, overpriced: Humira Special Report (2018), available at <https://tinyurl.com/ybrmx8kj>

⁵ Medicare Trustees, 2018 Annual Report 105, available at <https://tinyurl.com/y5ghtwsz> (2019) (“Over the next 10 years, aggregate benefits are projected to increase at 6.9 percent annually, on average, while the average per capita rate of growth is 3.9 percent”).

⁶ *Id.*

⁷ CMS, Chronic Condition Data Warehouse (CCW), (2019), available at <https://tinyurl.com/yxvy6trj> (estimating premium cost to beneficiaries).

⁸ Kaiser Family Foundation, Kaiser Health Tracking Poll: August 2015, (2015), available at <https://tinyurl.com/y4qrpqy4>.

⁹ Darby Herkert et al., Cost-Related Insulin Underuse Among Patients With Diabetes, JAMA INTERNAL MEDICINE (2019).

¹⁰ See e.g., US Dep’t of Health & Human Services, Prescription Drugs: Innovation, Spending, and Patient Access (2016), available at <https://tinyurl.com/y2df5563> (“Drug manufacturers often point to high drug development costs as a justification for high drug prices and understanding the R&D costs and time to develop a new drug is important. However, the relationship between R&D costs and drug prices is subject to a number of misconceptions. In reality,

Evidence that the core of the problem relates to monopoly power comes from the outsized role that branded drugs play in the drug pricing problem. Brand-name drugs account for three-quarters of drug spending overall.¹¹ Over the past five years, the list prices of the most commonly used brand-name drugs rose by 62.1%.¹² Although there are salient examples of price increases for generic drugs,¹³ on average, the prices for the most commonly used generics declined 36.9% over the same period.¹⁴ Brand-name drug prices are also central to the exploding costs of Medicare drug programs. The Office of Inspector General recently found that reimbursement for Part D brand-name drugs increased by 77% from 2011 to 2015, despite a 17% decrease in the number of prescriptions for these drugs.¹⁵ Even after taking into account manufacturer rebates, reimbursement for brand name drugs in Part D still increased by 62%.¹⁶

Patents and market exclusivity fuel excessive prices because these monopolies are easily abused. Some such abuses have received substantial attention recently, including the process of building “thickets” of patents around lucrative drugs to forestall competition,¹⁷ and reaching collusive deals with generic competitors in “pay for delay” settlements.¹⁸ The more significant abuse is the abuse of a companies’ pricing power: against the backdrop of exclusive rights, companies can impose prices that impose significant losses on society.¹⁹ Their returns may be far in excess of the returns anticipated, or that were required to bring the company into the market in question. This kind of excessive pricing is both economically inefficient and harmful to patients, and requires public regulatory power to counteract.

It is important to note that patented and market-exclusivity protected drugs do not always enjoy monopoly or market power in the classic sense. While exclusive rights prevent competitors from selling the same drug, other treatments may be available, creating some competition for the

the prices charged for drugs are unrelated to their development costs. Drug manufacturers set prices to maximize profits. At the time of marketing, R&D costs have already occurred and do not affect the calculation of a profit-maximizing price.”)

¹¹ Aaron Kesselheim et al, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858 (2016).

¹² Express Scripts, 2018 Drug Trend Report, available at <https://tinyurl.com/y3wskltc>.

¹³ See e.g., Ariana Cha, CEO Martin Shkreli: 4,000 percent drug price hike is ‘altruistic,’ not greedy, THE WASHINGTON POST (Sept 22, 2015), available at <https://tinyurl.com/onls5v5> & Tara Pope, EpiPen price rise sparks concern for allergy sufferers, NY TIMES (AUG. 22, 2016), available at <https://tinyurl.com/yxlmsxhp>

¹⁴ Express Scripts, 2018 Drug Trend Report, available at <https://tinyurl.com/y3wskltc>.

¹⁵ OIG, *Increases in Reimbursement for Brand-Name Drugs in Part D (2018)*, available at <https://tinyurl.com/ybnxmda4>.

¹⁶ *Id.*

¹⁷ Robin Feldman, *May Your Drug Price Be Ever Green*, *J. of Law and the Biosciences* (2018) (finding that “78% of the drugs associated with new patents were not new drugs, but existing ones, and extending protection is particularly pronounced among blockbuster drugs”); IMAK, *Overpatented, overpriced: How excessive pharmaceutical patenting is extending monopolies and driving up drug prices* (2018), available at <https://tinyurl.com/yyezww4by>.

¹⁸ Michael A. Carrier, *High Prices & No Excuses: 6 Anticompetitive Games*, Testimony for FTC Workshop on “Understanding Competition in Prescription Drug Markets” (2017), available at <https://ssrn.com/abstract=3066514>; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. (2006).

¹⁹ For a description of the deadweight losses associated with patents, see e.g., Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q. J. Econ. 1137, 1140-42 (1998).

relevant market. But while new launches within class do sometimes lower prices,²⁰ on the whole, evidence suggests that within-class competition between brand-name manufacturers “does not usually result in substantial price reduction,”²¹ perhaps because pricing remains oligopolistic. Counter-intuitively, introductions of new medicines sometimes are followed by *increases* the prices of competing products.²² For example, a recent study found when two new TNF-inhibitors for rheumatoid arthritis entered the market, prices of the existing three TNF-inhibitors, including the best-selling drug in America, Humira, increased.²³ The reasons for this are likely complex, but include changing expectations about how much payers are willing to pay for in-class medicines, and misaligned incentives in the supply chain.

In addition, medicines are essential goods, making patients and doctors very sensitive to even small differences in treatment profile.²⁴ This is exacerbated by the opacity and complexity of our healthcare system, as well as by the extraordinary amount that companies spend on marketing their drugs. Exclusive rights give companies incentives to intensively advertise their medicines, influencing prescribing practices towards higher-cost brand-name medicines.²⁵

As the aggregate figures cited above illustrate, competition within drug class has also, on the whole, been unable to prevent rising prices. This trend will continue. Overall, high-priced “specialty” drugs are projected to become a significantly larger share of the pharmaceutical market in coming years.²⁶ Many companies are now focusing on developing products that treat a small number of patients, including treatments for specific cancers and rare diseases. Orphan drugs could represent 45% of new active substances launched in the next five years.²⁷ Given the small market size and highly specialized area of research, many of these treatments will likely not face in-class competition.

Pharmaceutical companies have recently sought to shift the blame for high prices to pharmaceutical benefit managers (with whom they negotiate) and to wholesalers. PBMs and wholesalers do play a role, but it is important to keep it in perspective. High prices are in the

²⁰ See e.g., Ned Pagliarulo, *AbbVie surprised investors with its hepatitis C success. Will it last?*, BioPharma Dive (2018), available at <https://tinyurl.com/y5jnxnvc> (noting how competition reduced hepatitis C treatment prices).

²¹ Aaron Kesselheim et al, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858 (2016) (providing examples and evidence).

²² See e.g., Alvaro San-Juan-Rodriguez et al, *Assessment of Price Changes of Existing Tumor Necrosis Factor Inhibitors After the Market Entry of Competitors*, JAMA INTERNAL MEDICINE (2019); Dan Hartung et al., *The cost of multiple sclerosis drugs in the US and the pharmaceutical industry*, 84 NEUROLOGY 21 (2015) (finding substantial increases in price for first-generation multiple sclerosis treatments after introduction of second-generation treatments).

²³ San-Juan-Rodriguez et al, *supra*.

²⁴ Peter Siminski, *The Price Elasticity of Demand for Pharmaceuticals Amongst High-Income Older Australians: A Natural Experiment*, 43 APPLIED ECON. 4835, 4844 (2011) (detailing consumer inelasticity of demand for pharmaceutical products); Richard G. Frank & David S. Salkever, *A Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT STRATEGY 75 (1997) (same).

²⁵ See e.g., James Yeh et al., *Association of industry payments to physicians with the prescribing of brand-name statins in Massachusetts*, 176 JAMA INTERNAL MEDICINE 6 (2016) (concluding that “industry payments to physicians are associated with higher rates of prescribing brand-name statins”).

²⁶ See Adam J. Fein, *The State of the Specialty Industry*, available at <http://drugchannelsinstitute.com/files/State-of-Specialty-Pharmacy-2018-Fein-Asembia.pdf>.

²⁷ IQVIA, *Global Use of Medicine in 2019 and Outlook to 2023* (2019), available at <https://tinyurl.com/yxptt9c9>.

first instance set by, and primarily benefit, the pharmaceutical industry. Recent research shows that the US spent \$480 billion on pharmaceuticals in 2016.²⁸ Around 5% of this went to PBMs (\$24 billion), with less than 4% going to wholesalers (\$18 billion).²⁹ More than 67% of the revenue retained went to the pharmaceutical industry (\$323 billion).³⁰ They are clearly the biggest beneficiaries and biggest drivers of high drug prices.

Do monopoly rights require high prices? Europe has much lower drug prices than we do,³¹ but a very similar intellectual property regime. That is because they have a more robust regulatory system to mandate fair pricing. Fundamentally, any country that awards monopoly rights and that treats medicines as essential goods requires something similar.

II. Congress Should Consider Policies that Mandate Fair Pricing, Increase Competition, and Enhance R&D

Congress should consider a range of solutions to the drug pricing problem. The most promising solutions permit constraint on prices while also rewarding valuable innovation. With this in mind, the highest priority for Congress should be legislation that can ensure fair prices in both the public and private sectors, while also ensuring adequate returns to companies. Also important are a series of measures that can improve competition in pharmaceutical markets, and that can begin to explore alternative R&D structures as well as compensate for gaps in our current R&D system.

The highest priority for Congress should be measures that can give the public the negotiating authority to ensure fair prices. This hearing has an emphasis on Medicare drug pricing, and I will focus on measures that address this piece of the puzzle, in particular by creating more negotiating leverage in the Medicare Part D program. But it is important to note that similar design principles could be applied both to the Medicare Part B program and to the private sector.

Approximately 30% of all dollars spent on retail prescription drugs in the US are spent by Medicare Part D,³² but the federal government currently cannot consolidate this purchasing power to bring prices down because of the so-called noninterference clause.³³ Congress should introduce government negotiating power to the Part D program. Doing so raises two key design challenges. The first involves how to define fair prices and the second is how to establish the “backstop” position that will apply if the negotiations fail.

²⁸ Nancy Yu et al., Spending On Prescription Drugs In The US: Where Does All The Money Go?, HEALTH AFFAIRS BLOG (2018), available at <https://www.healthaffairs.org/doi/10.1377/hblog20180726.670593/full/>.

²⁹ Id.

³⁰ Id.

³¹ See e.g., Hagop Kantarjian & S. Vincent Rajkumar, Why Are Cancer Drugs So Expensive in the United States, and What Are the Solutions?, 90 MAYO CLINIC PROC. 500, 500 (2015), available at <https://perma.cc/G3ND-KR9A> (noting differing prices for cancer drugs); OECD, Pharmaceutical Spending, (2017), available at <https://data.oecd.org/healthres/pharmaceutical-spending.htm> (noting that US spending per capita is \$1208 while UK is \$476 and France is \$663).

³² CMS, Projected National Health Expenditure Data (2018), available at <https://tinyurl.com/pwzmt65>.

³³ 42 U.S.C. 1395w-111(i).

Defining Fair Prices

Defining a fair price for a drug is complex and requires consideration of a variety of factors. If necessary, the number of drugs for which such analysis must be conducted could be limited by focusing on those imposing the highest costs for Medicare, or those deemed overpriced by a variety of criteria (for example, as measured against prices in selected countries).

To set a fair price is to establish innovation incentives, so the decision of what prices are fair should be conducted against a background understanding of what we want out of pharmaceutical innovation. Important considerations here include:

- The clinical effectiveness of a drug;
- The comparative effectiveness of a drug (against existing alternatives);
- The costs and risks associated with the development of the drug, including those incurred by the public;
- The impact of prices on patient access and program sustainability; and
- The share of the market and profits in the US and abroad.

A simpler means of incorporating some of these same factors would be to use reference pricing, relying for example on prices in selected OECD countries. As noted above, such countries typically have far lower prices than the US, because they impose measures to contain price. Relying on prices in other countries, in effect, imports their conditions on drug pricing, while saving the administrative cost of imposing them. This approach might be viewed as a first step toward implementing fair pricing, and could also be combined with programs that directly establish fair prices (for example, with reference prices used to help identify excessively priced drugs that would be subject to further negotiations or used for a subset of drugs).

Defining Backstop Conditions

One key design question when government seeks to negotiate prices is what happens if a company rejects the price offered by the government. Three main options are currently in discussion.

The first option, which effectively operates in programs like the one run by the Department of Veterans Affairs, is that the drug is excluded from formularies.³⁴ This option has the drawback of pitting patient access against fair pricing. A large purchaser like a consolidated Medicare Part D program would have sufficient market size to make it difficult for firms to walk away, but this approach would still leave the government vulnerable to excessive prices, particularly for important new medicines with few therapeutic alternatives. It is worth noting, in addition, that the approach proposed recently by the Trump administration, which would permit exclusions of drugs in certain classes to permit more negotiation within these classes, involves the risk of cutting off access to needed medicines, while having no clear benefits.

³⁴ Veterans Health Administration, VHA Formulary Management Process, VHA HANDBOOK 1108.08 (2009), available at <https://www.pbm.va.gov/PBM/directive/vhadirective.pdf>.

The second option under discussion is the use of arbitration.³⁵ In this option, when negotiations fail, private arbitrators would step in to establish a fair price. The most commonly discussed such option involves so-called “baseball arbitration.” Here, the two sides each would submit a proposed price along with a justification, and the arbitrator would pick between the bids. Given the substantial public implications of drug pricing, especially for programs like Medicare, arbitration is an awkward fit.

A dispute between the government and a firm regarding the appropriate price for a drug and a dispute between two private parties to a contract (as in the baseball context) differ in important respects.

- The public has a more significant interest in the appropriate setting of prices of drugs than it does in the resolution of a private dispute among two parties to a labor contract. Issues of oversight, transparency, and the quality of decision-making in any drug pricing arbitration therefore are more significant. To serve the public’s interest in fair pricing of medicines, for example, arbitral decisions would need to be guided by standards established by Congress defining the appropriate size of the reward. To ensure that these were accurately incorporated into the arbitral award, genuine review would be needed.
- There are serious information asymmetries between the government and companies, which would have to be remedied prior to any bids if the process were to be rendered fair.

As legal scholars have noted, theoretically, “judges are agents of the state, charged with implementing its law through public decision making; arbitrators are creatures of contracts, obliged to effectuate the intent of the parties. The distinction is presumed to be constitutionally respectful and welfare-maximizing, enabling the enforcement of public rights and protecting the autonomy of contractual relationships.”³⁶ The use of arbitrators to decide major questions of public policy is in significant tension with the historic justification of arbitration.

There are several additional concerns regarding the implementation of arbitration in this context. Individual arbiters are typically drawn from the ranks of private arbitration bodies such as the American Arbitration Association. Private arbiters are typically attorneys with industry experience and may be subject to pro-corporate biases, especially given that corporations are repeat players and that arbitral associations compete for corporate business.³⁷ Arbitration is often also subject to limited oversight and review in the courts, and to limited transparency requirements. Here, oversight, review, and transparency would be essential, diminishing the speed and low cost that are the main benefits of arbitration. Finally, might a company refuse to sell the drug at the price established by an arbitrator? If so, arbitration could lead to the same constraints on patient access to medicines as the formulary approach.

³⁵ Richard Frank & Joseph Newhouse, Should Drug Prices Be Negotiated Under Part D Of Medicare? And If So, How?, 27 HEALTH AFFAIRS 1 available at <https://www.healthaffairs.org/doi/10.1377/hlthaff.27.1.33>

³⁶ Judith Resnik, Diffusing Disputes: The Public in the Private of Arbitration, the Private in Courts, and the Erasure of Rights, 124 YALE L. J 2804, 2806 (2015).

³⁷ Jean R. Sternlight, Creeping Mandatory Arbitration: Is it Just?, 57 STAN. L. REV. 1631, 1650 (2005).

A third approach under consideration holds more promise than the other two.³⁸ If the government and company fail to come to an agreement, the government could exercise its right to purchase the drug on the competitive market, affording the originator company a royalty while ensuring that patients are able to access the medicine in question. This approach can be accomplished by making clear that the result of a failed negotiation would be the exercise of the government's existing patent use authority (and the expansion of this authority to data and marketing exclusivities). Existing law already permits the federal government and its contractors to procure products without regard to patents, as long as "reasonable" compensation is afforded.³⁹ In fact, it has never been possible, throughout the long history of the United States, to enjoin the federal government for patent infringement.⁴⁰ The government used this authority in the 1960s to procure generic medicines, and has since relied on it frequently in different technological fields.⁴¹

The government patent use power is sometimes referred to as "compulsory licensing," or criticized by industry as "breaking patents." More properly, it should simply be understood as the exercise of a long-standing government right to avoid the risk of hold-up that attends private exclusive rights, particularly when they are applied against the government. If a railroad is being designed, the last property-holder remaining can hold the project up for far more than the value of his land, so the government has a right, enshrined in the Constitution, to take land subject to fair compensation.⁴² The government patent use power follows a similar logic, preventing hold-up as might occur if a private party possessing exclusive rights on a socially valuable drug refused to accede to a fair price. Compensation should be afforded when it is used, with compensation factors similar to those described above.

Finally, it is important to note that government negotiation need not significantly harm innovation, and indeed can improve innovation if designed well. Exclusive rights are intended to support innovation and have helped bring many important medicines to market. But innovations cannot work if patients cannot afford them. Increased affordability brings real benefits to many patients, and these could well outweigh any costs in terms of innovation. As Ian Ayres and Paul Klemperer have shown, even small decreases in price under monopolistic conditions result in extensive welfare gains.⁴³ The latest estimates of the elasticity of innovation in the industry are

³⁸ This approach is implemented by the Medicare Negotiation and Competitive Licensing Act of 2019 (H.R. 1046/S. 377), <https://www.congress.gov/116/bills/hr1046/BILLS-116hr1046ih.xml>.

³⁹ 28 U.S.C. § 1498(a).

⁴⁰ Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health, 18 YALE J. OF L. & TECH (2017); Amy Kapczynski and Aaron Kesselheim, 'Government Patent Use': A Legal Approach To Reducing Drug Spending, Health Affairs, Vol. 35 No. 5, May 2016, <https://doi.org/10.1377/hlthaff.2015.1120>.

⁴¹ Brennan et al.; Kapczynski and Kesselheim.

⁴² U.S. CONST. amend. V.

⁴³ Ian Ayres & Paul Klemperer, Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non Injunctive Remedies, 97 MICH. L. REV. 985, 1007-08 (1999) (showing that "[t]he last bit of monopoly pricing produces large amounts of deadweight loss for a relatively small amount of patentee profit").

relatively low, suggesting that the impact of price reductions on innovation would be small in comparison to the benefits.⁴⁴

In addition, if designed well, government negotiation can have a positive impact on incentives to innovate. For example, if negotiation guidelines assure reliable and larger returns for drugs that provide more value to patients, companies will have incentives to focus on developing drugs with more patient value. Today, activities with minimal social benefit, such as bringing a fourth or fifth “me too” drug in class to market, patenting minor variations of existing treatments to delay generic competition, and drug advertising may provide more attractive returns to companies than higher-risk but higher-social-reward projects that focus on breakthrough new drugs. On average, for example, industry spends twice on marketing what it does on R&D.⁴⁵ While marketing may have some salutary informational effects, it is clearly not optimized for that purpose. Evidence suggests, for example, that the drugs most heavily promoted to doctors are less likely than top-selling and top-prescribed drugs to be effective, safe, affordable, novel, and represent a genuine therapeutic advance.⁴⁶

Government negotiators guided by evidence can help bringing prices into alignment with social value, and direct companies toward more socially beneficial activities, including breakthrough research. In addition, government can choose to direct savings from drug price reductions toward high-impact innovation, further leveraging price reductions to improve the innovation environment.

Congress should also prioritize measures that can improve competition

Congress should also adopt policies that work to improve competition at the margins of existing monopolies. Examples of such reforms include:

- Bills to prevent collusive pay-for-delay deals between brand-name drugs and generics.
- Bills to prevent Risk Evaluation and Mitigation Strategies (REMS) abuse.
- Measures to resolve regulatory barriers to biosimilar competition.

These are worthwhile, but likely will have less impact, because they tend to curb pricing power only at the end of monopoly life. They will not solve the main issue, which is high and rising prices for drugs that are not close to the end of their exclusivity period.

More impactful would be a move to shorten exclusivity periods, for example by reducing the market exclusivities enjoyed by biologics from 12 years to 7. Similarly, limiting price hikes would curb industry’s ability to abuse their market position.

⁴⁴ Pierre Dubois, Olivier de Mouzon, Fiona Scott-Morton, & Paul Seabright, Market Size and Pharmaceutical Innovation, 46 *Rand J. Econ.* 844, 845 (2015) (estimating an elasticity of innovation of approximately 0.25, such that “when a market increases in potential size by 10%, that stimulates a 2.5% increase in the number of treatments to serve that market”).

⁴⁵ Marc-Andre Gagnon & Joel Lexchin, The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States, *PLOS MEDICINE* (2008) (finding that “pharmaceutical companies spend almost twice as much on promotion as they do on R&D”).

⁴⁶ Tyler Greenway & Joseph Ross, US drug marketing: How does promotion correspond with health value? 357 *BMJ* 1855 (2017).

Congress should also explore measures that can improve innovation

Public funding already plays a substantial role in the research and development of new medicines. Public research supports the knowledge base on which industry builds. For example, research funded by the National Institutes of Health was associated with all 210 drugs approved by the Food and Drug Administration from 2010–2016.⁴⁷ Congress should adopt policies that strengthen this role, and improve the innovation landscape. In doing so, Congress should also include sufficient safeguards to ensure affordability of the fruits of federally-funded research, and guard against weakening of existing standards.⁴⁸

Examples of such reform include:

- Funding more late-stage research through grants, subsidies (e.g., tax credits) and prizes, such as innovation funds.
- Funding that addresses gaps in the current research environment. For example, currently, companies have little incentive to perform the head-to-head trials that might help resolve uncertainties in prescribing practices. Federally funded R&D programs to evaluate the comparative effectiveness of existing products should be explored. Firms also have relatively weak incentives to conduct research on off-label uses of their medicines, and several recent court cases have called into question the FDA promotional restrictions that provide that incentive.⁴⁹ Because off-label uses are common, more systematic research on off-label uses could help provide better information to patients and doctors and curb costs.

Given the problems posed by a monopoly-based innovation system, alternative mechanisms to incentivize research and development should be explored and expanded. Particularly promising are approaches such as grants and prizes that “delink” innovation incentives from drug prices.⁵⁰ The US government has developed some of the most transformational innovations of the past century—everything from the global positioning system (GPS) to the internet. The lessons from these successes might be brought to the medicines field, advancing both innovation and access to medicines together.⁵¹

Congress, and this Committee, should be commended for taking up the urgent problem of drug pricing. As Congress considers reform measures, it should also take new steps to experiment with R&D funds and programs that can fill gaps in our existing research system and build experience with novel mechanisms for R&D.

⁴⁷ Ekaterina Cleary et al., Contribution of NIH funding to new drug approvals 2010–2016, 115 PNAS 10 (2018).

⁴⁸ For an example of proposed weakening of these standards, see National Institute of Standards and Technology, Return on investment initiative: Draft green paper (2018), available at <https://tinyurl.com/yyf4aj2u>.

⁴⁹ Amy Kapczynski, Free Speech and Pharmaceutical Regulation—Fishy Business, JAMA Internal Medicine, 2016;176(3):295-296. doi:10.1001/jamainternmed.2015.8155.

⁵⁰ See Delinkage, <https://delinkage.org/>

⁵¹ UCL Institute for Innovation & Public Purpose, The people’s prescription: Re-imagining health innovation to deliver public value (2018), available at <https://tinyurl.com/yxhcgatt>.