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Promoting Competition to Lower Medicare Drug Prices

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Chairman Doggett and esteemed members of the Committee, I am honored to be here today to address an issue that is causing real pain for patients and their families, and also for those who are trying to help them.

Prescription medicines are making headlines these days--not because of their ability to save lives, but because of their soaring prices. Consider the drug Achthar Gel, which is used to treat infant seizures, as well as arthritis. Today, that drug costs \$40,000 per vial. This represents an 100,000% increase since 2001. Eighteen years ago, Achthar Gel cost \$40. In Canada today, a vial only costs \$33 dollars. It is tough to tell patients in Chicago that they have to pay \$40,000 for a vial of this drug when their cousin in Toronto only has to pay \$33.00.

Prices for specialty drugs are causing distress. But drug companies have raised prices most sharply for commonly used medications that treat diabetes, high cholesterol, and asthma. In fact, 80% of the growth in profits from the 20 largest drug companies came from raising prices on existing drugs—not from introducing new drugs or increasing sales.¹

These price rises are burdening patients and many budgets, including the government's, to the breaking point. According to the Health and Human Services Inspector General's report, for example, Medicare spending for brand-name drugs rose 62% in the five years between 2011 and 2015, even taking rebates into account. It does not take a fancy degree in economics to know that at some point, these price increases are unsustainable.

So what is going on? Prescription drugs continue to dramatically improve people's lives. Innovations such as life-saving antibiotics, treatments for heart disease, psychopharmacological medicines, and new cancer drugs are having an extraordinary effect on people's health outcomes.

In fact, to encourage drug innovation, research, and development, the Federal Government has created a crucial system of incentives. In theory, we should see a cycle of innovation and reward, followed by timely competitive entry into the market by companies that help bring down prices. However, that is not what is happening.

Instead, our regulatory system is allowing companies to drive patients towards more expensive drugs, while preventing cheaper drugs from gaining a foothold in the market. Perverse incentives are creating Alice-in-Wonderland results and moving our system away from innovation.

To understand the incentives that are driving drug prices, one can start by focusing on the activity that occurs after a drug enters the market.² Unfortunately, it is a shadowy and tangled web of secret deals and convoluted reimbursement schemes.

¹ Joseph Walker, *For Prescription Drug Makers, Price Increases Drive Revenue*, WALL. ST. J. (Oct 5, 2015) www.wsj.com/articles/for-prescription-drug-makers-price-increases-drive-revenue-1444096750.

² Portions of these comments are derived from the following works of mine, which contain additional, in-depth explorations of the issues: *DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES* (Cambridge 2019); *May Your Drug Price Be Ever Green*, 5 OXFORD J.L. & BIOSCIENCES 1 (2018) (peer reviewed); *Regulatory Property: The New IP*, 40 COLUMBIA J. L. & ARTS 53 (2016); *One-and-Done for New Patents Could Cut Patent Thickets and Boost Generic Competition*, STAT (February 11, 2019); *Why prescription drug prices have skyrocketed: And why the government needs to take action*, THE

At the center of the web lies the highly secretive and highly concentrated intermediaries known as Pharmacy Benefit Managers or PBMs. PBMs negotiate prices on behalf of health insurance plans. PBMs also help determine a patient's access to medicines, setting what are known as the formularies. Each health plan has a different formulary, and formularies dictate whether patients can access a particular medicine and how much the patient will have to pay.

The contracts between PBMs and drug companies are claimed as trade secrets and staunchly protected, even from a PBM's own client, the health plan.³ In other words, the health plan knows what it paid when John Smith picked up this month's heart medication. But the plan does not know the real price. Sometime down the line, a health plan's PBM will send the plan a rebate check that may combine rebates for a group of patients or a group of drugs. Thus, the health plan does not see the true net price. Markets thrive on information, and from the standpoint of fair and efficient markets, such an industry design is less than ideal. In fact, one industry consultant describes the situation as, "buying blind."⁴

The system starts with a structure that looks healthy on the surface. Health plans pay their PBMs based on the discount that a PBM can negotiate with individual drug companies. In theory, this should encourage the PBM to drive prices down. But that is not how the system has played out in practice. Instead, drug companies have simply raised their starting prices. This increases how much of a "discount" the PBM can claim to have negotiated. It is a little like a department store raising prices right before a sale so the sale discount looks more appealing.

WASHINGTON POST (Nov. 26, 2018); Robin C. Feldman, Betty Chang Rowe, and Rabiah Oral, *Viral Licensing: Ensuring the Public Interest When Taxpayers Fund Pharmaceutical Research* (forthcoming Santa Clara L. Rev.), available on SSRN.com; *Cultural Property and Human Cells*, 21 INT'L J. CULTURAL PROP. 1, 6 (2014).

³ See Linda Cahn, *Don't Get Trapped By PBMs' Rebate Labeling Games*, MANAGED CARE (Jan. 1, 2009), <https://www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games> (industry consultant explaining that audit materials are limited to client-specific materials, and given that rebates are not client-specific, the PBM can refuse to provide information about them); Michael Hiltzik, *How 'price-cutting' middlemen are making crucial drugs vastly more expensive*, LA TIMES (2017) <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html> (quoting another insurance industry consultant that "insurers generally don't have the right to audit PBMs' collections and distributions . . . The PBMs will say the rebate contracts are between them and the pharmaceutical companies, and it is none of our business."); see also Neil Weinberg and Robert Langreth, *Inside the 'Scorpion Room' Where Drug Price Secrets are Guarded*, BLOOMBERG (May 4, 2017), <https://www.bloomberg.com/news/articles/2017-05-04/in-scorpion-room-auditor-gets-scant-look-at-drug-contracts> ("PBMs still often put auditors in secure rooms, limit the number of contracts they can see and restrict and review note-taking, according to people in the industry and contracts reviewed by Bloomberg."); Stephen Barlas, *Employers and Drugstores Press for PBM Transparency*, 40 PHARMACY AND THERAPEUTICS 3, 206-208 (March 2015) (quoting an accredited health care fraud investigator, "PBMs make it near impossible to audit both their 'secret agreements' for rebates with pharmaceutical companies and retail network agreements with pharmacy chains.")

⁴ Michael Hiltzik, *How 'Price-Cutting' Middlemen Are Making Crucial Drugs Vastly More Expensive*, LA TIMES (2017) <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html>. Scott Gottlieb, Commissioner of the FDA recently referred to this system as "Kabuki drug-pricing constructs—constructs that obscure profit taking across the supply chain that drives up costs; that expose consumers to high out of pocket spending; and that actively discourage competition." Scott Gottlieb, Commissioner of Food & Drugs, Remarks at America's Health Insurance Plans' National Health Policy Conference: Capturing the Benefits of Competition for Patients (March 7, 2018).

All of this might not be so bad if no one paid the high list price. But many people do. Nearly 30% of employer-sponsored plans require that patients pay 100% of costs up to a defined amount, and other plans require coinsurance payments. Both of these payments are based on the list price. In addition, many people do not have insurance coverage at all or do not have coverage for prescription drugs. Thus, many people are forced to pay the full price at various times. Worse yet, the entire structure creates perverse incentives, encouraging drug companies to compete, not by cutting prices, but by actually offering higher prices.

Pharmaceutical companies offer the same types of rebate deals to hospitals, to clinics that administer medications, and to doctors who deliver medications in their offices—such as injections, infusions, or vaccines. The hospital, clinic, or doctor charges the patient a higher list price and then later receives a rebate from the drug company, pocketing the difference.

Pharmaceutical companies also provide other types of payments under labels such as “administrative fees” and “data fees.” In exchange for these lucrative payments, the drug company wants to ensure that its drug receives a favorable or exclusive position on the formulary, and that competing drugs are disadvantaged. This narrows prescription choices and undermines competition from generics and from other drugs within the same class of medications that might provide excellent results at a lower price.

The name of the game is volume. The more volume a drug company has with a particular PBM or hospital, the better deal it can offer as a temptation to exclude rival drugs. One Medicare plan administrator, commenting on a bundling and volume rebate scheme that one brand company put into place, explained that a competitor could give their new drug away for free, and the numbers still wouldn’t work.⁵

Returning to the issue of the existing market power that helps brand companies offer volume discounts, it is important to understand the origins. Much of that power flows from what is euphemistically known as “life-cycle management.” Specifically, during the period in which the company holds a government-sanctioned monopoly, through patents and non-patent exclusivities, the company can use its monopoly position to create contract terms—such as most favored nation status—that can protect the brand drug after new entrants arrive.⁶

Moreover, much of the patent activity these days relates to extending protections for existing medications, often by making minor changes to a drug’s dosage, timing, or delivery system. I have learned in my research that drug companies are largely recycling and repurposing drugs, rather than inventing new ones. For example, I researched all non-biologic drugs on the market from 2005-2015, tracking every time a company extended a drug’s protection cliff. I found that more than three-quarters of the drugs associated with new patents are not new drugs coming on

⁵ It is a little like a major beer company going to a bar owner with the following offer: “At the end of the year, I’ll pay you 50 cents a bottle if you’ve sold 40,000 bottles of my beer. Better yet, I’ll make it \$1 a bottle if you don’t put any of that craft beer on the menu.” If the craft brewery starts out by selling a limited number of bottles, it could never offer enough off the price on its few beers to compensate for the tens of thousands of dollars the bar owner would forgo by rejecting the beer company’s offer.

⁶ See, e.g., *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 400 (3d Cir. 2016) (with contract clause preventing hospitals from giving competing drugs priority status).

the market, but existing ones.⁷ Thus, instead of innovation, we are seeing a large amount of churn, in which additional protections are piled onto old drugs, over and over again, to hold off generic entry.

While many of the changes made to those old drugs may earn new patents and exclusivities, the changes may not be particularly significant from a therapeutic standpoint. In addition, the investment necessary to create a secondary change to medicine—such as adjusting a drug’s dosage—is likely to be far less of an investment than the initial development of the drug. Thus, society may be lavishing expensive rewards on behavior that is suboptimal.

These secondary patents and exclusivities create walls that block out competitive entry, as well as conferring power that can be used for playing formulary games. Consider the cancer drug Imbruvica. The company extended the drug’s protection cliff from 2018 to 2031, using 24 additions to its protection.⁸ Or consider the cholesterol drug Crestor. The company extended the protection cliff from 2008 to 2022, piling on 32 additions.⁹ Or consider the drug Lyrica—used to treat nerve pain from diabetes and other conditions. The company extended the protection cliff from 2009 to 2018 with 16 additions.¹⁰ These are not outliers; this is the normal business practice for the industry.

Certain federal tax provisions also help incentivize the contracting and formulary games. For example, drug companies can donate inventories to their own foundation, or to independent charitable organizations, that support the purchase of the company’s drugs, earning charitable deductions in the process.¹¹ In this manner, the company drives utilization to its own drugs, purchasing brand loyalty, along with the volume that protects its position with PBMs and keeps lower-cost competitors from gaining a foothold. In fact, drug company patient assistance programs represented 10 of the largest 15 charitable foundations in the United States as of 2014.¹²

The activity is so popular, in part, because these donations are particularly valuable. Under a certain tax code provision, the company gets to deduct an amount that is greater than the cost of the drug.¹³ Specifically, branded drugs are relatively inexpensive to make, with the bulk of

⁷ DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES (Cambridge 2019).

⁸ Robin Feldman, Connie Wang, & Nick Thieme, *Identifying Extensions of Protection in Prescription Drugs: Navigating the Data Landscape for Large-Scale Analysis* (Dec. 17, 2018), available at <https://www.openicpsr.org/openicpsr/project/104781/version/V2/view>.

⁹ *Id.*

¹⁰ *Id.*

¹¹ Austin Frerick, *The Cloak of Social Responsibility: Pharmaceutical Corporate Charity*, 153 TAX NOTES 1151 (2016); see also Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets*, Working Paper 30, HUTCHINS CTR. ON FISCAL & MONETARY POL’Y AT BROOKINGS 57 (May 2017) (discussing the implications of the Frerick paper).

¹² See Morton & Boller, at 29 (citing Frerick).

¹³ See *id.*, at 29; see also Roger Colivaux, *Enforcing the Enhanced Charitable Deduction*, URBAN INST. CTR. ON NONPROFITS AND PHILANTHROPY AT URBAN-BROOKINGS TAX POL. CTR 1 (2012) (describing the history of the enhanced deduction, including that Congress first restricted corporate deductions of “income property” to the donor’s cost and then eased that restriction as a means of incentivizing the donation of medical supplies rather than disposing of them).

expenditures coming from research and development, as well as the approval processes. A special, enhanced-deduction provision allows drug companies to deduct not only the cost basis of the inventory they donate, but also the basis plus half the difference between that and the fair market value, up to twice the basis. In other words, the provision gives the company an enhanced deduction for the appreciation in the value of the product. This tax provision makes the donations unusually valuable, and the higher the list price, the greater the benefit to the company—at least until the company reaches the cap.

Patient advocacy groups, as opposed to patient *assistance* programs, are another way in which drug companies can influence market behavior. Ostensibly, these groups are formed by patients who have a particular disease in order to engage in education and advocate for policies and practices in the interests of everyone with the same disease. These organizations are not required to disclose their funding sources, however, and research shows that the majority of patient advocacy groups receive significant support from drug and device companies.¹⁴ One analysis concluded that in 2015, 14 drug companies donated \$116 million to patient advocacy groups, far exceeding the \$63 million that those companies spent in lobbying activities that year.¹⁵ When patient advocacy groups are 501(c)(3) organizations, drug companies again receive tax deductions for their contributions.

To maintain the flow of donations from drug companies, patient advocacy groups may directly (or indirectly) advocate for policies that push drug prices higher. As I have noted in the past, one must be mindful of the delicate pull of friends with money.¹⁶

The opioid crisis offers an example of the role of patient advocacy groups can play in advancing pharmaceutical company interests. According to one report, patient advocacy groups amplified industry messages and lobbied for policies that the industry favored, while receiving more than \$9 million in donations from opioid makers.¹⁷

Consumer advertising is another way in which the tax code may drive strategic behavior. The United States and New Zealand are the only nations that allow full, direct-to-consumer advertising. Companies receive a business expense deduction for their advertising costs, and those expenses can be substantial.

The results, however, are not always in the consumer's best interest. Advertising can be used to drive patients into overpriced drugs, when the same medication is available inexpensively. For example, the migraine medicine Treximet just combines an old migraine medicine with

¹⁴ See Norman R. Augustine, Guru Madhavan & Sharyl J. Nass, *Making Medicines Affordable: A National Imperative*, NAT'L ACADEMIES OF SCI., ENG'G, AND MED. 94 (2018) (citing Matthew S. McCoy et al., *Conflicts of Interest for Patient-Advocacy Organizations*, 376 NEW ENG. J. MED. 880 (2017)).

¹⁵ See Emily Kopp, Sydney Lupkin & Elizabeth Lucas, *Patient Advocacy Groups Take in Millions From Drugmakers: Is There a Payback?*, KAISER HEALTH NEWS (Apr. 6, 2018).

¹⁶ See Robin C. Feldman, Mark A. Lemley, Jonathan Masur & Arti Rai, *Open Letter on Ethical Norms in Intellectual Property Scholarship*, 29 Harv. J.L. & Tech. 339, 339 (2016).

¹⁷ See Paul Thacker, *Big Pharma is Quietly Using Nonprofits to Push Opioids*, LA TIMES (Jul. 19, 2018).

naproxen. Treximet can cost more than \$900 for nine pills. However, the two components can be purchased separately for about \$5 a dose.¹⁸

Similarly, advertising by brand-name companies can be designed to drive patients away from generics. For example, Pfizer's co-pay coupon for the mental health drug Geodon instructs patients, "Tell your doctor to write the brand-name GEODON on your prescription, not the generic. . . Make sure your prescription says, 'Dispense as Written' or 'No Substitutions' depending on the state you live in."¹⁹ These practices drive patients into high-priced drugs, and are supported by the tax deductions that the company can take.

There is plenty of praise and blame to go around. The more important question is, how do we fix it?

Managing the regulatory game-playing will require a multi-pronged approach. One could use an analogy from the medical field itself. In the past, physicians would attack a tumor by trying to reduce its size or block the substances that seemed to be feeding it. However, later medical research demonstrated that tumors seem to operate in a networked or systems fashion. Cutting off one approach may simply lead the tumor to develop a work-around, and the new approach may be even more dangerous and damaging than the original pathway.

And so it is with reform of the pharmaceutical regulatory system. Without work on multiple fronts, adjustments from one part of the system could lead to counter-veiling action in another. For example, if one cuts off rebates and the flow of persuasion payments simply shifts to another vehicle, the positive impact could be lost. In light of the volume effects described above, that is a real risk. Consider, for example, if anti-kickback provisions leave a safe harbor for various other types of flat payments. Even if those payments are for services rendered, a large company can offer a volume of "services rendered" across a large number of drugs in exchange for more favorable formulary treatment. The new entrant could never match that deal and would be limited in its ability to penetrate the market. One can call something a rebate, or a flat fee, or an elephant. Regardless of the label, it represents a lucrative flow of money, and the influence that goes along with it.

In reforming the Medicare drug price system, one of the most challenging questions is simply, what should a drug cost? As a starting point, drug companies must be able to recoup their R&D investments, along with a significant profit. That incentive structure is critical for fostering innovation. However, although the costs of research and development are substantial, the amount may not be quite as high as the industry suggests. Industry numbers for the costs of producing a drug are unverified, and evidence suggest that all kinds of odd things may be getting thrown into the basket or left out.

In addition, as someone who values a free market economy, I am troubled when companies argue that the "cost of producing a drug" should include the cost of failed attempts to produce

¹⁸ ROBIN FELDMAN, DRUGS, MONEY, & SECRET HANDSHAKES, 118 n.6; *see also* Diane Archer, *Pharma Profits from Patenting OTC Drugs*, JUST CARE (Nov. 22, 2017) (listing other examples) <https://justcareusa.org/pharma-profits-from-patenting-otc-drugs/>.

¹⁹ https://s3.amazonaws.com/pfizerpro.com/fixtures/geodon/docs/Geodon_TakeAction_Tool_Release_7.29_14.pdf

other drugs. That is a strange concept, when the patent system is designed to reward success. Yes, we want to incentive innovation, but a patent is not a participation trophy. Inventors do not get a patent for the inventions they tried and failed to create. Similarly, the reward they receive with a patent should not include compensation for those other failures.

Incentives should drive companies to succeed, and to succeed as quickly and efficiently as possible. Otherwise, one risks subsidizing failure, rather than incentivizing success.

In deciding how to price a particular drug, the notion of value-based pricing is drawing support from a number of corners. Value-based pricing attempts to measure the quantity and quality of additional life generated by a particular medical treatment. Value is a particularly powerful notion when used as a negative concept, for example, when one can say, “no, this drug is not delivering much value to patients at all,” or “no, this drug is not delivering a value anywhere near its price.”²⁰

With any value measure, however, the notion of value must be carefully limited. When my own life and well-being are at stake, the value to me may be infinite, or, at least, well beyond any budget capacity. As one commentator explained, the value of giving my child a polio vaccine may be \$1 million per dose, because it would be worth that to avoid my child succumbing to polio.²¹ The healthcare system would collapse, however, if each vaccine were to cost \$1 million.

In contemplating value, it is useful to think in terms of what I would call “cumulative value.” If the national budget for drug spending is a certain amount (or the average person’s budget for drug spending is a certain amount), how much of that amount does it make sense to spend on this particular advance? Otherwise, if value is open-ended and has no sense of total, upper boundaries, we could value ourselves into budget oblivion.

The problem of high drug prices presents enormous challenges. Although reforming the PBM system and taming rebates will be critical, bringing about true change will require a partnership between Congress and the regulatory agencies, including HHS, the FDA, and the USPTO. And it will require changes both large and small. With so many citizens upset, and often scared, about the cost of their medications, the time is ripe for a coordinated approach.

With this in mind, I would respectfully suggest that policymakers consider the following changes to improve our nation’s pharmaceutical markets: 1) closing tax loopholes; 2) implementing one-and-done; 3) providing transparency; and 4) using the power of the purse.

Close the Tax Loopholes

²⁰ The Institute for Clinical and Economic Review (ICER) has been active in providing economic valuations of drugs that demonstrate the gap between price and value. See <https://www.statnews.com/pharmalot/2019/02/22/drug-prices-sma-cost-effective/>.

²¹ Marie McCullough, *Breakthrough Cancer Therapy Raises Tough Questions About Drug Costs, Value*, THE INQUIRER (Feb. 6, 2018) (quoting David Mitchell, founder of Patients for Affordable Drugs).

First and foremost, close the tax loopholes that allow the drug companies to essentially deduct the costs of lobbying and other self-serving and strategic behaviors.

Drug companies should not receive enhanced deductions for donating their drugs. At best, the deduction should be the simple marginal cost. Drug companies also should not receive deductions for donations to patient advocacy groups that advocate in the interests of the company.

One-and-Done

To minimize the ability of a brand-name drug company to keep “refreshing” a drug’s protection and using its market power to restrict competitors from the marketplace, implement a “one and done” principle.

With one-and-done, a drug would receive one period of exclusivity, and only one, under the Hatch-Waxman and Biologic systems. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made at the moment of FDA drug approval.²² Perhaps development and approval of the drug has gone swiftly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps those processes languished, such that designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, would be that a pharmaceutical company must choose whether its period of exclusivity should be a patent, or an orphan drug designation, or a period of data exclusivity, or something else – but not all of the above and more.

Many variations of “one-and-done” could be implemented. The notion is less how many rights are allowed (perhaps one is too few.) The basic notion is simply the following: pick a period of protection—some period of protection. Allow competitors to know precisely when that period ends. And when it ends, it ends.

Transparency

Markets, like gardens, grow best in the sun. They wither without information. Thus, when an industry’s pricing information and rebate relationships are secret, deeply hidden, or obscured even from payors, one should not be surprised to see significant distortions and problematic outcomes. Quite simply, entrants and prospective entrants power the economic engines of competition; information provides the fuel for those engines.

²² Much of “one and done” could be implemented through legislative changes to the FDA drug approval system, which would apply to patents granted going forward. For additional details, see ROBIN FELDMAN, *DRUGS, MONEY & SECRET HANDSHAKES* 102-108 (Cambridge 2019). In addition, if Congress contemplates one-and-done, one could argue that the length of rights might be extended. After all, patent holders would be losing the ability to stretch their patents – an ability they have enjoyed for some time. Of course, one could also argue that the various techniques employed to extend a drug’s protection cliff either distort the intent of the system or constitute outright abuse. Nevertheless, Congress did indeed intend to allow delay of the protection cliff in at least some cases with the creation of certain exclusivities.

To begin restoring sanity to pharmaceutical markets, information must flow. That includes pricing information. All aspects of the deals, including rebates and financial benefits in any form, should be transparent, at a minimum, to the payors and the government.

In addition, given the government's limited resources, these markets ideally should be public and visible. In an open and democratic society, we would be foolish to bypass the power embodied in the press, a company's competitors, and individual citizens to ferret out objectionable behavior, especially in the age of crowdsourcing and social media.

Some have expressed concern that transparency could result in collusion among parties setting bids. To the extent that is a problem—and I have my doubts—the problem could easily be solved by a minor delay in publishing the information.

Secrecy shrouds conspiracy, and it is rarely good for competition. It is the realm of backroom deals, secret handshakes, winks and nods. In contrast, a free market thrives on an open and vigorously competitive market. We should not put shackles around two of our greatest powers: the free market and an informed citizenry.

The Power of the Purse

The federal government, through the National Institutes of Health and other federal agencies, funds an extraordinary amount of research into basic science.²³ Many medicines currently on our shelves began with such government-funded research. From that perspective, the public pays three times over: with public money for the research, with personal funds at the pharmacy counter; and with taxes to support government programs for those who cannot afford medications.

Through the addition of a few contractual provisions in grant agreements, the NIH and other government funding bodies could improve consumer choice and access to the drugs developed with such publicly funded research.

As a general matter, most pharmaceutical innovation happens at research universities or smaller companies.²⁴ As the system winds its way from federal funds to private products, the government

²³The federal government provides grants to graduate programs at universities working on drug development or researching tools that aid in the drug development process. *See e.g.*, Arti K. Rai & Bhaven N. Sampat, *Accountability in Patenting of Federally Funded Research*, 30 NATURE BIOTECHNOLOGY 953, 953-956 (2012); Stephen V. Frye et al., *Academic Drug Discovery in the US: A Survey and Analysis*, 10 NAT REV DRUG DISCOV 6, 409-410 (2011) (federal grants or contracts accounted for an average of 41% of total funding, by far the largest source). Although the amount of federal funding has declined since a high in 2008, the federal government still provided \$24.6 billion in university research grants in 2013. In addition, universities received over \$120 billion in non-research specific funding from federal and state budgets.

²⁴*See* Robert Kneller, *The importance of new companies for drug discovery: origins of a decade of new drugs*, NATURE REVIEWS DRUG DISCOVERIES 9, 867-882 (2010) at 869 (between 1998 and 2007 stating that of scientifically novel drugs, only 44% were from pharmaceutical companies, 25% were from biotech companies, and 31% were from universities); Jonathan D. Rockoff, *Big Pharma, Short on Blockbusters, Outsources the Science*, WALL ST. J. (Dec. 6, 2016), <https://www.wsj.com/articles/big-pharma-short-on-blockbusters-outsources-the-science-1481042583>

does not relinquish all of its interests. University patents derived from government-funded research are supposed to include “government interest” statements as a result of information provided by the patent applicant. Such statements provide notice that the patented invention was funded, at least in part, by federal dollars and that the government retains a so-called “march-in right,” a rarely used patent provision that allows the government to ignore patent rights and grant a license to competitors to produce the drug.²⁵

NIH grants could complement and enhance transparency efforts in this regard. For example, a standard NIH grant could require that companies who produce drugs developed either directly with government-funded research or by licensing innovations developed with government funding must agree to provide open-pricing information, either for a) the drug being licensed; b) any drugs developed through use of a tool being licensed; or c) any improvements made to the core technology or innovation being licensed. Such open pricing information has the potential to foster competition.

In addition to stipulating transparency, the NIH could include behavioral limitations within its granting agreements—limitations that could enhance the public interest and combat other types of market imperfections embodied in the pharmaceutical and health care industry. On a granular level, NIH grants could forbid particular types of behaviors, such as obtaining follow-on patents on the invention that make minor modifications, refusing to provide samples to generic hopefuls, or filing citizen petitions to block generic entry.

Purse strings are powerful weapons. Such an approach would reflect the leadership role that the NIH plays, not only in shaping young minds, but also in shaping the future.

Conclusion

There is no silver bullet for solving the crisis of soaring drug prices. Nevertheless, tax loophole reform, one-and-done, transparency measures, and the power of the purse (e.g. improvements to the NIH grant process) could help the pharmaceutical marketplace return to health. Our challenge as a society is to restore the balance provided by the patent and regulatory system itself, in which the inventor of a truly innovative product receives a limited period of time in which to attempt to garner a return, after which open competition reigns supreme.

Thank you for the opportunity to testify, and I look forward to your questions.

(citing a Boston Consulting Group study stating that about 70 percent of drug industry’s new sales in 2016 come from drugs originated in small companies, up from 30 percent in 1990). *See also* Aaron S. Kesselheim et al., *The Roles of Academia, Rare Diseases, and Repurposing in the Development of the Most Transformative Drugs*, 34 HEALTH AFFAIRS 2, 286-293 (2015) (study finding that more than half of 26 transformative drugs approved by the 1984 and 2009 had origins in publicly funded research).

²⁵ *See* 35 U.S.C. § 203. Research has shown, however, that such notice and reporting are woefully incomplete, and these statements are frequently omitted. *See e.g.*, Rai & Sampat.