

**Written Testimony of Amy Kapczynski
Professor of Law at Yale Law School**

**Before the Senate Committee on Finance
Subcommittee on Fiscal Responsibility and Economic Growth**

**Hearing on the Hospital Insurance Trust Fund and the Future of Medicare Financing
Wednesday, February 2, 2022**

Chair Warren, Ranking Member Cassidy, and distinguished members of the Subcommittee, I appreciate the opportunity to testify about the important topic of the future of Medicare financing.

My name is Amy Kapczynski, and I am a Professor of Law at Yale Law School, as well as a faculty co-director of the Yale Global Health Justice Partnership and the Law and Political Economy Project. I teach and write about intellectual property law, innovation policy, and law and political economy. My research has had a particular focus on the pharmaceutical industry and organization of biomedical research and development in the US.

The focus of my remarks today will be on the problem that high drug prices pose for the Medicare program and for Medicare beneficiaries. At the root of this problem is the monopoly power that companies can exert through patents and other market exclusivities. As I will describe, the vast majority of Medicare's rising drug expenditures are attributable to high-cost, monopolized medicines. Ensuring the stable financing of Medicare, and the health and wellbeing of Medicare beneficiaries, requires concerted legislative action to ensure fair pharmaceutical prices.

There is a great deal of talk in Washington today about inflation. I urge you to consider why drug price inflation – which we know how to handle, and which hurts so many vulnerable Americans – has been allowed to persist without Congressional action. To protect Medicare, and to protect Americans, Congress should pass strong legislation to curb price increases and ensure that medicine prices reflect genuine investment and therapeutic value, and also consider measures to address patent-abuse and other anticompetitive conduct in the industry.

High Drug Prices Are a Critical Problem for Americans and for Medicare

High drug prices in the US are a major problem today, both for patients and for the sustainability of our health insurance system. From 1980 to 2018, pharmaceutical spending increased more than tenfold in real terms (i.e. excluding economy-wide inflation).¹ US spending on prescription drugs

¹ CONG. BUDGET OFF., PRESCRIPTION DRUGS: SPENDING, USE, AND PRICES 1 (2022).

reached \$535.3 billion in 2020.² Pharmaceutical spending accounts for at least 14% of overall US healthcare spending.³

Price increases beyond the pace of inflation are commonplace, for example with net prices increasing by 60% from 2007 to 2018.⁴ More than 100 drugs saw price increases beyond inflation in 2021.⁵ The average new cancer drug in the US today is priced at more than \$175,000, and this price does not in any logical way track benefits or R&D costs.⁶ The US is also distinctive among other wealthy countries. We lack comprehensive tools to ensure fair prices, and as a result have prices that are on average 256% higher than all other OCED countries.⁷

Unsurprisingly, high drug prices are also one of the leading concerns of voters today.⁸ More than two-thirds of Americans across political affiliations say, for example, that lowering high drug prices should be a high priority for the current Administration.⁹ Almost two in five (39%) of Americans did not take a prescription drug as prescribed because of cost.¹⁰ One in five (21%)

² Eric M. Tichy, *National Trends in Prescription Drug Expenditures and Projections for 2021*, 78 AM. J. HEALTH-SYSTEM PHARM. 1294, 1295 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8365501/pdf/zxab160.pdf>. CMS also produces an estimate of US pharmaceutical spending. See CTRS. FOR MEDICARE AND MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES 2020 HIGHLIGHTS 2 (2021) (estimating US pharmaceutical spending at \$348.4 billion). However, the CMS estimate only captures drug spending in *retail* outlets. Although estimates of retail – i.e., pharmacy-dispensed – drugs come in around 9% of total healthcare spending, including *non-retail* drugs increases estimates by as much as 50%. CMS counts this form of spending as “physician, hospital, and nursing home services,” making traditional estimates of standalone drug spending problematic. See Rena M. Conti et al., *Projections of US Prescription Drug Spending and Key Policy Implications*, JAMA HEALTH F. (2021), <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2776040>.

³ Tichy, *supra* note 2, at 1294; see also Charles Roehrig, *Projections of the Prescription Drug Share of National Health Expenditures Including Non-Retail*, ALTARUM RESEARCH BRIEF (June 13, 2019), <https://altarum.org/publications/projections-prescription-drug-share-national-health-expenditures-including-non-retail-0> (finding total prescription drug spending to be 13.9% not the more oft-quoted 9% figure); Aaron S.

Kesselheim, *Improving Competition to Lower U.S. Prescription Drug Costs*, WASH. CTR. FOR EQUITABLE GROWTH (Feb. 18, 2020) (suggesting that the share is closer to 20%, or even 25% for some private insurers).

⁴ Inmaculada Hernandez et al., *Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018*, 323 JAMA 854 (2020), <https://jamanetwork.com/journals/jama/fullarticle/2762310>.

⁵ PATIENTS FOR AFFORDABLE DRUGS, A NEW YEAR BRINGS THE SAME OLD BAD BEHAVIOR BY BIG PHARMA (2022), <https://patientsforaffordabledrugs.org/2022/01/12/a-new-year-brings-the-same-old-bad-behavior-by-big-pharma>; see also Dena Bunis, *Prescription Drug Price Increases Continue to Outpace Inflation*, AARP (June 7, 2021), <https://www.aarp.org/politics-society/advocacy/info-2021/prescription-price-increase-report.html> (describing how “prices for 260 commonly used medications whose prices AARP has been tracking since 2006 increased 2.9 percent while the general rate of inflation was 1.3 percent”).

⁶ Vinay Prasad, Kevin De Jesús & Sham Mailankody, *The High Price of Anticancer Drugs: Origins, Implications, Barriers, Solutions*, 14 NAT. REV. CLINICAL ONCOLOGY 381 (2017), <https://doi.org/10.1038/nrclinonc.2017.31>.

⁷ ANDREW W. MULCAHY ET AL., RAND CORP., INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: CURRENT EMPIRICAL ESTIMATES AND COMPARISONS WITH PREVIOUS STUDIES (2021), https://www.rand.org/pubs/research_reports/RR2956.html.

⁸ Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (2021), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>.

⁹ Dan Witter, *In U.S., Most Say Reducing Cost of Care High Priority for Biden*, GALLUP (Jan. 28., 2021), <https://news.gallup.com/poll/328757/say-reducing-cost-care-high-priority-biden.aspx>.

¹⁰ Katie Adams, *Rising Costs Force 39% of Americans to Skip, Ration Meds, Survey Says, Becker’s Hospital Review*, BECKER’S HOSP. REV. (March 22, 2021), <https://www.beckershospitalreview.com/pharmacy/rising-costs-force-39-of-americans-to-skip-ration-meds-survey-says.html> (citing a survey of roughly 1000 Americans conducted by GoodRx).

reported taking on debt or declaring bankruptcy in order to pay for their prescriptions.¹¹ The same percent also reported struggling to pay for basic needs such as food or shelter as a result of their prescription drug spending.¹²

The effects of the costs of treatment are so dramatic and clear to clinicians that some oncologists have even coined the term “financial toxicity” to describe the consequences of high treatment prices on cancer patients.¹³ Indeed, recent estimates indicate that medical debt has become the single leading source of delinquent consumer debt in the US, surpassing credit cards, utilities, and phone bills over the last decade.¹⁴

Another vivid example of the problem is insulin, a drug that type one diabetics must take regularly or face life-threatening consequences. In the past two decades, the cost of analogue insulins has skyrocketed, even as the drugs themselves remain unchanged. For example, Novolog, an insulin that has been on the market since 2001, saw its price rise by 353% between 2001 and 2016.¹⁵ The human costs are severe. Researchers have found that as many as 1 in 4 patients now do not take insulin as prescribed due to its unaffordability.¹⁶

High Drug Prices Have a Significant Impact on Medicare

The impact of high drug prices on Medicare specifically is well-documented. Medicare covers retail prescription drugs through Part D, drugs provided in physicians’ offices and hospital outpatient departments through Part B, and inpatient and nursing facilities through Part A. These programs cover an estimated 27% of all US drug spending.¹⁷

These expenditures make up a significant part of Medicare budgets. Between 2006 and 2017, drug spending through Medicare Part D rose from 9% of total benefit payments to 14%.¹⁸ This in part

¹¹ *Id.*

¹² *Id.*

¹³ Cathy J. Bradley, K. Robin Yabroff & Ya-Chen Tina Shih, *A Coordinated Policy Approach to Address Medical Financial Toxicity*, 7 JAMA VIEWPOINT 1761 (2021), <https://jamanetwork.com/journals/jamaoncology/fullarticle/2784986>; see also Scott D. Ramsey, et al., *Financial Insolvency as a Risk Factor for Early Mortality Among Patients With Cancer*, 34 J. CLINICAL ONCOLOGY 980 (2016) (finding an association between medical debt and early mortality among cancer patients).

¹⁴ Raymond Kluender, Neale Mahoney & Francis Wong, *Medical Debt in the US, 2009-2020*, 326 JAMA 250 (2021), <https://jamanetwork.com/journals/jama/fullarticle/2782187>. Kluender and coauthors estimated that the amount of medical debt currently in collections – a tiny fraction of the total medical debt burden – to be \$140 billion. In contrast, an earlier study estimated medical debt in collections in 2016 to be \$81 billion. See Michael Batty, Christa Gibbs & Benedic Ippolito, *Unlike Medical Spending, Medical Bills In Collections Decrease With Patients’ Age*, 37 HEALTH AFFS. 1257 (2018), <https://doi.org/10.1377/hlthaff.2018.0349>.

¹⁵ The Endocrine Society, *Addressing Insulin Access and Affordability: An Endocrine Society Position Statement*, 106 J. CLINICAL ENDOCRINOLOGY & METABOLISM 935, 936 (2021).

¹⁶ Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, 179 JAMA INTERNAL MED. 112 (2019).

¹⁷ OFF. HEALTH POL’Y, OFF. ASS. SEC. FOR PLANNING AND EVAL., *MEDICARE PART B DRUGS: TRENDS IN SPENDING AND UTILIZATION, 2016–2017* (2020), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/197396/Part-B-Drugs-Trends-Issue-Brief.pdf.

¹⁸ JULIETTE CUBANSKI & TRICIA NEUMAN, KAISER FAM. FOUND., *THE FACTS ON MEDICARE SPENDING AND FINANCING* (July 2017), <https://collections.nlm.nih.gov/master/borndig/101717009/Issue-Brief-The-Facts-on-Medicare-Spending-and-Financing.pdf>; see also XAVIER BECERRA, *REPORT TO THE WHITE HOUSE COMPETITION*

reflects increases in drug prices that significantly outpaced inflation.¹⁹ Indeed, among Medicare Part D drugs, the median price increases were 3.5 times the rate of inflation.²⁰

High drug prices thus are a major challenge for Medicare financing. One study estimated that reducing the prices paid by Medicare for only brand-name drugs to those paid by other government providers such as the Veterans Health Administration would decrease taxpayer contributions by at least \$11 billion each year.²¹ Similarly, the CBO has estimated that various legislative proposals that would allow the government to negotiate drug prices through Medicare would save the program anywhere from \$80 to nearly \$500 billion over 10 years.²²

High drug prices are not just a problem for the fiscal sustainability of the program. They are also a major problem for Medicare beneficiaries because they translate into greater cost sharing burdens. Medicare patients are on the hook for a percentage of their treatment costs due to coinsurance obligations, which apply even after they have met their deductibles and out-of-pocket maximums. These sums can be exorbitant when drugs cost as much as \$75,000 per year.²³ On top of this, Medicare deductibles have risen faster than inflation, including for the Part D drug

COUNCIL (2021), <https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf> (“Medicare spending on drugs is growing faster than Medicare spending on other services: 5.9 percent annually on Part B Fee-for-Service drugs and Part D, compared to 5.3 percent for the program as a whole. Drug spending per beneficiary on Medicare Part B, which covers drugs administered in physician offices and hospital outpatient departments, has increased roughly eight percent each year since 2006, and nearly 10 percent from 2017-2018, compared to about six percent annually for overall Part B spending. Medicare Part B drug spending has been growing even more sharply in recent years. With no cap on out-of-pocket spending in Medicare Part D, beneficiaries who need expensive drugs or many different drugs to treat chronic conditions can be hit particularly hard: in 2019, nearly 1.5 million beneficiaries had out-of-pocket spending above the catastrophic threshold that is currently set at \$6,550, with 3.6 million beneficiaries having had out-of-pocket spending above the catastrophic threshold in at least one year over the ten year period from 2010-2019.”).

¹⁹ Drug prices outpaced inflation in half of all Part D-covered drugs (1,646 drugs) between July 2018 and July 2019. JULIETTE CUBANSKI & TRICIA NEUMAN, KAISER FAM. FOUNDATION, PRICE INCREASES CONTINUE TO OUTPACE INFLATION FOR MANY MEDICARE PART D DRUGS (2021), <https://www.kff.org/medicare/issue-brief/price-increases-continue-to-outpace-inflation-for-many-medicare-part-d-drugs/>. The inflation rate in this article is based on CPI-U.

²⁰ *Id.*

²¹ MARC-ANDRE GAGNON & SIDNEY WOLFE, PUB. CITIZEN, MIRROR, MIRROR ON THE WALL: MEDICARE PART D PAYS NEEDLESSLY HIGH BRAND-NAME DRUG PRICES COMPARED WITH OTHER OECD COUNTRIES AND WITH U.S. GOVERNMENT PROGRAMS (2015), <https://www.citizen.org/wp-content/uploads/2269a.pdf>.

²² See CONG. BUDGET OFF., DIVISION A – PRESCRIPTION DRUG PRICING REDUCTION ACT OF 2019 (2020), <https://www.cbo.gov/system/files/2020-03/PDPRA-SFC.pdf>; Report from Phillip L. Swagel, Dir., Cong. Budget Off., to Frank Pallone Jr., Chairman, H. Comm. on Energy & Com. (Dec. 10, 2019), https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf (Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act); see also Lovisa Gustafsson and Rachel Nuzum, The Case for Drug-Pricing Reform — The Cost of Inaction, Commonwealth Fund (May 26, 2021), <https://www.commonwealthfund.org/blog/2021/case-drug-pricing-reform-cost-inaction> (describing generally various possible reforms and their potential for significant cost-savings).

²³ Michelle Andrews, *Doughnut Hole Is Gone, But Medicare’s Uncapped Drug Costs Still Bite Into Budgets*, KAISER HEALTH NEWS (March 29, 2019), <https://khn.org/news/doughnut-hole-is-gone-but-medicare-uncapped-drug-costs-still-bite-into-budgets/>

program.²⁴ And increases in premiums can also be driven by the introduction of expensive new medicines, as this year's 14.5% increase in Part B premiums shows.²⁵

For seniors on Medicare who have common, chronic conditions (like diabetes and high blood pressure), out-of-pocket costs rose by over 40% between 2009 and 2019.²⁶ Note that this figure understates the true cost of the price increase because the overall costs of medication are shared by all Medicare beneficiaries through their premiums. Even so, this increase far outstripped the overall inflation rate over that period.²⁷ This increase was driven not by exogenous factors like supply shortages or labor costs, but by the development of new, patent-protected drugs without generic competitors. The same researchers found that costs for patients whose conditions were treated with generic drugs saw out-of-pocket costs fall during the same period, while those who were treated with brand drugs lacking generic competitors saw the largest increases.²⁸

A 2021 study published in the *Journal of the American Medical Association* found that 11% of Medicare beneficiaries reported delaying care due to concerns about cost, 11% reported difficulty paying medical bills, and 16% reported at least one of these problems.²⁹ The burden, predictably, fell hardest on the poor and those with multiple chronic conditions.³⁰ Since then, the problem has continued to worsen, with the most recent evidence showing dramatic increases in the number of Americans skipping treatment due to cost concerns.³¹ According to one study, approximately

²⁴ Mark Miller, *How to Cope With Medicare's Rising Costs*, N.Y. TIMES (Dec. 22, 2021), <https://www.nytimes.com/2021/12/22/business/medicare-retirement-costs.html?smid=url-share>.

²⁵ Dena Bunis, *AARP Urges Feds to Lower 2022 Part B Premiums*, AARP HEALTH (Jan. 25, 2022), <https://www.aarp.org/health/medicare-insurance/info-2022/part-b-premium-increase-reassess-alzheimers-drug.html>.

²⁶ Reshma Ramachandran, Tianna Zhou & Joseph S. Ross, *Out-of-Pocket Drug Costs for Medicare Beneficiaries Need to Be Reined in*, STAT NEWS (Jan 7, 2022), <https://www.statnews.com/2022/01/07/out-of-pocket-drug-costs-for-medicare-beneficiaries-need-to-be-reined-in>.

²⁷ The overall inflation rate in the period was roughly 19%, according to U.S. BUR. LAB. STATS., CPI INFLATION CALCULATOR (last visited Jan. 31, 2022), https://www.bls.gov/data/inflation_calculator.htm (calculating the rise in CPI-U from January 2009 to January 2019).

²⁸ Ramachandra, *supra* note 25.

²⁹ Jeanne M. Madden, et al., *Affordability of Medical Care Among Medicare Enrollees*, JAMA HEALTH F., Dec. 2021, doi:10.1001/jamahealthforum.2021.4104; see also MICHAEL KARPMAN, ET AL., URBAN INSTITUTE, IN THE YEARS BEFORE THE COVID-19 PANDEMIC, NEARLY 13 MILLION ADULTS DELAYED OR DID NOT GET NEEDED PRESCRIPTION DRUGS BECAUSE OF COSTS (2021), <https://www.urban.org/research/publication/years-covid-19-pandemic-nearly-13-million-adults-delayed-or-did-not-get-needed-prescription-drugs-because-costs>; JULIETTE CUBANSKI ET AL., KAISER FAM. FOUND., THE FINANCIAL BURDEN OF HEALTH CARE SPENDING: LARGER FOR MEDICARE HOUSEHOLDS THAN FOR NON-MEDICARE HOUSEHOLDS (2018), <https://www.kff.org/fb23909/>.

³⁰ Beneficiaries who make less than \$50,000 per year were twice as likely to delay care as those who make more than \$50,000, and those with four or more chronic conditions were twice as likely to delay care as those with one or no chronic conditions. Madden, *supra* note 28, at 6.

³¹ *New Poll: Major Spike in Percent of Americans Skipping Medical Treatment due to Cost*, WEST HEALTH (Dec. 14, 2021), <https://www.westhealth.org/press-release/2021-healthcare-in-america-report-2/>. A poll by Gallup and West Health found that one fifth of Americans in 2021 reported negative health consequences after they or a family member delayed care due to cost. The rate of delayed care was comparable between Medicaid beneficiaries (37%) and the uninsured (39%), and Black adults were twice as likely as white adults to personally know someone who died after delaying their medical care. Although the study did not separately provide results for Medicare beneficiaries, research has generally confirmed that the financial burdens associated with healthcare are at least as high if not higher among Medicare beneficiaries compared to the general population. See *supra* notes 21–29.

112,000 Medicare beneficiaries will die each year by 2030 due to skipping treatment because of high costs.³²

The High Drug Price Problem Is a Monopoly Problem

Why are prices so high in the US? The core of the problem is quite simple: drug companies have exclusive rights that permit them to set high prices, and unlike almost every other wealthy country, the US has no concerted system to constrain this monopoly power to ensure fair prices.³³ Companies also engage in anti-competitive conduct that exacerbates the problem.

The drug industry's high prices reflect a specific kind of monopoly problem. Even without industry concentration, government-backed rights create forms of market power that allow companies to set high prices, particularly in a context of widespread insurance and even mandates to cover monopolized products.³⁴ For example, the US government allows many kinds of patents on drugs, including not only patents on new molecules or active ingredients, but also patents on new dosages, formulations, and minor modifications of a chemical compound like a salt or isomeric form.³⁵ All of these patents last 20 years, and allows patentees to exclude others from making, using, importing, or selling the covered inventions. Companies can create “thickets” of such patents, ring-fencing lucrative medicines to forestall competition. Other forms of market exclusivity are also granted at the regulatory interface, such as data exclusivity that prevents generic or biosimilar drug registration based on originator data for a certain number of years.

This is why though most prescriptions in the US are for generic drugs, spending is heavily concentrated on patented medicines. Brand-name drugs, for example, account for three-quarters of drug spending overall.³⁶ And a small number of newer medicines without generic competition comprise the bulk of our spending. Medicare offers an example. Just 7% of drugs in Medicare Part D drive 60% of spending.³⁷ Medicare, of course, is forbidden by law from negotiating for lower prices for medicines.

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

³² COUNCIL FOR INFORMED DRUG SPENDING ANALYSIS, HIGH DRUG PRICES AND PATIENT COSTS: MILLIONS OF LIVES AND BILLIONS OF DOLLARS LOST (Nov. 18, 2020), <https://www.cidsa.org/publications/xcenda-summary> (CIDSA is a non-partisan group of experts funded by West Health).

³³ Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858 (2016), <https://doi.org/10.1001/jama.2016.11237>.

³⁴ Rachel Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307 (2018) (noting that federal law also requires that Medicaid and Medicare “cover most, and in many cases all, FDA-approved drugs,” and that private insurers are also required to cover many drugs, mandated by the ACA’s “essential health benefits” requirement and many state laws).

³⁵ Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of ‘Secondary’ Pharmaceutical Patents*, 7 PLOS ONE e49470 (2012), <https://doi.org/10.1371/journal.pone.0049470>.

³⁶ Aaron Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858 (2016).

³⁷ JULIETTE CUBANSKI, ET AL., KAISER FAMILY FOUNDATION, RELATIVELY FEW DRUGS ACCOUNT FOR A LARGE SHARE OF MEDICARE PRESCRIPTION DRUG SPENDING (2021), <https://www.kff.org/medicare/issue-brief/relatively-few-drugs-account-for-a-large-share-of-medicare-prescription-drug-spending/>.

to R&D.³⁸ 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.

So, we see that the largest pharmaceutical companies spend significantly more on marketing than they do on R&D even during a global pandemic, with some exceeding R&D two-fold.³⁹ We see old drugs – with no new innovation, like analogue insulins – rising in price. And we see companies engaging in exploitative and anti-competitive conduct, lining their pockets not by investing in breakthrough innovations, but by investing in patent lawyers to engage in “life-cycle management” by creating patent thickets rather than investing in new drugs.⁴⁰

We know also that it is government funding, not industry funding, that is disproportionately likely to lead to breakthrough medicines.⁴¹ The unfortunately reality is that high drug prices are not guaranteeing us investment in the right kind of innovation.⁴² The silver lining is that it is possible to act on high prices without undermining innovation, and indeed while *improving* innovation incentives by ensuring that only real innovation is rewarded.

Patent Abuse: Patent Thickets and Pay-for-Delay

³⁸ See, e.g., US DEP’T HEALTH & HUM. SERVS., PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS (2016), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/192456/DrugPricingRTC2016.pdf (“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, 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.”).

³⁹ AHIP, NEW STUDY: IN THE MIDST OF COVID-19 CRISIS, 7 OUT OF 10 BIG PHARMA COMPANIES SPENT MORE ON SALES AND MARKETING THAN R&D (2021), <https://www.ahip.org/news/articles/new-study-in-the-midst-of-covid-19-crisis-7-out-of-10-big-pharma-companies-spent-more-on-sales-and-marketing-than-r-d>.

⁴⁰ Kerstin N. Vokinger et al., *Strategies That Delay Market Entry of Generic Drugs*, 177 JAMA INTERNAL MED. 1665 (2017).

⁴¹ See Aaron S. Kesselheim, Yongtian Tina Tan & Jerry Avorn, *The Roles of Academia, Rare Diseases, and Repurposing in the Development of the Most Transformative Drugs*, 34 HEALTH AFFS. 286 (2015) (“We studied the developmental histories of twenty-six drugs or drug classes approved by the Food and Drug Administration between 1984 and 2009 that were judged by expert physicians to be transformative (in two cases, the first drug in a transformative class was approved before 1984). Most of the twenty-six were first approved early in the study period; only four were approved in 2000 or later. Many were based on discoveries made by academic researchers who were supported by federal government funding. Others were jointly developed in both publicly funded and commercial institutions; the fewest number of drugs had originated solely within pharmaceutical industry research programs.”); Aaron S. Kesselheim, *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study*, 367 BMJ 1 (2019), <https://www.bmj.com/content/bmj/367/bmj.l5766.full.pdf>; Ekaterina Cleary, Matthew Jackson & Fred Ledley, *Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019* (Inst. for New Econ. Thinking, Working Paper No. 133, 2020), <https://www.ineteconomics.org/research/research-papers/government-as-the-first-investor-in-biopharmaceutical-innovation-evidence-from-new-drug-approvals-2010-2019>.

⁴² Unlike government, which funds research in order promote public health, corporations assign their research funds based on marketability and profit, rather than therapeutic benefits. As a result, research in the most important biomedical sectors is chronically underfunded. See Massimo Florio, *Biomed Europa: After the Coronavirus, A Public Infrastructure to Overcome the Pharmaceutical Oligopoly*, 92 ANNALS PUB. COOP. ECON. 387, 388 (2021); see also Son Le, et al., *Reaching for Mediocrity: Competition and Stagnation in Pharmaceutical Innovation*, 64 INT. REV. L. & ECON. 1 (2020) (describing substantial underinvestment by private firms in developing novel drugs, but overinvestment in marginal, “me too” drugs).

Consider the problem of “patent thickets.” Patent thickets occur when pharmaceutical firms file numerous patents on an existing product in order to create barriers to competition and to extend effective patent life. In a study of all new molecular entities approved in the US from 1998 to 2005, colleagues and I showed that “secondary” patents (for example, on formulations, methods of treatment, or isomers) are extremely common in the industry – in fact, more common than patents on chemical compounds.⁴³ We also showed that where both compound patents and secondary patents existed, the latter added between 4 and 5 years of nominal additional patent term.⁴⁴ A more recent study looked at biologic drugs litigated from 2010 to 2020 and found that only 6% of patents on biologics covered innovative new molecules. Most others instead covered associated manufacturing processes, alternative uses of a medicine, and formulations.⁴⁵

One of the most infamous examples of patent thicketing is Humira, the world’s best-selling drug. AbbVie, the drug’s manufacturer, filed over 130 patents related to the drug’s manufacturing methods and formulations just a few years before the patent’s expiration date.⁴⁶ Conveniently, AbbVie tripled the price of Humira, a drug used to treat arthritis, between 2006 and 2017.⁴⁷ This is not a unique tactic. One study found that on average, across the top twelve grossing drugs in the United States, there are 125 patent applications filed per drug, with associated prices increasing by 68% between 2012 and 2018.⁴⁸

The same study finding extreme patent thickets around the top twelve grossing drugs in the United States also observed “38 years of attempted patent protection blocking generic competition sought by drugmakers for each of these top grossing drugs.”⁴⁹ These anti-competitive measures help prop up prices, especially of the most profitable drugs where this kind of evergreening is the most common.⁵⁰

Pay-for-delay tactics are another form of anticompetitive practice that increase drug prices. Reverse payment patent settlements, the most frequently cited example of pay-for-delay tactics, take place during patent litigation when generic firms decide to abstain from entering a market in exchange for large sums of money from a brand-name manufacturer. This benefits the patent-holder by staving off open competition for a period, and the patent holder then turns over some of the spoils to the generic company. The ulcer drug Zantac provides an example. Glaxo—the drug’s manufacturer—agreed to pay the generic firm seeking entry a large, undisclosed sum (some

⁴³ See Amy Kapczynski, Chan Park & Bhaven Sampat, *supra* note 34, at 4.

⁴⁴ *Id.*

⁴⁵ Ed Silverman, *Patent Thickets Are Thwarting U.S. Availability of Lower-Cost Biosimilar Medicines, Study Finds*, STAT NEWS (Jan. 18, 2022), <https://www.statnews.com/pharmalot/2022/01/18/patent-biosimilar-abbvie-biologic/>.

⁴⁶ PATRICIA KELMAR, U.S. PUB. INT. RSCH. GROUP, HACKING THROUGH THICKETS OF DRUG PATENTS TO GET TO AFFORDABLE MEDICINE (2021), <https://uspig.org/blogs/blog/usp/hacking-through-thickets-drug-patents-get-affordable-medicine>.

⁴⁷ *Id.*

⁴⁸ IMAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES (2018), <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>.

⁴⁹ *Id.* at 2.

⁵⁰ The Drug Prices Team, 'Evergreening' Stunts Competition, Costs Consumers and Taxpayers, ARNOLD VENTURES (Sept. 24, 2020), <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers>.

estimate a number upwards of \$100 million) in exchange for an extended period without competition which, at the time, yielded Glaxo \$2 billion a year.⁵¹

The Federal Trade Commission estimated in 2010 that “pay-for-delay agreements would cost consumers \$35 billion over the next ten years.”⁵² More recent estimates have suggested that pay-for-delay tactics deals cost roughly \$26 billion a year.⁵³ Pharmaceutical companies have also innovated a number of other illegitimate ways to prevent competition, including denying generic manufacturers access to drug samples necessary for bioequivalence testing, misusing risk evaluation and mitigation strategies, and filing citizen petitions with the US Food and Drug Administration (FDA).⁵⁴ The 2019 CREATES Act targeted two such strategies, sample blockades and safety protocol filibusters, and shows that concerted Congressional action can help curb such activity.⁵⁵

This is “Inflation” that We Know How to Address

There is a great deal of concern in Washington today about inflation. In closing, it is worth noting that this is fundamentally inflationary environment, and has been for a long time. I’d like to stress two things about inflation in this context.

First, some have cast doubt on the idea that there is a relationship between monopolies and inflation. This is one domain where the link is perfectly clear. Opportunities for monopoly power have increased in recent decades, as exclusive rights have expanded, as firms have innovated new ways to abuse their market power, and as insurer mandates to cover pharmaceuticals have expanded. It is generally agreed that increases in monopoly power will cause increases in prices.

The problem is exacerbated by certain features of this market, including the fact that medicines are essential and often do not have good substitutes, and that third-party payers can both spread costs and obscure price increases (and so interfere with concerted responses and accountability). Intellectual property law is being exploited to allow monopolists to increase real prices without corresponding increases in quality, and without jeopardizing market share.

The only thing that really checks the ability of monopolies to raise drug prices is political pressure, and ultimately the willingness of the government to intervene.⁵⁶ This is particularly true when their biggest buyer – Medicare – is barred from even negotiating what it pays.

⁵¹ C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1568–69 (2006).

⁵² Robin Feldman et al., *Pharmaceutical “Pay-for-Delay” Reexamined: A Dwindling Practice or a Persistent Problem?*, 71 HASTINGS L.J. 959, 961 (2020).

⁵³ Symposium, *Assessing Strategies to Delay Generic Drug Entry*, 11 N.Y.U. J. INTELL. PROP. & ENT. L. 60, 71 (2021).

⁵⁴ Aaron S. Kesselheim, *Strategies That Delay Market Entry of Generic Drugs*, 177 JAMA INTERN. MED. 1665 (2017).

⁵⁵ Michael Kades, *The CREATES Act Shows Legislation Can Stop Anticompetitive Pharmaceutical Industry Practices*, WASH. CTR. EQUITABLE GROWTH (May 27, 2021), <https://equitablegrowth.org/the-creates-act-shows-legislation-can-stop-anticompetitive-pharmaceutical-industry-practices/>.

⁵⁶ See Rena M. Conti, *How Do Commercial Insurance Plans Fare Under Proposed Prescription Drug Price Regulation?* JAMA HEALTH F., Dec. 2021, <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2787467> (explaining why drug companies, despite being monopolists, might not always price their drugs at the profit maximizing level out of the gate in order to reap second order benefits like public and political goodwill, thereby preserving their ability to hike prices down the road).

This is also a sector where inflated prices are causing enormous pain, as described earlier. And yet, for many years – and still, as we sit here today – this Chamber has taken no serious action. Why is this not treated as an emergency, given the urgency for people’s lives? And given that the government has clear, sector-specific tools that are well mapped out to address the problem? Many would also argue sector-specific approach to inflation is better than taking economy-wide action, for example through the Fed.

We also know how to curb inflation in this sector. The path is extremely well mapped out, particularly when as compared to other sectors of the economy. Other countries have successfully curbed drug prices, implementing many different versions of fair pricing regulation that are well studied. Congress has now had years of legislative hearings, taking evidence about those experiences and considering draft legislation. It is past time to act, to pass serious legislation to curb high drug prices and anti-competitive practices in the industry.

Recommendations

I close with several recommendations. In order to protect the future of the Medicare program, and Medicare beneficiaries, Congress should:

- Pass legislation that curbs high launch prices, by enabling HHS negotiators to establish fair prices, either through negotiation or administratively. Inputs to fair prices should include measures of R&D expenditures, public funding, investment risk, and therapeutic benefit of the drug. These negotiations must be backed by strong enforcement measures, such as the ability to allow generic competitors into the market if a company refuses to sell at the established price.
- Pass legislation to penalize price spikes, to prevent price gouging on existing drugs.
- Explore legislation that would curb anti-competitive patent thicketing and that would strengthen rules against pay-for-delay settlement deals that delay generic entry.
- Provide the FTC with more resources and authority to address anti-competitive conduct in this sector.