IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., *Plaintiff*, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services, et al., *Defendants.*	Civil Action No. 1:23-1615-CKK

PROPOSED BRIEF OF THE AMERICAN PUBLIC HEALTH ASSOCIATION, THE AMERICAN COLLEGE OF PHYSICIANS, THE SOCIETY OF GENERAL INTERNAL MEDICINE, AND THE AMERICAN GERIATRICS SOCIETY AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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individual health. *Amici* have long advocated for evidence-based and value-oriented public policy regarding drug pricing.[2] Controlling unsustainable drug prices and fixing the market failures that contribute to the astronomical cost of prescription drugs is necessary to preserve patient health and to ensure the longevity and sustainability of the social safety net.

For decades, Medicare did not cover prescription drug costs for older adults. Older adults had to find their own private plans to access care. Congress, in 2003, amended the Medicare statute to create Part D pharmacy benefits. *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 & 749 n.2 (3d Cir. 2017). "At the time, more than 14 million seniors in America had no access to drug coverage and more than one-third reported not taking their medicines as prescribed due to cost."[3] Starting in 2006, older adults could enroll in plans run by private companies that contracted with Medicare. These plans generally charge older adults a

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[2] *See, e.g.*, Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* (Nov. 8, 2022), https://tinyurl.com/4v7c35j8; Am. Pub. Health Ass'n, *APHA Applauds Senate Passage of Inflation Reduction Act* (Aug. 8, 2022), https://tinyurl.com/3etz4e7d; Am. Pub. Health Ass'n, *Ensuring That Trade Agreements Promote Public Health* (Nov. 13, 2015), https://tinyurl.com/b2et6uvp; Am. Pub. Health Ass'n, *Creating the Healthiest Nation: Advancing Health Equity*, https://tinyurl.com/5xn4ue8n (last visited Sept. 18, 2023); Am. Pub. Health Ass'n, *Regulating Drugs for Effectiveness and Safety: A Public Health Perspective* (Nov. 8, 2006), https://tinyurl.com/5n7zv9bd; Am. Coll. Physicians, *ACP: Passage of Inflation Reduction Act Improves Access to Health Care Services, Treatments*, https://tinyurl.com/44wmn2b6 (last visited Sept. 18, 2023); William Fox, *ACP Comments on CMS' Proposed Changes to Medicare Advantage and Part D*, Am. Coll. Physicians (Feb. 13, 2023), https://tinyurl.com/5a8bxdf7; Ryan D. Mire, *Internal Medicine Physicians Call Inflation Reduction Act a Win for Health in U.S.*, Am. Coll. Physicians (Aug. 15, 2022), https://tinyurl.com/4rhr7skw; Ryan D. Mire, *ACP Letter in Support of Provisions of the Inflation Reduction Act*, Am. Coll. Physicians (Aug. 2, 2022), https://tinyurl.com/4rzhymm3; Hilary Daniel & Sue S. Bornstein, *Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs: A Position Paper From the American College of Physicians,* Annals Internal Med., 2019, https://tinyurl.com/3tsxa443; Am. Coll. Physicians, *Address Prescription Drug Costs*, https://tinyurl.com/4hyh2326 (last visited Sept. 18, 2023).

[3] Reshma Ramachandran, Tianna Zhou, & Joseph S. Ross, *Out-Of-Pocket Drug Costs for Medicare Beneficiaries Need to Be Reined In* (Jan. 7, 2022), https://tinyurl.com/33jjrr8b.

premium and, for each prescription filled, older adults pay co-insurance or make a co-payment. Part D benefits allowed older adults, especially low-income people, to access critical care: "annual out-of-pocket drug costs dropped an average of 49% among those who previously did not have drug coverage."[4] Part D was incredibly successful and, in 2022, 49 million of the 65 million people covered by Medicare were enrolled in Part D plans.[5]

Medicare became one of the single largest underwriters of drug therapy in the United States but, unlike private health insurance providers, it was not allowed to negotiate directly with drug manufacturers for the prices of the drugs it was paying for. *See* 42 U.S.C. §§ 1395w-111(i). Drug prices—especially for drugs targeted at people over 65 who have Medicare's guaranteed coverage—have ballooned over the last two decades. They have put the system at peril, have bankrupted older Americans, and have undercut the core public health mission Congress was advancing through its 2003 revisions.

Fixing Part D is vital, and Congress finally acted by passing the Inflation Reduction Act. It empowered CMS to identify certain drugs that have long been on the market for negotiation, taking their total cost to Medicare and other considerations into account. *See* 42 U.S.C. § 1320f. CMS is mandated to negotiate prices for these drugs over the course of multiple years. *Id.* §§ 1320f-1(a)-(b). Manufacturers can choose to withdraw their drugs from large government health insurance systems if they do not wish to negotiate prices. *See* Defendants' brief in opposition to Plaintiff's motion for summary judgment and in support of Defendants' motion for summary judgment, at 5-6, ECF No. 24-1. Plaintiff Merck and other drug companies are seeking

[4] *Id.*

[5] Kaiser Fam. Found., *An Overview of the Medicare Part D Prescription Drug Benefit* (Oct. 19, 2022), https://tinyurl.com/ya3fhu69.

to gut the law, which would stop these vital reforms. The Court should deny Plaintiff's motion for summary judgment, ECF No. 23, and grant Defendants' cross-motion for summary judgment, ECF No. 24.

retail inflation, their average annual cost would have gone up by only about $2,000 during this same period; a saving of almost $50,000 per drug.[17] This disproportionate growth has continued since the AARP's 2017 study: KFF, formerly known as the Kaiser Family Foundation, estimated that between 2018 and 2021 gross Medicare spending for the top selling Part D drugs has more than doubled.[18]

The Drug Negotiation Program intervenes in the unsustainable growth in prices of drugs already on the market. The AARP found that prices for drugs chosen for negotiation under the Program increased far above inflation, unmoored to any additional costs associated with research and development.[19]

Plaintiff Merck's Januvia, which treats type 2 diabetes, is a case in point. The cumulative rate of retail inflation since 2006 (when Januvia was released) and the present is approximately

[17] *Id*. at 1 ("Between 2016 and 2017, retail prices for 97 specialty prescription drugs widely used by older Americans, including Medicare beneficiaries, increased by an average of 7.0 percent. In contrast, the general inflation rate was 2.1 percent over the same period. . . . Retail prices for 27 chronic use specialty drugs that have been on the market since the beginning of the study (i.e., between January 2006 and December 2017) increased cumulatively by an average of 226.4 percent over 12 years. In contrast, general inflation in the US economy rose 25.1 percent during the same 12-year period.").

[18] Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, Kaiser Fam. Found. (July 12, 2023), https://tinyurl.com/ycytf6wm. The Office of Health Policy with the Department of Health and Human Services estimated that there were 1,216 products whose prices increased more than general inflation between July 2021 and July 2022. The average price increase was 31.6%, though some prices increased as much as 500%. *See* Arielle Bosworth et al., *Issue Brief, Price Increases for Prescription Drugs, 2016-2022*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't Health & Human Servs. 1 (Sept. 30, 2022), https://tinyurl.com/44tmd4rr.

[19] Leigh Purvis,

52%.[20] In contrast, Januvia's price went up by 275% in that period.[21] It cost Merck roughly $320 million to develop Januvia and to get it approved by the FDA; after it was already on the market, Merck spent another $5 billion to identify ws(he)4 ottifact o-2 (he)4 (F3 ($54 (ont)d-2 (t)-2 (a-2 (on t-1

The table below summarizes data (where available) for the drugs chosen for negotiation.

Prescription Drugs Chosen for Negotiation: Price Hikes, Revenue, and Research

Drug	**Year of FDA approval**	**Percentage increase in price since approval**[25]	**Medicare Part D Gross Cost (June 2022-May 2023)**[26]	**Global lifetime sales (2021)**[27]	**Total R&D costs (2021)**[28]
Enbrel	1998	701%	$2.8 bn	$132.5 bn	unknown[29]
Novolog[30]	2000	628%	$2.6 bn	$42.8 bn	unknown
Januvia	2006	275%	$4.1 bn	$54.1 bn	$5.3 bn
Stelara	2009	184%	$2.6 bn	$54.8 bn	$2.1 bn
Xarelto	2011	168%	$6.0 bn	$54.3 bn	$7.8 bn
Eliquis	2012	124%	$16.5 bn	$57.1 bn	$4.3 bn
Imbruvica	2013	108%	$2.7 bn	$36.8 bn	$1.4 bn
Jardiance	2014	97%	$7.1 bn	$18.3 bn	$3.5 bn
Farxiga	2014	81%	$3.3 bn	$15.8 bn	$5.2 bn
Entresto	2015	78%	$2.9 bn	$14.3 bn	$4.8 bn

[25] Purvis, *supra* note 19; @AARP, Twitter (Sept. 8, 2023, 5:56pm), https://tinu35I 0.388 0(.004 Tw 6.69 0 Td66-19.12 -1.15 Td[(ht)-2 (t 13[(ht)-64)re(hu2xBDC /CS1 B8 TcSpan.0

R Americans, especially older adults, cannot sustain these high prices.

Even though most of the cost of high-priced medication is borne by Medicare, a significant portion is also borne by older Americans who pay premiums for Medicare Part D plans that can cost hundreds of dollars a month.[31] In addition to premiums, Medicare

Part D spending, up from 14% in 2006.[35] In some cases, the movement of patients into "catastrophic" levels in Medicare Part D can be traced to the increase in price of just one or a few drugs.[36] More than a third of older people have had medical debt recently.[37] Twenty-four percent of people over 65 with medical debt trace it to prescription drugs.[38]

Of course, the effects of high drug prices are not limited to older Americans: According to polls conducted by KFF in 2022, "[a]bout half of U.S. adults say that it is very or somewhat difficult for them to afford their health care costs (47%)."[39] One in six older adults in the United States report difficulty affording out-of-pocket costs for drugs.[40] Thirty percent of people experiencing medical debt reported it was due to their need for prescription drugs.[41] Fears about medical costs and debt have topped peoples' list of financial worries for many years.[42]

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[35] *An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 5.

[36] *See* Hilary Daniel & Sue S. Bornstein, *Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs: A Position Paper From the American College of Physicians,* Annals Internal Med., 2019, at 825 (analyzing the effects of increasing prices of multiple sclerosis drugs).

[37] Noam N. Levey, *100 Million People in America Are Saddled with Health Care Debt*, KFF Health News (June 16, 2022), https://tinyurl.com/4hapcdbj.

[38] Lunna Lopes et al., *Health Care Debt in the U.S.: The Broad Consequences of Medical and Dental Bills*, Kaiser Fam. Found. (June 16, 2022), https://tinyurl.com/bddpnkk6.

[39] Alex Montero et al., *Americans' Challenges with Health Care Costs*, Kaiser Fam. Found. (July 14, 2022), https://tinyurl.com/yck7juez.

[40] Steven Morgan & Augustine Lee, *Cost-Related Non-Adherence to Prescribed Medicines Among Older Adults: A Cross-Sectional Analysis of a Survey in 11 Developed Countries*, BMJ Open, Jan. 2017, at 4, https://tinyurl.com/2u8tfn8e.

[41] Lopes et al., *supra* note 38.

[42] Montero et al., *supra* note 39.

The impact of an expensive prescription drug delivery system is most poignant when reviewing cost-related nonadherence (CRNA) to medications. CRNA is the widely reported phenomenon where patients stop taking prescription drugs because of rising prices, even where the drug is "essential" to their health.[43] In 2022, "[a]bout a quarter of [US] adults [said] they or [a] family member in their household have not filled a prescription, cut pills in half, or skipped doses of medicine in the last year because of the cost, with larger shares of those in households with lower incomes, Black and Hispanic adults, and women reporting this."[44]

Although Americans covered by Medicare are insulated from some of the challenges faced by uninsured Americans under 65, they are not immune. A recent analysis by the Office of Health Policy using the National Health Interview Survey found that 6.6% of all adults over 65 (a total of 3.5 million people) faced affordability problems due to prescription costs, and 2.3 million of these older adults did not take needed prescriptions due to cost.[45] The same survey found that "Black and Latino beneficiaries were 1.5 to 2 times as likely to experience medication-related affhif.5 .3.w -7.68 -0.008 Tw 8.04 0 0 82Pt-4 (t)-6 (oal)--16 (l)-6 6 (en)-4 (g)-4 (es)-5 ( )]TJ0

with Medicare Part D.[47] By the summer of 2023, that figure had increased by 5 percentage points.[48] These figures would likely be higher still, except that some older people—8.5% according to one 2022 survey—choose the rock instead of the hard place and forego other basic needs, such as food, in order to afford their prescription drugs.[49]

Older adults in other countries do not struggle so mightily. Cost-related medication nonadherence in the United States is two to four times higher than in other developed countries.[50] Public health researchers have estimated that, "[c]ontrolling for age, sex, health status and household income, adults aged 55 and older in the USA were approximately six times more likely to report CRNA than adults aged 55 and older in the UK."[51]

Beyond these direct effects, CRNA has downstream effects on healthcare costs and patient wellbeing, because the same financial barriers that prevent people from filling prescriptions for "drugs taken for symptom relief" also "impede the use of essential, preventative

[47] Montero et al., *supra* note 39; *see also* Stacie B. Dusetzina et al., *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, JAMA Network, May 2023, at 3, https://tinyurl.com/4mccyu7x (estimating "20.2% [of older adults] reported any cost-related medication nonadherence").

[48] Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, Kaiser Fam. Found. (Aug. 21, 2023), https://tinyurl.com/hun2y8bn.

[49] Stacie B. Dusetzina et al., *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*, JAMA Network, May 2023, at 1; *see also* Karthik W. Rohatgi et al., *Medication Adherence and Characteristics of Patients Who Spend Less on Basic Needs to Afford Medications*, J. Am. Board Fam. Med., June 2021, https://tinyurl.com/ybzbf9nf.

[50] Morgan & Lee, *supra* note 40, at 4.

[51] *Id.* at 1.

medications" that would save them from death or serious injury.[52] Collectively, that leads to greater use of inpatient and emergency medical services by those patients.[53] Indeed, the initiation of Medicare Part D—which reduced CRNA—was itself associated with a drop in hospitalization rates for several conditions.[54] Some analysts have estimated that "high out-of-pocket costs for drugs will cause 1.1 million premature deaths of seniors in the Medicare program and will lead to an additional $177.4 billion in avoidable Medicare medical costs" between 2021 and 2031.[55]

Members of *amici* have observed and treated patients who ration their use of lifesaving medications because of the high co-pay costs passed on to them. For instance:

afford gas to the appointment, he had reduced how often he took his medication so it would last longer."

A doctor in Minnesota: "Bob (not his name) is in his early 60s. He's a single guy, no kids, living a bit on the margins and somewhat isolated. Income is limited but he works no fewer than 3 jobs driving a delivery truck in the Minneapolis metro area. Bob is on Metformin which is the appropriate first choice medication for diabetes, but this is not adequate for his diabetes control, so a second medication is warranted. So Bob must make a difficult decision. Begin [Novolog, Januvia, Farxiga, or Jardiance] as his second medication, and if needed, add a third medication from this list. To do this, he would have to basically stop living the life he wishes to lead [due to the expense of such medications]. Having no support network (no family or close friends), his solitary pursuits to live his life would have to end, despite working 3 jobs almost every day of the week."

A doctor in Delaware: "Patients consistently resist trying to get us to change them from Lisinopril to Entresto despite what the data shows when it comes to readmissions and quality of life. It is the same issue with Jardiance. If we convince them it often means they are giving up something else in their life given many are on a limited income."

A doctor in Florida: "I have patients who are stable on their oral anticoagulant like Xarelto or Eliquis and then they hit the doughnut hole [gap in coverage in Medicare] and have to stop their medications. They run the risk of blood clots and stroke but they can't afford [their medications]."

A doctor in Georgia: A patient had “atrial fibrillation and his cardiologist and primary care physician agree[d] that Eliquis is safer for him than Warfarin. He

the federal government negotiating prices on goods it purchases from private companies; it routinely does so for a wide variety of other products for which it is the sole or primary purchaser (for instance, for purchasing defense equipment).[57] Here, the benefit to the public will be substantial: KFF has estimated that many older Americans would save over 60% of their out-of-pocket costs under the new standards set by the IRA.[58] Merck's dramatic characterization of drug price negotiation as "radical central planning," ECF No. 23-1 at 1, notwithstanding, the Program will restore some semblance of freedom to a market that has, for many years, been shielded from market forces by the largest purchaser's inability to negotiate the prices it pays.

Two other federal government programs that provide prescription drug coverage and allow for direct negotiation between the government and drug manufacturers illustrate the value of drug price negotiation. *See* 38 U.S.C. §§ 8126(a)-(h). The Veterans Health Administration (VHA) operates as a closed system and provides care directly to veterans, covering several million people. It purchases drugs and other pharmaceuticals directly from manufacturers and has a national formulary that does not exist in Medicare or Medicaid. The Government Accountability Office (GAO) found that, in 2017, the VHA paid an average of 54% less per unit of medicine than Medicare, including for brand name drugs.[59] In more than half the 399 drugs

[57] Nat'l Acads. of Scis., Eng'g, & Med., *Making Medicines Affordable: A National Imperative* 52 (Norman R. Augustine et al. eds., 2018), https://tinyurl.com/2zjvmfk2.

[58] Juliette Cubanski, Tricia Neuman, & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, Kaiser Fam. Found. (Jan. 24, 2023), https://tinyurl.com/3adurnbk.

[59] U.S. Gov't Accountability Off., *GAO-21-111, Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017*, at 1 (2020), https://tinyurl.com/bdusnnrt.

the GAO analyzed, the VHA paid less than half the price per unit Medicare paid; for 106 drugs, the VHA paid less than 25% of what Medicare paid.[60]

Another example is the Department of Defense (DoD) uniform drug formulary (TRICARE formulary), which provides prescription drug coverage for roughly 9.5 million active-duty and retired military personnel, their dependents, and others. Within two years of being implemented in 2005, the DoD drug formulary led to roughly $1 billion in cost savings, representing approximately a 13% reduction in drug expenditures.[61] In its most recent report from 2022, the Defense Health Agency estimated $1 billion annual savings in retail pharmacy refunds on most brand-name retail drugs and reported a very low rate of annual growth in costs in recent years

The importance of negotiation to reducing prices is also illustrated by the differences in drug prices between the US and other similarly situated countries. The United States is the only country in the 34-member Organisation for Economic Co-operation and Development (OECD) that lacks some degree of government oversight or regulation of prescription drug pricing, and it is the only developed country other than New Zealand that allows the drug industry to set its own drug prices independent of government authority.[65] Studies have shown repeatedly that drug prices in the US are between 2 and 2.5 times more expensive than in other comparable countries.[66] Medicare's inability to negotiate drug prices, as compared to the ability of other large public health systems, is a key reason for higher US drug prices.[67]

III. Public Health Research Shows That The Program Is Unlikely To Have Substantial Negative Effects On Drug Availability Or Patient Outcomes.

Plaintiff Merck and other drug companies opposed to the negotiation program are correct that the United States leads the world in bringing drugs to market. But their claim that the Program will make it uneconomical to continue this pace of innovation, and thereby irretrievably hurt public health, is unsupported.

Prices Compared with Other OECD Countries and With U.S. Government Programs 11 (2015), https://tinyurl.com/2zuydwj7 (noting that the VA and Medicaid often pay the similar prices for drugs, while Medicare Part D pays almost twice as much).

[65] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, 165 Annals Internal Med., no. 1, 2016, at 50; Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* 2 (Nov. 8, 2022).

[66] Andrew W. Mulcahy et al., *U.S. Prescription Drug Prices Are 2.5 Times Those in Other OECD Countries*, Rand Corp. (2021).

[67] *See* Kaiser Permanente Inst. for Health Pol'y, *Pharmaceutical Pricing: Lessons from Abroad* (2015), https://tinyurl.com/3nbaj9a6; Dana O. Sarnak, et al., *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?*, Commonwealth Fund (Oct. 2017).

First: While it is true that developing new pharmaceuticals is an expensive and risky enterprise, it is not clear that the price reductions that result from the Program will lead to substantial reduction in the number of high-impact drugs brought to market. The CBO estimates that the Program will lead to only 13 fewer drugs being brought to market in the next 30 years, for an overall reduction of 1% in volume.[68] The Brookings Institute has similarly found that the Program is unlikely to substantially change the future development of medications, based on drug manufacturers' public market activity.[69] This is unsurprising, in part, because the Program does not apply to new drugs on the market and continues to grant pharmaceutical companies almost unfettered discretion to price new drugs at exorbitant rates.[70] Even without changing the price of new drugs, the public health benefits from lower drug prices for drugs that have been on the market for several years are likely to be orders of magnitude greater than the harm caused by this 1% reduction in new drugs: making existing drugs more affordable will enable more patients—especially low-income older people—to actually take and maintain existing necessary medication.

Second: Drug manufacturers' claim

marketing and lobbying, rather than research and development.[71] A 2015 study from the National Bureau of Economic Research estimated that nearly one third of the growth in drug spending is attributable to an increase in advertising.[72] Other estimates suggest that marketing and administration can contribute more than twice the cost of R&D to the total cost of bringing a drug to market.[73] The US is one of the only countries that allows such a vast scale and scope of direct-to-consumer advertising. Research has shown that direct to consumer advertising increased substantially after the introduction of Medicare Part D and may have been targeted to reach older Americans who were newly covered by governmental prescription drug insurance.[74] Even if the Program results in lower prices for certain drugs, any difficulty bringing new viable products to market may just as likely be attributable to self-imposed marketing overhead.

Third: New pharmaceutical development in the United States, and especially private corporate research priorities, does not always align with the goal of long-term effective increases in public health. In particular, the US regulatory system for pharmaceutical drugs does not require drug developers to routinely evaluate the marginal benefit of new and expensive

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[71] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, 165 Annals Internal Med., no. 1, 2016, at 11; Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* 3 (Nov. 8, 2022).

[72] Abby Alpert, Darius Lakdawalla, & Neeraj Sood, *Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D* 33 (Nat'l Bureau Econ. Rsch., Working Paper No. 21714, 2015), https://tinyurl.com/ytewscn3; *see also* Lisa M. Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997-2016*, JAMA Network, Jan. 2019, https://tinyurl.com/4hctxutv (noting that between 1997 and 2016, spending on marketing almost doubled, from $17.7 to $29.9 billion (in 2016 dollars)).

[73] Am. Pub. Health Ass'n, *Ensuring Equitable Access to Affordable Prescription Medications* 10 (Nov. 8, 2022).

[74] Abby Alpert, Darius Lakdawalla, & Neeraj Sood, *Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D* 17-18 (Nat'l Bureau Econ. Rsch., Working Paper No. 21714, 2015), https://tinyurl.com/ytewscn3.

Fourth: Drug manufacturers' claims about private innovation and market prices for drugs ignores the large share of research and development carried out or funded by the government or universities. The National Institutes of Health (NIH) have historically made the largest government investments in basic research and play a key role in spurring new innovations and breakthroughs.[80] Major innovative drugs have been discovered in public universities funded through grants from the NIH, and patent rights have been purchased after drug discovery by private companies, generating enormous revenues for drug companies.[81] Sitagliptin, for example, the active compound in Plaintiff Merck's Januvia, was in part originally patented with support from an NIH grant to Tufts University.[82] Between 1988 and 2005, federal research funding contributed to 45% of all drugs approved by the FDA and to 65% of drugs that received

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the total pharmaceutical R&D pipeline in 2018. *See* IQVIA Inst., *The Changing Landscape of Research and Development* (Apr. 2019), https://tinyurl.com/2p943hre.

[80] Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, 165 Annals Internal Med., no. 1, 2016, at 11.

[81] *Ensuring Equitable Access to Affordable Prescription Medications*, *supra* note 73, at 2. Studies have suggested that between 6 and 10% of "new molecular entities" (new innovative drugs) were first patented by public sector or academic institutions and that up to 40% of new molecular entities were first synthesized or purified in academic institutions. *See* Ekaterina Galkina Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010–2016*, 115 Proc. Nat'l Acad. Scis., no. 10, Mar. 2018, at 2332.

[82] *See* Nat'l Ctr. for Biotechnology Info., *PubChem Compound Summary for CID 4369359, Sitagliptin*, https://tinyurl.com/3srwt3x2 (last visited Sept. 18, 2023) (listing Patent No. 6,890,898 as one of the patents underlying Sitagliptin (Januvia)); U.S. Patent No. 6,890,898 B2 (issued May 10, 2023), https://tinyurl.com/bdzcwntx (patent application filed by Tufts University "supported by finding from the National Institutes of Health," disclosing that the "United States Government has certain rights in the invention"); Nat'l Acads. of Scis., Eng'g, & Med., *The Role of NIH in Drug Development Innovation and Its Impact on Patient Access: Proceedings of a Workshop* 32 (2020), https://tinyurl.com/yc4cfwfz.

priority review.[83] From 2010 through 2016, every one of the 210 new drugs approved by the FDA was the result of research funded by the NIH.[84] Insulin is a great example of this kind of process. It was developed in a non-commercial laboratory in the early 20th century and its patent was sold to the University of Toronto for $3, which in turn allowed manufacturers to license it royalty-fee.[85] Despite being the product of public and academic research a century ago, insulin prices have skyrocketed in recent years. Amongst the most expensive of these insulin-based treatments are Fiasp and Novolog, both of which are on the list of drugs eligible for negotiation under the Program. Combined, they accounted for $2.6 billion in total Medicare Part D spending between June 2022 and May 2023.[86]