[ORAL ARGUMENT NOT YET SCHEDULED]
Case No. 19-5222

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MERCK & CO., INC., *et al.*,

Plaintiffs-Appellees,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia
Case No. 1:19-cv-01738-APM

BRIEF OF AARP AND AARP FOUNDATION AS AMICI CURIAE IN SUPPORT OF DEFENDANTS-APPELLANTS URGING REVERSAL

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CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Plaintiffs in district court, and appellees here, are Merck & Co., Inc., Eli Lilly and Company; Amgen Inc.; and the Association of National Advertisers, Inc.

Defendants in district court, and appellants here, are the United States Department of Health and Human Services; Alex M. Azar II, in his official capacity as Secretary, United States Department of Health and Human Services; Centers for Medicare & Medicaid Services; and Seema Verma, in her official capacity as the Administrator of the Centers for Medicare & Medicaid Services. There were no amici curiae in the district court.

B. Rulings Under Review

Defendants-Appellants have sought review of the July 8, 2019 opinion and order of the United States District Court for the District of Columbia. *See Merck & Co., Inc., et al. v. U.S. Dep't of Health & Human Servs*., 385 F. Supp. 3d 81 (D.D.C. 2019) (Mehta J.).

C. Related Cases

The case on review has not previously been before this Court or any other court, save the district court where it originated. Counsel for Amici Curiae, AARP and AARP Foundation, are not aware of any related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

Date: September 30, 2019 /s/ Barbara Jones
Barbara Jones

CORPORATE DISCLOSURE STATEMENTS

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and D.C. Circuit Rule 26.1, Amici hereby submit the following disclosure statements:

AARP and AARP Foundation

The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) of the Internal Revenue Code and is exempt from income tax. The Internal Revenue Service has determined that AARP Foundation is organized and operated exclusively for charitable purposes pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. AARP and AARP Foundation are also organized and operated as nonprofit corporations under the District of Columbia Nonprofit Corporation Act.

Other legal entities related to AARP and AARP Foundation include AARP Services, Inc., and Legal Counsel for the Elderly. Neither AARP, nor AARP Foundation, has a parent corporation, nor has either issued shares or securities.

STATEMENT REGARDING CONSENT TO FILE, SEPARATE BRIEFING, AUTHORSHIP, AND MONETARY CONTRIBUTIONS

All parties have consented to the filing of this brief. Amici Curiae certify that no party or party's counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission. Amici Curiae also certify that only Amici Curiae provided funds to prepare and submit this brief. Federal Rules of Appellate Procedure 29(c)(5).

Pursuant to D.C. Circuit Rule 29(d), Amici certify that a separate brief is necessary to provide the perspective of older adults because they will be directly impacted by the Court's decision.

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GLOSSARY

ACA	Affordable Care Act
CMS	Centers for Medicare & Medicaid Services
DTC	Direct-to-Consumer
FDA	Food and Drug Administration
HHS	U.S. Department of Health and Human Services
KFF	Kaiser Family Foundation
PhRMA	Pharmaceutical Research and Manufacturers of America

STATUTUES AND REGULATIONS AT ISSUE

The joint appendix will include copies of the relevant regulations at issue. *See* Statement of Intent Regarding Appendix Deferral, Document No. 1807722 filed on September 23, 2019.

INTEREST OF AMICI CURIAE

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans age fifty and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial stability, and personal fulfillment. AARP's charitable affiliate, AARP Foundation, works to end senior poverty by helping vulnerable older adults build economic opportunity and social connectedness. Among other things, AARP and AARP Foundation fight for access to affordable healthcare, including access to lower-cost prescription drugs. AARP and AARP Foundation advocate for more affordable prescription drugs, including through participation as Amici Curiae in state and federal courts. *See, e.g.*, *Oil States Energy Servs.*, *v. Greene's Energy Grp.*, 138 S. Ct. 1365 (2018); *Sandoz, Inc. v. Amgen, Inc.*, 137 S. Ct. 1664 (2017); *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017).

Approximately ninety-five percent of people on Medicare are over the age of 50.[1] Because drug prices dramatically impact healthcare expenditures, AARP's

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[1] AARP Pub. Policy Inst., *AARP: Medicare Population*, AARP, https://data explorer.aarp.org/indicator/12/medicare-population#/rankingTable?dist1=40,47, 48,11,12,653,44,45,46,13,15,49&dist2=10&dist5=31&loc=1&tf=45&fmt=106 (last visited Sept. 27, 2019).

Public Policy Institute has tracked the price of widely used prescription drugs since 2004 and publishes the Rx Price Watch series, reporting on changes in drug prices that older Americans use widely.[2] Older adults are more likely to take prescription drugs: nine in ten report taking a prescription drug, and more than half report taking four or more prescription drugs.[3]

Amici have a strong interest in protecting the public from the ever-escalating costs of prescription drugs. These high costs disproportionately harm older adults, as they typically take more prescription drugs and live on fixed or lower incomes. Amici's participation in the case will assist the court to understand how the high price of prescription drugs harm consumers, the Medicare and Medicaid programs, and the national economy. It will also assist the court in understanding how prescription drug price transparency rules, such as the U.S. Department of Health and Human Services Direct-to-Consumer Advertising Rule (DTC Rule), can help combat the rising price of drugs. Amici urge this Court to reverse the district court's ruling and permit the DTC Rule to go forward.

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[2] The latest reports on trends in the retail prices of generic, brand name, and specialty drugs are available at: www.aarp.org/rxpricewatch.

[3] Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs*, KAISER FAM. FOUND. fig.7 (Mar. 1, 2019), https://www.kff.org/ health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/.

SUMMARY OF ARGUMENT

It is indisputable that the prices of prescription drugs have been increasing for years. Many Americans have been forced to compromise the quality of their medical treatment, and potentially their day-to-day lives, as a result of their inability to afford needed prescription drugs.

Because of its role as the health insurer for millions of Americans through the Medicare and Medicaid programs, the United States government is the single largest payer of prescription drugs in the nation. The price of prescription drugs has become exorbitantly high and has had a foreseeable impact on the Medicare and Medicaid programs. The "dramatically increasing costs are a threat to the sustainability of the programs and harm CMS [Centers for Medicare & Medicaid Services] beneficiaries every day." Medicare & Medicaid Programs; Regulations to Require Drug Pricing Transparency, 84 Fed. Reg. 20,732 (May 10, 2019).

Improving drug price transparency is a key way to help address escalating costs. Improving transparency shreds the cloak of secrecy around drug prices by revealing valuable information to consumers and other stakeholders so they can seek viable, cost-reducing solutions. Greater transparency helps make consumers more informed about potential drug costs when they talk with their health care providers about treatment options.

The DTC Rule is an important step towards improving drug price transparency nationwide.[4] The district court's decision should be reversed. Older adults need help to reduce their out-of-pocket costs now.

ARGUMENT

I. The Skyrocketing Price of Prescription Drugs Harms Consumers and the Medicare and Medicaid Programs.

Current prescription drug price trends are simply not sustainable. Escalating drug prices affect all Americans in some way. The cost is passed along to everyone with health coverage through increased health care premiums, deductibles, and other forms of cost-sharing. High prescription drug prices are also driving larger spending increases for a variety of taxpayer-funded programs including the Medicare and Medicaid programs which U.S. Department of Health and Human Services (HHS) oversees.

CMS is HHS's delegate to administer Medicare and Medicaid. Section 1302(a) of title 42, United States Code tasks HHS Secretary Azar with "mak[ing] and publish[ing] such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which each is

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[4] *See, e.g.*, Robert Wood Johnson Found., *How Price Transparency Can Control the Cost of Healthcare* (Mar. 2016), https://rwjf.ws/2x0DFGZ (reporting that health economists and other experts are convinced that significant cost containment cannot occur without widespread and sustained transparency in health care prices).

charged under this chapter." 42 U.S.C. § 1302(a). Efficiently managing the Medicare and Medicaid programs falls under Secretary Azar's purview pursuant to Section 1395hh(a)(1), which reads "[t]he Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter." 42 U.S.C. § 1395hh(a)(1).

Because of its role as the health insurer for millions of Americans through the Medicare and Medicaid programs, the United States government is the single largest payer of prescription drugs in the nation. The rising price of prescription drugs and their effect on the Medicare and Medicaid programs could have serious consequences not only on the nation's healthcare system, but also the nation's long-term fiscal well-being.[5]

In recent years, HHS has pursued a number of initiatives to help combat rising drug prices. HHS Op. Br. 8. The DTC Rule is an initiative that requires direct-to-consumer television advertisements for prescription drugs covered by the Medicare or Medicaid programs to include the "list price" of the advertised drug

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[5] Peter G. Peterson Found., *Trustees: Funding Challenges Threaten Medicare's Future* (Apr. 30, 2019), https://bit.ly/ 2mnmcsH ("[Medicare] will represent an increasing proportion of the federal budget going forward. The program will account for 20 percent of federal spending by 2048, up from just three percent in 1970."); Peter G. Peterson Found., *How Will the Rising Cost of Prescription Drugs Affect Medicare?* (Sept. 4, 2018), https://www.pgpf.org/blog/2018/09/how-will-the-rising-cost-of-prescription-drugs-affect-medicare.

for a thirty-day supply or typical course of treatment. 42 C.F.R. § 403.1202. The list price is defined as the cost that wholesalers or direct purchasers pay for the drugs, without any discounts. § 403.1201(c)-(d). The rule exempts drugs with a list price under $35 per month. § 403.1200(b). The rule also requires a qualifier to let consumers know that if they have insurance, their costs may be different. § 403.1202. The DTC Rule is one step towards ensuring the Medicare and Medicaid program's financial sustainability.

A. The Medicare Program

Medicare pays for specified health care services for persons aged 65 and older and certain people with disabilities. *See* 42 U.S.C. §§ 1395, *et seq.* Medicare expenditures are driven by a variety of factors, including the level of enrollment, the complexity of medical services, and the price of prescription drugs. Medicare consists of four distinct parts: Part A (Hospital Insurance which includes inpatient prescription drug coverage); Part B (Supplemental Medical Insurance); Part C (Medicare Advantage); and Part D (an optional outpatient prescription drug benefit that is subsidized by the federal government).[6] The majority of Medicare prescription drug spending ($129 billion in 2016) is for drugs subsidized under the

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[6] Patricia A. Davis, Cong. Research Serv., Report No. RS20945, *Medicare: Insolvency Projections* 1 (July 3, 2019), https://fas.org/sgp/crs/misc/RS20946.pdf.

Part D prescription drug benefit.[7] Prescription drugs account for nearly $1 out of every $5 in Medicare spending.[8]

In 2018, Medicare provided benefits to 59.9 million persons at a cost of $741 billion.[9] "Over the next 10 years, the . . . total Medicare expenditures will increase . . . to close to $1.6 trillion in 2028."[10] These costs are simply not sustainable for beneficiaries or taxpayers, and the DTC Rule is a key step in efforts to rein in drug costs which comprise a significant part of the program.

Medicare Part D beneficiaries are required to pay a substantial percentage of a drug's cost. That percentage could be as high as 50 percent for non-preferred drugs and 33 percent for specialty tier drugs.[11] Specialty tier drugs are defined by

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[7] *Prescription Drug Coverage (Parts A, B, and D)*, MEDICAREINTERACTIVE, https://bit.ly/2kNfcVQ (last visited Sept. 27, 2019).

[8] Kaiser Fam. Found., *10 Essential Facts About Medicare and Prescription Drug Spending* (Jan. 29, 2019), https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/.

[9] Davis, *supra* note 6, at 1; Ctrs. for Medicare & Medicaid Servs., *Trustees Report & Trust Funds* (Apr. 2019), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html.

[10] Patricia A. Davis, Cong. Research Serv., Rep. No. R43122, *Medicare Financial Status: In Brief* 8 (July 2, 2019), http://fas.org/sgp/crs/misc/R43122.pdf.

[11] Ctrs. for Medicare & Medicaid Servs., *Announcement of Calendar (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 212-213, tbl.23 (Apr. 1, 2019), https://www.cms. gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/ Downloads/Announcement2020.pdf.

CMS as drugs that cost at least $670 per month, although the prices for those drugs can be substantially higher.[12]

As a specific example, a Medicare beneficiary with rheumatoid arthritis could pay as much as $29,390 in annual out-of-pocket expenses for a specialty drug if they do not respond to an alternate medication.[13] A Medicare beneficiary with chronic myelogenous leukemia could pay as much as $49,969 in annual out-of-pocket expenses for a specialty drug when lower cost alternatives are not suitable for them.[14] Patients typically have variability in response to many drugs that are currently available. FDA, *Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development* 8 (Oct. 2013), https://bit.ly/2mef8ys. Because it is often difficult to predict who will benefit from a medication and who will experience adverse results, patients with the same disease may need different medications. *Id.*

According to the AARP Public Policy Institute, the "average annual cost for a single specialty medication used on a chronic basis was almost $79,000 in

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[12] *Id;* Patient Access Network Found., *Out-of-Pocket Costs and Specialty Medications* 2 (2018), https://panfoundation.org/files/PAN-Foundation-Issue-Brief-7.pdf.

[13] Patient Access Network Found., *supra* at note 12.

[14] *Id.*

2017."[15] These costs are woefully out of reach for many Medicare beneficiaries whose median income is only $26,200.[16]

B. The Medicaid Program

The high price of drugs also harms the Medicaid program. Medicaid is a cooperative federal-state program that provides federal funding for state medical services to the poor. 42 U.S.C. § 1396a. Medicaid, provided healthcare coverage to about one in five Americans, or about 74 million people as of June 2017.[17] In fiscal year 2016, total Medicaid spending was $553 billion, with 62.5 percent paid by the federal government and 37.5 percent by states.[18] The Medicaid program alone

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[15] Stephen Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update* 1 (June 2019), www.aarp.org/rxpricewatch.

[16] *Id.* at 7.

[17] Robin Rudowitz & Allison Valentine, *Medicaid Enrollment & Spending Growth: FY 2017 & 2018,* KAISER FAM. FOUND. 2 (Oct. 19, 2017), http://files.kff.org/attachment/Issue-Brief-Medicaid-Enrollment-and-Spending-Growth-FY-2017-and-2018. In 2017, the percentage of Medicaid enrollees over the age of 46 was 28 percent. Ctrs. for Medicare & Medicaid Servs., *Who Enrolls in Medicaid & CHIP?*, MEDICAID.GOV, https://www.medicaid.gov/state-overviews/scorecard/national-context/enrollment/index.html (last visited Sept. 27, 2019).

[18] Kaiser Fam. Found., *Federal and State Share of Medicaid Spending*, https://www.kff.org/medicaid/state-indicator/federalstate-share-of-spending/?dataView=0¤tTimeframe=0%20&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Sept. 27, 2019) (analyzing Form CMS-64 Data); *see, also*, *Rudowitz* & Valentine, *supra* note 17.

accounts for 10 percent of all prescription drug spending.[19] In 2015, the Medicaid program spent $9.9 billion on specialty drugs.[20]

State Medicaid programs may offer outpatient prescription drug coverage, although the precise coverage requirements and copayments vary by states. 42 U.S.C. § 1396a(12). The Medicaid Act's provisions for coverage of Medicaid-eligible drugs are set forth in 42 U.S.C. § 1396r-8. Medicaid programs typically cover prescription drugs with some limitations. 42 U.S.C. §1396r-8(d). States may deny Medicaid drug coverage if, among other reasons "the drug is subject to restriction pursuant to an agreement between the state and drug manufacturer; or if the drug has been excluded by a state-established formulary." *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1327 (S.D. Fla. 2006).

Additionally, Medicaid eligibility for adults in states that did not expand their programs under the Affordable Care Act (ACA) is quite limited: the median income limit for parents in these states is just 43 percent of the federal poverty

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[19] Ctrs. for Medicare and Medicaid Servs., *National Health Expenditures 2017 Highlights* 1, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last visited Sept. 30, 2019).

[20] Peter G. Peterson Found., *How Will The Rising Cost of Prescription Drugs Affect Medicare?* (Sept. 4, 2018), https://www.pgpf.org/blog/2018/09/how-will-the-rising-cost-of-prescription-drugs-affect-medicare.

level, or an annual income of $8,935 for a family of three in 2018, and in nearly all these states adults without minor children remain ineligible.[21] As a result, there is less access to Medicaid in states that have not been passed. Those states include: Alabama, Florida, Georgia, Kansas, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Wisconsin, and Wyoming.[22]

II. Rising Prescription Drug Prices Harm All Americans, and Older Adults in Particular, Because They Often Have to Sacrifice their Healthcare and Financial Security to Afford Life-Saving Prescription Drugs.

Drug prices are greatly outpacing the growth of the incomes of many older adults with calamitous consequences. In 2017, the average annual retail price for 754 brand name, generic, and specialty prescription drugs used to treat chronic conditions was almost $20,000 per year. However, the average Social Security retirement benefit was only $16,848, and the median annual income of a Medicare

[21] Rachel Garfield et al., *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid*, KAISER FAM. FOUND. 1 (Mar. 21, 2019), http://files.kff.org/attachment/Issue-Brief-The-Coverage-Gap-Uninsured-Poor-Adults-in-States-that-Do-Not-Expand-Medicaid.

[22] Kaiser Fam. Found., *Status of State Action on the Medicaid Expansion Decision* (Sept. 20, 2019), https://bit.ly/2kZkq0u.

beneficiary was just over $26,000.[23] Given the exorbitant price of many drugs it is not surprising that, "three in ten adults ages 50 to 64 report having difficulty affording their prescription medicines (30 percent) compared to about one-fourth of those ages 65 and over with Medicare (23 percent) and one-fifth of those under the age of 50 (21 percent), who take fewer drugs on a regular basis."[24] Medicare beneficiaries and enrollees in commercial (nongovernment) insurance programs alike struggle to afford prescription drugs. Prescription drugs are the single largest health care expense for consumers with private commercial insurance.[25] Rising prescription drug costs also "account for more than 22 percent of every [commercial] premium dollar–outpacing physician, inpatient, and outpatient hospital services."[26]

People who cannot afford drugs will sometimes attempt to mitigate the problem by not taking their medication as prescribed or, alternatively, forgoing the

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[23] Stephen Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2017 Year-End Update* 1-2*,* AARP PUBLIC POL'Y INST. (Sept. 2019), www.aarp.org/rxpricewatch.

[24] Kirzinger et al., *supra* note 3, at fig.9.

[25] Kristine Grow, *Prescription Drugs are Largest Single Expense for Consumer Premium Dollar*, AM.'S HEALTH INS. PLANS (AHIP) (Mar. 2, 2017), https://www.ahip.org/prescription-drugs-are-largest-single-expense-of-consumer-premium-dollars/.

[26] *Id.*

treatment altogether.[27] According to AARP research data, in 2016, twenty-eight percent of Americans stopped taking a prescription drug as prescribed due to cost.[28] Alternatively, some consumers report they will take an over-the-counter drug instead of their prescribed drug.[29]

When drugs prices rise so high that people can no longer afford to purchase necessary medication, it can irreparably harm their health and even put their lives at risk. Courts have held that poor people who rely on government programs to provide their medication are irreparably harmed when they are denied access to their medication. *See, e.g., Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1342 (S.D. Fla. 2006) (holding that Medicaid recipients who were prescribed Neurontin were irreparably harmed when denied access to prescribed medication) (citing *inter alia*, *Dodson v. Parham*, 427 F. Supp. 97, 108 (N.D. Ga. 1977) (cutting off Medicaid recipients from prescribed medication overnight, over a weekend, or indefinitely constituted irreparable harm)).

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[27] AARP, *How United States Residents Are Impacted by High Rx Costs* (2019), https://www.aarp.org/content/dam/aarp/politics/advocacy/2019/09/rx-state-infographic-three-issues-national.pdf.

[28] *Id*.

[29] Kirzinger et al., *supra,* note 3, fig.10.

Likewise, retirees on fixed incomes also may be irreparably harmed when their prescription drug co-pays increase, because the increased cost can limit their access. *See, e.g.*, *Helwig v. Kelsey-Hayes Co.*, 857 F. Supp. 1168 (E.D. Mich. 1994) (changing retiree health package so that retirees had higher deductibles and were required to pay increased prescription drug copayments constituted irreparable harm).

Unaffordable prescription drug prices fall most heavily on consumers who do not have insurance. In the fourth quarter of 2018, 13.7 percent of the U.S. adults were uninsured.[30] According to 2018 U.S. Census data this equates to approximately 44.8 million people.[31] Many of these people pay the full cost of prescription drugs.[32]

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[30] Dan Witters, *U.S. Uninsured Rate Rises to Four-Year High*, GALLUP (Jan. 23, 2019), https://news.gallup.com/poll/246134/uninsured-rate-rises-four-year-high.aspx.

[31] U.S. Census Bureau, *QuickFacts United States* (July 2018), https://www.census.gov/quickfacts/fact/table/US/PST045218. The U.S. population as of July 1, 2018 was 327,167,434.

[32] Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set,* TIME (Apr. 9, 2019).

Merck argued below that many people benefit from drug discounts or coupons.[33] Even though a coupon or discount may be available for some uninsured consumers, consumers covered by a Federal health care program (including Medicare Part D and Medicaid beneficiaries) are not eligible for copayment coupons. 42 U.S.C. § 1320a-7b(b).[34] Furthermore, coupons for brand-name prescription drugs usually have a limited time frame within which they can be used. In other words, the short-term cost may shrink for the consumer, but over the long-term their use will lead to higher premiums because any remaining cost is absorbed by their insurer.[35] Moreover, long-term coupons are rare.[36] Consumers who take brand-name medications despite the availability of a generic equivalent "face copayments for these brand-name medications that are higher than those for

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[33] *Merck, et. al v. HHS,* Compl. ¶ 64, ECF No. 1, No. 19-CV-01738 (D.D.C. June 24, 2019); Pls.' Mem. of Law in Supp. of Pls.' Mot. for a Stay at 14-15, ECF 12-1.

[34] *See* Dep't of Health and Human Servs., *Pharmaceutical Manufacturer Copayment Coupons* (Sept. 2014), https://oig.hhs.gov/fraud/docs/alertsand bulletins/2014/SAB_Copayment_Coupons.pdf.

[35] Joseph Ross & Aaron Kesselheim, *Prescription Drug Coupons—No Such Thing as a Free Lunch*, 369 NEW ENG. J. MED. 1188, 1188-89 (2013). Some coupons can only be used once, others more than once, but few offer savings for more than a year. *Id.* Once the coupon ends, patients still pay the higher cost of the medication. *Id.*

[36] *Id.*

generic alternatives."[37] Thus, consumers need thoughtful solutions to reduce the price of drugs.

III. Drug Price Transparency Shreds the Cloak of Secrecy Around Drug Prices and Empowers Consumers to Seek Cost-Reducing Solutions.

Improving drug price transparency is a key component in the fight against escalating drug prices. Improving transparency shreds the cloak of secrecy around drug prices by revealing valuable information to consumers and other stakeholders so they can seek viable, cost-reducing solutions.

Requiring drug prices in DTC television advertising benefits consumers. It allows them to be more informed about drug costs and cost effective alternatives when they talk with their health care providers about their treatment options.[38] They can compare list prices of various drugs and know the launch price of a new drug. The current pharmaceutical distribution system does not make essential pricing information available to patients and providers, information that they need when evaluating treatment options.[39] As a result, physicians are often "unaware of

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[37] *Id.*

[38] *See* Henry Waxman et al., *Getting to the Root of High Prescription Drug Prices: Drivers and Potential Solutions*, COMMONWEALTH FUND (July 10, 2017), https://www.commonwealthfund.org/sites/default/files/documents/_media_filespublications_fund_report_2017_jul_waxman_high_drug_prices_drivers_solutions_report.pdf.

[39] *Id.* at 30.

the cost implications of their prescription choices."[40] Having drug price information empowers consumers to discuss affordability with their health care provider as they explore an appropriate course of care.

Disclosing the list price of a drug is also a valuable price marker. Drug manufacturers are certain to know the list price of their products, making it easy for them to comply with this requirement. Also, many consumers pay the list price.[41] According to the Pharmaceutical Research and Manufacturers of America (PhRMA), commercially insured patients pay the undiscounted list price for one in five brand prescriptions.[42] Likewise, uninsured people often pay the list price.[43] Knowing the list price allows these consumers to accurately assess their costs. They can then decide with their health care provider if the drug is a viable treatment option.

While some people with insurance may not ultimately pay the full list price of the drug, knowing the list price provides these consumers a window into how

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[40] *See, e.g.*, Ross & Kesselheim, *supra* note 35, at 1188-1189.

[41] Entis, *supra* note 32; PhRMA, *Commercially-Insured Patients Pay Undiscounted List Prices for One in Five Brand Prescriptions, Accounting for Half of Out-of-Pocket Spending on Brand Medicines*, https://onphr.ma/2m95o8K.

[42] PhRMA, *supra* note 41.

[43] Entis *supra* note 32.

list prices affect their healthcare costs.[44] Many consumers pay drug prices that are calculated based on the list price. According to CMS, older adults "on Medicare Part D have coinsurance for certain types of drugs, which means their out-of-pocket expenses are calculated as a share of list price."[45] And consumers value this information. A 2019 Kaiser Family Foundation poll found that 88 percent of people favored requiring drug companies to include list prices in ads.[46] Using DTC television advertising to disclose list prices also makes sense because DTC drug advertising is so prevalent.[47] Drug manufacturers reportedly spent $4.2 billion on national television ads in 2017. *See* 83 Fed. Reg. at 20,755-56.

Most of us are familiar with the myriad television ads showing people with serious conditions running, biking, dancing and leading better, curated lives allegedly because of these drugs. Given these highly optimistic images, it is no

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[44] Avik Roy, *In A Significant Step For Price Transparency, Trump Finalizes Rule Requiring List Prices In Drug Ads*, FORBES, (May 8, 2019), ("If a drug's list price is $100,000, and the cost after insurance is $50, that is useful to know—because it explains why your insurance premiums are so high.").

[45] Ctrs. for Medicare & Medicaid Services, *CMS Drug Price Sheet* (May 2019), https://www.hhs.gov/about/news/2019/05/08/cms-drug-pricing-transparency-fact-sheet.html.

[46] Kirzinger, et al., *supra* note 3, at fig.4.

[47] *See* Natasha Parekh & William H. Shrank, *Dangers and Opportunities of Direct-to-Consumer Advertising*, 33 J. GEN. INTERN. MED. 586, 586-87 (2018).

surprise that DTC drug advertising raises can confuse consumers, and cause them to demand unnecessary expensive treatments and physician office visits.[48] Requiring DTC advertisements to include price information will help improve the balance between education and overutilization by encouraging more informed conversations between patients and prescribers.

CONCLUSION

Older adults cannot afford to wait for drug prices to be lower. They need change now. The DTC Rule and other price transparency laws are important steps in the right direction. We respectfully request that the judgment of the district court be reversed.

Date: September 30, 2019

Respectfully submitted,

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[48] Lisa Schwartz & Steven Woloshin, *Medical Marketing in the United States, 1997-2016,* 321(1) JAMA 80, 80-96 (Jan. 2019).

CERTIFICATE OF COMPLIANCE WITH RULE 32(A)

1. This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 32(a)(7) and Circuit Rule 32(a)(2) because: this brief contains 3,837 words, (excluding the parts of the brief exempted by the Federal Rules of Appellate Procedure 32(a)(7)(B)(iii)) as determined by the word counting feature of Microsoft Office Word 2016).

2. This brief complies with the typeface requirements of Federal Rules of Appellate Procedure 32(a)(5) and the type style requirements of the Federal Rules of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office Word 2016 14 point Times New Roman font.

Dated: September 30, 2019

/s/ Barbara Jones
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CERTIFICATE OF SERVICE

I hereby certify that on September 30, 2019, I electronically filed the foregoing Brief of Amici Curiae AARP and AARP Foundation, in Support of Defendants-Appellants with the Clerk of the Court for the United States Court of Appeals for the DC Circuit using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: September 30, 2019

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