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The Patient Assistance Problem

Daniel O'Brien Lichtenauer

THE PATIENT ASSISTANCE PROBLEM

Daniel O'Brien Lichtenauer[*]

Implemented in January 2006 as a voluntary enrollment supplement to standard Medicare plans, Medicare Part D coverage subsidizes the cost of prescription drugs for participants. However, significant gaps in coverage exist for those suffering from rare diseases that require costly drugs. Pharmaceutical companies seek to remove the powerful market force of patient price sensitivity by directly sponsoring or substantially funding "patient assistance programs" that help cover out-of-pocket costs. While pharmaceutical donors insist that their goal is strictly altruistic, the reality is that many of these programs offer a financial windfall for drug makers because they help funnel patients towards new pharmaceuticals with generic alternatives while collecting the drug's market price at the expense of taxpayers. This Note argues that industry-sponsored patient assistance programs violate the anti-kickback statute and should be outlawed. To preserve a safety net of assistance while discouraging illegal activity, an industry-sponsored, CMS-administered fund should be established for the appropriate disbursement of pharmaceutical industry charity, opening access

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[*] J.D. Candidate, Brooklyn Law School, 2022. A.B., Hamilton College, 2014. I would like to thank my parents, Karen O'Brien and Stephen Lichtenauer, champions of my education. Thank you to my wife, Julia Lubbock, for her ceaseless encouragement and belief in me. I am deeply grateful for the inimitable counsel of my brother Charles, which he readily dispensed, and the support of my brothers Andrew and John. Thanks to Professors Karen Porter and Frank Pasquale for their advice, to Noah Sexton for his camaraderie, and to the *Journal of Law and Policy* staff for their hard work. This Note is dedicated to the patients of Memorial Sloan Kettering Cancer Center, and all patients suffering from rare diseases, whose experiences deserve meaningful discussion and progress in health care. All errors and omissions are my own.

to costly, life-saving medications to a broader population of needy patients in a manner uninfluenced by corporate bottom lines.

INTRODUCTION

Walter Feigenson is a seventy-two-year-old retired entrepreneur living on a Social Security income of roughly $26,000 per year.[1] He also happens to be taking a prescription drug with a $225,000 per year price tag.[2] Walter has a potentially fatal heart condition called transthyretin amyloid cardiomyopathy ("ATTR-CM"), for which Pfizer's new drug tafamidis is the only FDA-approved treatment.[3] Tafamadis, sold under the names Vyndaqel and Vyndamax,[4] is now the most expensive[5] cardiovascular drug ever put on the market in the United States.[6] So how do patients like Walter pay for the drug?

The answer for Walter, and for many other low-income Medicare beneficiaries with rare or life-threatening diseases that require treatment with advanced pharmaceuticals, is a combination of sources.[7] Under the 2021 standard Medicare drug benefit,

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[1] Eleanor Laise, *Pfizer Suit Could Be an 'Earthquake' for Drug Pricing*, BARRON'S, https://www.barrons.com/articles/pfizer-suit-could-be-an-earthquake-for-drug-pricing-51602242101?mod=article_signInButton?mod=article_signInButton?mod=article_signInButton (last updated Oct. 12, 2020).

[2] *Id.*

[3] *See id.*

[4] *Medical Information*, PFIZER, INC., https://www.pfizermedicalinformation.com/en-us/vyndaqel-or-vyndamax (last visited Nov. 22, 2020). Vyndamax and Vyndaqel both contain the active drug tafamidis but in different forms; Vyndaqel contains the salt form of tafamidis, tafamidis meglumine, while Vyndamax contains tafamidis alone.

[5] Rob Stein, *At $2.1 Million, New Gene Therapy is the Most Expensive Drug Ever*, NPR (May 24, 2019, 3:52 PM), https://www.npr.org/sections/health-shots/2019/05/24/725404168/at-2-125-million-new-gene-therapy-is-the-most-expensive-drug-ever. While tafamidis is the most expensive cardiovascular drug ever put on the market, Novartis's gene therapy for the rare childhood disorder spinal muscular atrophy ("SMA"), Zolgensma, is the most expensive drug ever put to market regardless of disease class. The therapy costs $2.125 million per patient for a one-time dose that addresses the genetic root cause of the disorder.

[6] Laise, *supra* note 1; *see id.*

[7] *See* Laise, *supra* note 1.

patients and their plan are required to pay $4,130 before they are limited to 25% co-pay.[8] Then, Medicare recipients are still required to pay the co-pays out of pocket until they have spent the $6,550 to cover the "donut hole" in coverage.[9] Once the donut hole threshold is met, beneficiaries will automatically receive "catastrophic coverage," and will not pay more than 5% of the cost for covered drugs for the rest of the year.[10] But drugs that cost $225,000 per year are affordable only to patients who can pay that 5% remainder, pay for costly Medigap plans,[11] or whose income is so low that they qualify for Medicare Extra Help.[12] For Walter—whose yearly income of $26,000 falls just above the Extra Help threshold for a married person living with a spouse[13]—lifesaving medication is covered by a combination of Medicare and funding from "independent" charities that are primarily funded by pharmaceutical companies.[14] When gaps in coverage arise, he gets free drugs from one of Pfizer's programs for lower-income patients.[15]

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[8] DEP'T OF HEALTH AND HUM. SERVS., MEDICARE & YOU 2021, THE OFFICIAL U.S. GOVERNMENT MEDICARE HANDBOOK 82, https://www.medicare.gov/sites/default/files/2020-12/10050-Medicare-and-You_0.pdf.

[9] *Id*; *see The Part D Donut Hole*, MEDICARE INTERACTIVE, https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-costs/the-part-d-donut-hole (last visited Nov. 20, 2020). The donut hole in coverage was eliminated in 2020 by the Affordable Care Act, but patients will still be responsible for coverage gap cost sharing of 25% of the cost of drugs.

[10] MEDICARE & YOU 2021, *supra* note 8, at 83; *see* Complaint for Declaratory Judgment at 16, 19, 21, Pfizer, Inc. v. U.S. Dept. of Health & Hum. Servs., No. 20-cv-04920 (S.D.N.Y. June 26, 2020). For tafamidis, the annual out-of-pocket costs for Medicare Part D patients is $13,000.

[11] *See* BARRY R. FURROW ET AL., HEALTH LAW CASES, MATERIALS AND PROBLEMS 638 (AM. CASEBOOK SERIES, 8th ed. 2018) (noting that most wealthy seniors purchase expensive Medigap plans that help contain the out-of-pocket costs of traditional Medicare).

[12] MEDICARE & YOU 2021, *supra* note 8, at 91–92; *see also* Hailey Konnath, *Pfizer Says HHS is Blocking Patient Access to Heart Drugs*, LAW360 (June 26, 2020), https://www.law360.com/articles/1287340/.

[13] *See* MEDICARE & YOU 2021, *supra* note 8, at 87.

[14] *See* Laise, *supra* note 1.

[15] *Id.*

Other patients simply can't make the system work for them. The Department of Health and Human Services ("DHHS") estimates that more than a quarter of Part D participants, Medicare's optional drug plan, who reach the "donut hole" exception in Part D coverage stop following their prescribed drug regimen.[16] Pharmaceutical companies have sought to remove the powerful market force of patient price sensitivity by directly sponsoring or substantially funding "patient assistance programs" ("PAPs") that help cover out-of-pocket costs,[17] but recent litigation over such programs due to ineffective guidance from the Office of the Inspector General ("OIG") of the DHHS has left the legality of these programs in doubt.

Part I of this Note provides background on Medicare Part D prescription drug coverage and the gaps in that coverage that beneficiaries face when they require high-cost prescription treatment. Part II examines the role that pharmaceutical companies have come to play in mitigating costs for low-income patients via patient assistance programs, and the benefits of such programs as argued by the pharmaceutical industry. Part III explains the Department of Justice ("DOJ") and OIG's objections to such programs under the anti-kickback statute, the OIG's guidance for proper PAP dealings, and the failure of such guidance to prevent ongoing litigation. Part IV examines legislative proposals to reform Medicare and assesses why these proposals have failed to address the problematic role that PAPs play in Medicare Part D's proper functioning. Part V argues for the creation of a central patient assistance fund administered by the Centers for Medicare & Medicaid Services ("CMS") to take the place of current PAPs as a target for fair, honest pharmaceutical industry beneficence. Such a fund would provide the pharmaceutical industry a tax-deductible opportunity to reduce the Extra Help threshold for Medicare beneficiaries, without violating the anti-kickback statute's ban on industry- and independently-run patient assistance programs. This

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[16] Jason Claffey, *Medicare 'Donut Hole' Checks in The Mail*, FOSTERS (Aug. 12, 2010, 3:15 AM), https://www.fosters.com/article/20100812/GJNEWS_01/708129744. As noted previously, the donut hole in coverage was eliminated by 2020 and replaced with 25% cost-sharing during the coverage gap period. *The Part D Donut Hole*, *supra* note 9.

[17] Laise, *supra* note 1.

Note further argues that patient assistance programs, while in violation of the anti-kickback statute, nonetheless benefit patients and should be allowed a phase-out period of ten to fifteen years while the CMS-run patient assistance fund is established. After the safe harbor period, the OIG of DHHS and the DOJ should fully prosecute pharmaceutical companies for violation of the anti-kickback statute as written, and disregard the past OIG guidance that simply created regulatory loopholes for pharmaceutical kickbacks.

I. MEDICARE PART D

When Medicare was created in 1965,[18] outpatient prescription drugs were not covered by private insurance because they were still relatively affordable and were not considered as important in medical management as they are today.[19] The Medicare Modernization Act of 2003 ("MMA")[20] created Medicare Part D in recognition of the growing importance and costs of pharmaceuticals.[21] The law narrowly passed with a one-vote margin in the House of Representatives and was implemented in January 2006 as a voluntary enrollment supplement to Medicare Part A and/or B.[22]

Medicare beneficiaries are eligible to enroll in a plan to receive drug benefits from one of three sources: (1) Medicare Advantage managed care plans that include drug benefits; (2) employers who

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[18] FURROW ET AL., *supra* note 11, at 635–37. As of 2017, 57.7 million elderly and disabled people are covered by Medicare—that is one in six Americans. Eligibility is linked to the Social Security program; those who are eligible for retirement benefits under Social Security are automatically eligible upon reaching age sixty-five. Disabled persons eligible for Social Security or Railroad Retirement benefits may also receive Medicare but only after a two-year period of eligibility for cash benefits.

[19] *Id.* at 639.

[20] *Id.* at 640. The Medicare Modernization Act of 2003 is also known as the Medicare Prescription Drug, Improvement, and Modernization Act.

[21] *Id.* at 640.

[22] *See* OFF. OF THE ASSISTANT SEC'Y FOR PLAN. AND EVALUATION, U.S. DEP'T OF HEALTH & HUM. SERVS., REPORT TO CONGRESS: PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS 54 (2016); FURROW ET AL., *supra* note 11, at 640.

offer drug coverage to beneficiaries (including the retired); and (3) private prescription drug plans ("PDPs").[23] PDPs submit bids to the Centers for Medicare & Medicaid Services ("CMS") to cover each of thirty-four PDP regions in the United States.[24] In turn, Medicare subsidizes 74.5% of the cost of "standard coverage" and provides "individual reinsurance" that covers 80% of the PDP's responsibility for beneficiaries who reach the "catastrophic" level of prescription drug costs.[25]

Under the 2021 standard Medicare drug benefit, patients and their plans are required to pay $4,130 before they are limited to 25% co-pay.[26] Then, Medicare recipients are still required to pay the co-pays out of pocket until they have spent the $6,550 to cover the "donut hole" in coverage.[27] Once the donut hole threshold is met, beneficiaries will automatically receive catastrophic coverage, during which period stop-loss coverage kicks in, and they will pay no more than 5% of the cost for covered drugs for the rest of the year.[28]

While the above scheme represents so-called "standard coverage," very few plans offer the standard drug benefit, instead offering "actuarially equivalent" coverage.[29] Instead of a flat 25% coinsurance copay, most plans will charge "tiered" copays after the deductible is met; 72% of PDP coverage plans in 2017 did not offer additional donut hole coverage beyond the required standard benefit, and additional gap coverage is generally limited to generic drugs.[30]

Currently, only those at the very low end of the resource spectrum qualify for the Medicare "Extra Help" program.[31] This program, which helps patients pay drug co-pays, is only available to single persons whose yearly income is under $19,140 and whose

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[23] FURROW ET AL., *supra* note 11, at 640.

[24] *Id.*

[25] *Id.*

[26] MEDICARE & YOU, *supra* note 8, at 78.

[27] *See id.*

[28] *Id* at 79; FURROW ET AL., *supra* note 11, at 641.

[29] FURROW ET AL., *supra* note 11, at 641.

[30] *Id.*

[31] *See* MEDICARE & YOU 2021, *supra* note 8, at 87.

other resources total under $13,110.[32] For a married person living with a spouse and no other dependents, the yearly income threshold is $25,860, and their other resources must fall under $26,160.[33] These thresholds are even more restrictive than at first blush because "resources" includes money in a checking or savings account, mutual funds, bonds, stocks, and IRAs.[34] These restrictions to co-pay support put those who cannot afford to pay for Medigap plans, but are not poor enough to qualify for Extra Help, between a rock and a hard place and many must rely on charity for support.[35]

Roughly 76.7% of Medicare beneficiaries voluntarily enrolled in Part D in 2017—a total of 44.5 million people.[36] The Part D benefit comprised 14% of that year's total Medicare benefit payment of $100 billion.[37] From 2007 to 2017, the ten highest-cost drugs in Part D accounted for approximately 20% of total gross drug costs, while the ten most frequently prescribed drugs in Medicare Part D usually account for less than 10% of total gross drug costs in a given year.[38] In 2017, the ten most frequently prescribed drugs accounted for 3% of total gross drug costs, reflecting the relative inexpensiveness of commonly prescribed drugs compared to the most expensive.[39]

In 2017, the ten most prescribed drugs to Medicare Part D beneficiaries were all available in generic form.[40] That same year,

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[32] *Id.*

[33] *Id.*

[34] *See id.*

[35] *See* Laise, *supra* note 1, at 1.

[36] PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS, *supra* note 22, at 4; FURROW ET AL., *supra* note 11, at 640.

[37] PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS, *supra* note 22, at 4; FURROW ET AL., *supra* note 11, at 640.

[38] PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS, *supra* note 22, at 4; FURROW ET AL., *supra* note 11, at 640.

[39] PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS, *supra* note 22, at 4; FURROW ET AL., *supra* note 11, at 640 (demonstrating that in 2017, Revlimid, a blood cancer drug, was responsible for more spending than any other drug. At $626.98 per unit (the lowest dispensable amount), each user was accounted for $88,442 GDC).

[40] PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS, *supra* note 22, at 4; FURROW ET AL., *supra* note 11, at 640.

the ten highest-cost drugs covered were all brand-name drugs.[41] These brand-name drugs cost so much not only because research and development for new drugs is incredibly expensive, but also because there is no guarantee that the research will yield positive results.[42] Nine out of ten tested drugs fail.[43] For the sixty-six companies that only had one approved medicine over a ten-year period, the average research and development cost was $953 million.[44]

II. THE ROLE OF PATIENT ASSISTANCE PROGRAMS IN MITIGATING DRUG COSTS

Patient assistance programs ("PAPs") are foundations that help provide under-insured patients with access to brand-name pharmaceuticals at little or no cost to them.[45] The majority of programs provide access to one or two specific drugs through copay assistance, pharmacy discount cards, rebates, or direct provision.[46] The two most prevalent types of PAPs are "Independent Charity PAPs" and "Pharmaceutical Manufacturer PAPs," both of which are typically run as tax-exempt 501(c)(3) nonprofit organizations.[47] Pharmaceutical Manufacturer PAPs are

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[41] *See* Juliette Cubanski & Tricia Neuman, *Assessing Drug Price Increases in Medicare part D and the Implications of Inflation Limits*, KAISER FAM. FOUND. (Oct. 18, 2019), https://www.kff.org/medicare/issue-brief/assessing-drug-price-increases-in-medicare-part-d-and-the-implications-of-inflation-limits/.

[42] *See* Matthew Herper, *The Cost of Developing Drugs Is Insane. That Paper That Says Otherwise Is Insanely Bad*, FORBES (Oct. 16, 2017, 10:58 AM), https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/#23911e4d2d45.

[43] *Id.*

[44] *Id.*

[45] Niteesh K. Choudhry et al., *Drug Company-Sponsored Patient Assistance Programs: A Viable Safety Net?*, 28(3) HEALTH AFFS. 827, 827 (2009).

[46] *See id.* at 829.

[47] John C. Hood, *Are Good Deeds Being Punished?: Independent Charity Patient Assistance Programs and the Anti-Kickback Statute*, 72 FLA. L. REV. 639, 643 (2020); SUZANNE M. KIRCHHOFF, CONG. RSCH. SERV., R44264,

directly owned by their associated pharmaceutical companies, while Independent Charity PAPs are, as the name suggests, operated by separate entities.[48] Despite that distinction, both PAPs are primarily supported by industry donations.[49] Pharmaceutical companies see their donations to these organizations as a lifeline for patients who make too much money to qualify for a free drug program but not enough to afford co-payments for advanced or specialized drugs.[50]

Pharmaceutical industry donations to PAPs are so substantial that PAPs are among the largest 501(c)(3) organizations in the U.S and growing rapidly,[51] surpassing the annual giving of such fundraising behemoths as the Ford Foundation.[52] A 2016 study found that the ten leading industry PAPs spent $6.1 billion in 2014, a whopping $5.724 billion more than they did in 2001.[53] Correlations have been drawn between PAPs' increased spending and (1) the increase in Americans with prescription drug coverage since the creation of Part D under the MMA and (2) the rise of specialty drugs[54] in the treatment of complex diseases like cancer, heart disease, and Hepatitis C.[55] As more Medicare Part D patients

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PRESCRIPTION DRUG DISCOUNT COUPONS AND PATIENT ASSISTANCE PROGRAMS (PAPS) 14 (2017).

[48] Hood, *supra* note 47, at 643–44; KIRCHHOFF, CONG. RSCH. SERV., *supra* note 47, at 15.

[49] *See* Hood, *supra* note 47, at 647; KIRCHHOFF, CONG. RSCH. SERV., *supra* note 47, at 18.

[50] Hood, *supra* note 47, at 645.

[51] *See* KIRCHHOFF, CONG. RSCH. SERV., *supra* note 47, at 21–22.

[52] *See* Hood, *supra* note 47, at 643–44.

[53] *See* KIRCHHOFF, CONG. RSCH. SERV., *supra* note 47, at 21.

[54] *See id.* at 3 ("There is no one set definition of specialty drugs, although insurers and other health care payers often characterize them as prescription products requiring extra handling or administration that are used to treat complex diseases, such as cancer. High cost can trigger a specialty drug designation. Biologics, or drugs derived from living cells, often are deemed to be specialty drugs.").

[55] *See* Austin Frerick, *The Cloak of Social Responsibility: Pharmaceutical Corporate Charity*, 153 TAX NOTES 1151, 1159–60 (2016). Specialty drugs account for just 1% of total prescriptions but make up nearly one third of prescription spending in the United States. A fine example of specialty medicine is the Hepatitis C vaccine. The disease, incurable until 2013, has potentially life-

take specialty drugs, more of these patients reach the catastrophic coverage period of their enrollment, which forces financially strapped beneficiaries to make tough decisions.[56] Part D beneficiaries can decide to pay steep out-of-pocket costs for their medication co-pays (after they've already spent $6,550 in donut-hole coverage) or forgo medication altogether.[57] Pharmaceutical companies would much prefer the former, so they are willing to step in to provide co-pay funding so that the lion's share of the price tag (95%) can be picked up by the taxpayer via Medicare.[58]

Although the enrollment eligibility criteria vary among PAPs, they typically consider the patient's "(1) annual income, (2) insurance status, (3) physician endorsement, (4) prescription information, and (5) proof of U.S. citizenship or legal residence."[59] Income eligibility limits are usually tied to the Federal Poverty Level ("FPL"), and some pharmaceutical companies increase income eligibility limits for pricier drugs.[60] Although data on the specific eligibility criteria for each PAP is limited,[61] drug makers release figures when it benefits their corporate reputation. For example, in 2015, Pfizer announced that it planned to expand its PAP, "Pfizer RxPathways," by doubling the income eligibility limit from 200% of the FPL to 400% FPL—making it available to more low-income patients.[62]

While pharmaceutical companies claim moral high ground for their donations to PAPs, criticisms mount.[63] Considered a "triple boon for manufacturers," PAPs "increase demand, allow companies to charge higher prices, and provide public-relations benefits."[64] Private insurers and Medicare officials alike view

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threatening side effects including cirrhosis. The $84,000 twelve-week treatment has a 94–97% twelve-week success rate.

[56] Hood, *supra* note 47, at 647–48.

[57] *See id.* at 644.

[58] *Id.* at 646.

[59] KIRCHHOFF, CONG. RSCH. SERV., *supra* note 47, at 17.

[60] Hood, *supra* note 47, at 645.

[61] Choudhry et al., *supra* note 45, at 832.

[62] KIRCHHOFF, CONG. RSCH. SERV., *supra* note 47, at 17.

[63] *See* Choudhry et al., *supra* note 45, at 833.

[64] Michael Hiltzik, *Why Big Pharma's Patient-Assistance Programs are a Sham*, L.A. TIMES (Sept. 25, 2015, 10:39 AM),

PAPs as counter-productive because they steer patients towards expensive, out-of-reach drugs whose price would have otherwise been driven down by market pressures.[65] They claim that most patients using PAPs as a safety net are doing so in lieu of choosing low-cost alternative drugs or generics—of the nearly 400 brand-name drug coupons examined by the *Los Angeles Times*, 62% were for drugs with lower-cost alternatives.[66] Indeed, a special advisory from the Office of the Inspector General of DHHS highlighted the risk of waste associated with PAPs on the proper administration of Medicare and other Federal health care programs.[67]

Under current tax law, corporations can deduct charitable contributions of up to 10% of their income.[68] Interestingly, only the pharmaceutical industry approaches this limit.[69] Pharmaceutical companies regularly take the maximum deduction for charitable giving, and often donate more money to charities than they can write off.[70] In fact, while corporate giving decreased by $1.2 billion during the Great Recession period between 2007 and 2009, pharmaceutical giving increased by $1.2 billion, an anomaly scholars have tied to the enactment of Medicare Part D and the rise of specialty drugs.[71] By donating to "independent" charity PAPs, pharmaceutical companies receive not only a tax deduction, but also the full sticker price of the drug via Medicare Part D.[72] As noted in a *Tax Notes* special report, these "are one-

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https://www.latimes.com/business/hiltzik/la-fi-mh-pharma-s-sham-patient-assistance-programs-20150925-column.html.

[65] *See* Choudhry et al., *supra* note 45, at 833; *see also* Hiltzik, *supra* note 64.

[66] Hiltzik, *supra* note 64.

[67] *See* Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 104, 31120 (May 30, 2014).

[68] 26 U.S.C. § 170(b)(2)(A); *see* Amy E. Heller et al., *CARES Act Increases Deductions for Certain Charitable Contributions*, SKADDEN, https://www.skadden.com/insights/publications/2020/03/cares-act-increases-deductions-for-certain (last updated Aug. 10, 2020) (recognizing that the CARES Act temporarily sets this limit at 25% for tax year 2021).

[69] *See* Frerick, *supra* note 55, at 1151.

[70] *See id.*

[71] *Id.* at 1156.

[72] *Id.* at 1157.

sided discounts."[73] That these companies donate more money than is deductible suggests they might engage in this kind of giving no matter the tax benefits, though funneling patients towards your own drug is even better when it comes with a rebate.[74]

Another main criticism of PAPs is their lack of transparency.[75] Only 6 out of 168 PAPs surveyed by researchers at Brigham Women's Hospital and Harvard University divulged the number of patients that had been directly provided benefits, and more than half of the programs surveyed would not reveal their income eligibility criteria.[76] The tight-lipped nature of PAPs thus limits the ability to ascertain the proportion and demographics of patients that were either directly aided by pharmaceutical companies or referred to government programs already in place.[77] Despite these valid and alarming criticisms, the OIG of the Department of Health and Human Services still believes that "properly structured" PAPs can help Medicare Part D enrollees by making cash donations to independent, *bona fide* charitable assistance programs and has issued guidance to pharmaceutical companies to help them avoid malfeasance.[78] The OIG's primary concern lies in pharmaceutical companies' potential for abuse of these systems in violation of the anti-kickback statute.[79] As explained in Part III, however, these guidelines do little to prevent pharmaceutical companies from abusing PAPs, and the anti-kickback statute is routinely violated.

III. THE ANTI-KICKBACK STATUTE AND ONGOING LITIGATION

In a 2014 special advisory bulletin in the Federal Register, which built upon a previous bulletin from 2005, the OIG of DHHS addressed "problematic features" of patient assistance programs with respect to the anti-kickback statute, 42 U.S.C. § 1320a-

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[73] *Id.*

[74] *See id.* at 1151.

[75] *See* Choudhry et al., *supra* note 45, at 832.

[76] *Id.* at 827, 829, 832.

[77] *Id.* at 832.

[78] *See* Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 104, 31121 (May 30, 2014).

[79] *See id.*

7b(b),[80] and the provision of the Civil Monetary Penalties Law which prohibits beneficiary inducements, 42 U.S.C § 1320a-7a(a)(5).[81] Additionally, the OIG pointed to other "risk areas," including liability under the False Claims Act.[82]

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[80] 42 U.S.C. § 1320a-7b(b). The anti-kickback statute imposes criminal penalties upon:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or kind – (A) in return for referring an individual to a person for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.
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> (2) Whoever knowingly and willfully offers or pays remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person – (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned not more than 10 years, or both . . . .

[81] Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 104 at 31121 (May 30, 2014); 42 U.S.C. § 1320a-7a(a)(5). The anti-kickback statute imposes a civil penalty and treble damages upon:

> Any person (including an organization, agency, or other entity, but excluding a beneficiary . . . that – (5) offers to or transfers remuneration to any individual eligible for benefits under title XVIII of this Act, or under a State health care program . . . that such person knows or should know is likely to influence such individual to order or receive from a

The anti-kickback statute imposes criminal penalties on those who "knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program, including Medicare and Medicaid."[83] The OIG has identified two "remunerative aspects" of patient assistance programs: (1) pharmaceutical company donations to PAPs and (2) PAPs' direct grants to patients.[84] If the donor (a drug maker) provides funding to a PAP that overtly or covertly induces the charity to recommend or arrange for the donor's "federally reimbursable items" (drugs), the

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> particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under title XVIII, or a State health care program . . . .

[82] U.S. Dep't of Health and Human Serv. Off. of Inspector Gen., Special Advisory Bulletin on Independent Charity Patient Assistance Programs, 79 Fed. Reg. 104 at 31121 (May 30, 2014). The False Claims Act imposes civil penalties and treble damages upon:

> [A]ny person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); (D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property; (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true; (F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government . . . .

[83] Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 104 at 31121.

[84] *Id.*

anti-kickback statute could be violated.[85] Along those same lines, a PAP's grant of financial assistance to a patient that is found to have influenced the patient's purchase or their physician's prescription of "federally reimbursable items" is also a potential violation of the anti-kickback statute.[86] These applications of the anti-kickback statute seek to distance the drug maker from the decision maker, and the "remuneration" involved can take many forms—the transfer of "anything of value, directly or indirectly, overtly or covertly, in cash or in kind" can be found to trigger the civil monetary penalties of the statute.[87] The anti-kickback statute is enforced by the DOJ and the OIG.[88] While the DOJ is responsible for imposing criminal punishment, the OIG has the authority to impose civil monetary penalties and/or exclude kickback statute violators from federal health care programs.[89]

While this legislation may appear significantly restrictive of patient assistance programs, the OIG has carved out guidelines allowing pharmaceutical manufacturers to continue their contributions to independent, "*bona fide* charitable assistance programs."[90] Factors that the OIG consider "fundamental to a properly structured Independent Charity PAP," many of which relate to the independence of the charity, fall under three categories: disease funds, eligible recipients, and the conduct of donors.[91]

The OIG recognizes that *bona fide* PAPs often focus their charitable efforts on helping patients with particular diseases, and it is careful to point out that, on its face, a pharmaceutical company's donation to a charity for a "broad disease group" does not trigger immediate concern.[92] However, the OIG warns against donations to charities with narrowly defined disease groups.[93]

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[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] Hood, *supra* note 47 at 653.

[89] 42 U.S.C. § 1320a-7a(a)(5).

[90] Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 104 at 31121.

[91] *Id.*

[92] *Id.*

[93] *Id.*

Funds that are defined by type of drug treatment or stage of disease, for example, may run into trouble with the anti-kickback statute if the majority of the drugs offered through them are the products of the pharmaceutical company donor.[94] The OIG has become "increasingly concerned" about PAPs that narrow their focus to a "subset of available products."[95] It believes that PAPs that cover copayments for "expensive or specialty drugs" tie beneficiaries to a single product in order to initiate or continue treatment due to the enticing discount those PAPs provide.[96] This drug maker subsidized cost-sharing, the OIG argues, is harmful to the federal health care programs because it hides the true cost of expensive specialty drugs for consumers (and steers them towards the expensive drugs), while Medicare (and the taxpayer) is on the hook for the vast majority of the bill.[97] This steering increases the likelihood that a corporate donor could abuse the PAP to specifically target their own products for patient subsidies. A rare exception to the general advice against corporate donations to "narrow" charities are those funds for diseases with only one drug covered by Medicare Part D or only one drug maker that makes all of the Part D covered drugs for that disease.[98] These "unusual circumstances" alone, the OIG advises, will not be violative; a wholistic analysis of the charities' operations is required.[99]

The OIG also uses the eligibility criteria of PAPs to judge their independence from drug maker control.[100] The OIG stresses that PAPs should use "reasonable, verifiable, and uniform measure[s] of financial need" in determining patient eligibility, regardless of whether the offer of assistance is limited to Medicare beneficiaries.[101] While PAPs may increase or decrease their Federal Poverty Level eligibility requirements based on a range of factors combined (including patient income, geographic area, total medical bills, etc.), they may not do so solely on the basis of the

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[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *See id.* at 31122.
[99] *Id.*
[100] *See id.*
[101] *Id.*

drug's cost.[102] This, too, would funnel certain patient populations into PAP programs in a way that would qualify as inducement under the anti-kickback statute, rather than benefitting the patients in most dire need.[103]

Interestingly, the OIG's concerns regarding the relationship between drug maker donors and PAPs are mostly directed towards the PAPs' disclosures to the donors, rather than obvious violations of the anti-kickback statute.[104] In its guidance, the OIG directs PAPs to provide pharmaceutical donors with reports that only provide patient application, qualifying applicants, and disbursement figures in the aggregate so that a corporate donor would not be able to select a PAP based on its ability to attract patients to the donor's own products.[105]

As one of the two key players in the identification and prosecution of anti-kickback statute violations, the OIG continues to offer advisory guidance to independent charity PAPs on the organizational and practical factors that might initiate an inquiry under the anti-kickback statute.[106] But this guidance has not prevented litigation. In 2018, Pfizer agreed to pay $23.85 million to settle a claim that it used its own 501(c)(3) nonprofit to funnel patients toward three drugs: Sutent, Inlyta, and Tikosyn.[107] Sutent and Inlyta are both used to treat renal cell carcinoma and Tikosyn is used for atrial fibrillation or atrial flutter.[108] In that suit, the U.S. Attorney's Office for the District of Massachusetts alleged that Pfizer used a third-party specialty pharmacy to transition some patients from an existing free drug program to the new foundation, which covered the patient's Medicare copays using Pfizer donations.[109] The foundation then allegedly provided data collected

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[102] *See id.*

[103] *See id.*

[104] *See id.* at 31123.

[105] *Id.*

[106] *See id.*

[107] Press Release, U.S. Dep't of Just., Pfizer Agrees to Pay $23.85 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation (May 24, 2018), https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

[108] *Id.*

[109] *Id.*

by the specialty pharmacy to Pfizer, which confirmed the foundation was paying for Sutent and Inlyta copays.[110]

In the same settlement, Pfizer also resolved allegations that it used a third-party patient assistance program to cover a 44% price increase for its drug Tikosyn.[111] Pfizer, knowing the price increase would balloon the copay obligations of Medicare beneficiaries, allegedly worked with the foundation to create and finance a fund for Medicare patients being treated for the very diseases treated by Tykosyn.[112] To ensure the fund was used for its own benefit, Pfizer allegedly coordinated the timing of the opening of the fund with the price increase; for the following nine months, Pfizer patients accounted for nearly all of the fund's beneficiaries.[113] As U.S. Attorney Andrew Lelling put it, "Pfizer used a third party to saddle Medicare with extra costs."[114] As part of the settlement, Pfizer agreed to enter into a corporate integrity agreement with the DHHS OIG.[115] The agreement, a five-year commitment, requires that Pfizer implement compliance measures to ensure its dealings with third-party PAPs are compliant with the anti-kickback statute and promote independent PAP operation.[116]

2020 has been awash with litigation over the use of patient assistance programs. On June 24, 2020, the U.S. Attorney's Office announced a complaint against Regeneron Pharmaceuticals, alleging the drug maker donated tens of millions of dollars to a third-party foundation to ensure that most Medicare patients would not need to pay a co-pay for its macular degeneration drug Eylea.[117] The U.S. Attorney alleged that in order to orchestrate the kickback, Regeneron first confirmed with the third-party patient assistance program, Chronic Disease Fund ("CDF"), a purportedly

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[110] *Id.*

[111] *Id.*

[112] *Id.*

[113] *See id.*

[114] *Id.*

[115] *Id.*

[116] *Id.*

[117] Press Release, U.S. Dep't of Just., United States Files Suit Against Drug Manufacturer Regeneron for Paying Kickbacks Through Co-Pay Foundation (June 24, 2020), https://www.justice.gov/usao-ma/pr/united-states-files-suit-against-drug-manufacturer-regeneron-paying-kickbacks-through-co.

independent foundation,[118] that it was in need of money to cover Medicare co-pays for Eylea rather than competing drugs, resulting in a windfall return on its investment in the patient assistance program.[119] When asked about the patients in need of co-pay assistance that took the other leading macular degeneration drug made by rival Genentech, Regeneron's former Chief Financial Officer said those patients were "Genentech's problem."[120]

The complaint against Regeneron suggests that patient assistance programs only "assist" patients in service of pharmaceutical company bottom lines.[121] The government alleged in its complaint that Regeneron employees repeatedly contacted CDF to inquire how much money the charity needed to cover the co-pays of Eylea patients, and then calculated the expected revenue from donating that amount.[122] The Regeneron employees predicted a return of over 400% on its "donations" to CDF.[123] The U.S. Attorney's office contends those donations were not charity; rather, they were payments to subsidize Eylea's artificially high price in order to reap Medicare's share of the cost.[124]

In June 2020, Pfizer rejoined the fray by filing a lawsuit against the United States Department of Health and Human Services, HHS Secretary Alex Azar, the Office of the Inspector General of HHS, and Christi Grimm, the Principal Deputy Inspector General of HHS.[125] Pfizer sued for the ability to provide financial assistance to Medicare beneficiaries who are unable to afford its $225,000-per-year medication for transthyretin amyloid cardiomyopathy

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[118] *See* Complaint, U.S. v. Regeneron Pharm., Inc., No. 20-11217 (D. Mass. June 24, 2020), https://www.justice.gov/usao-ma/press-release/file/1395526/download.

[119] Press Release, U.S. Dep't of Just., *supra* note 117.

[120] *Id.*

[121] *See* Complaint, U.S. v. Regeneron Pharm., Inc., No. 20-11217 (D. Mass. June 24, 2020), https://www.justice.gov/usao-ma/press-release/file/1395526/download.

[122] *Id.*

[123] *Id.*

[124] *See id.*

[125] Complaint for Declaratory Judgment, Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs., No. 20-cv-04920 (S.D.N.Y. June 26, 2020).

("ATTR-CM"), tafamidis.[126] It claimed that under the current "erroneous legal restrictions imposed by the OIG," it is unable to aid patients who cannot afford their copay because of the risk of criminal or other government enforcement action.[127] Pfizer's complaint requested declaratory judgment that its proposed patient assistance programs do not violate federal anti-kickback laws.[128] The company justified tafamidis's price tag as "well below comparable novel therapies approved to treat other rare diseases" and "substantially less than a dual heart and liver transplant, which is the other potential treatment option for patients with ATTR-CM."[129] Pfizer argued that it sought to aid ATTR-CM patients "caught between . . . financial extremes" who cannot afford the average $13,000 Medicare Part D co-pay for tafamidis because they were not "wealthy enough to pay the out-of-pocket costs" nor have "incomes so low that Medicare waives most of the out-of-pocket costs" under the Extra Help program.[130]

Pfizer's argument for patient assistance programs, however, hinged on tafamidis' status as the only available medication for a particular disease.[131] The pharmaceutical company asserted that the anti-kickback statutes were meant to prohibit kickbacks made "with the intent to corrupt medical decision making at the expense of federal healthcare programs."[132] They argued that their proposed programs are designed to remove financial obstacles to breakthrough treatment "*after* a physician has objectively determined that a patient has ATTR-CM and prescribed the only FDA approved medications for this terminal disease."[133] Pfizer argued that, since its drug is the only approved medication, its support to patients who need it could not constitute an illegal kickback.[134]

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[126] *Id.*
[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] *See id.*
[132] *Id.*
[133] *Id.*
[134] *See id.*

In its complaint, Pfizer argued that the OIG's strict construction of the anti-kickback statute, combined with the DOJ's aggressive steps to intervene in patient assistance programs, left it with "no alternative" to help the "very sick patients who will be denied these critical Medications."[135] Pfizer explained that it worked for a year with the OIG to construct a framework by which the company could lawfully assist its patients.[136] The OIG's failure to shift its perspective, argued Pfizer, violated the company's "established rights" to "participate in a charitable endeavor and engage in expressive giving in support of patients suffering from ATTR-CM," as the OIG persisted in "improperly singl[ing] out pharmaceutical manufacturers for special restrictions on this type of charitable giving."[137]

Pfizer went on to assert First Amendment concerns in the OIG's restriction on "pharmaceutical manufacturer's communications and donations to independent charities that provide financial assistance to Medicare patients," claiming that a prohibition on such communication is not "narrowly tailored to a compelling government interest in combatting fraud or abuse"—violating the First Amendment's Free Speech guarantee.[138]

In perhaps its strongest argument, Pfizer claimed that the OIG's position on copay assistance "[led] to perverse and unequal results depending on a Medicare beneficiary's economic status."[139] While the wealthiest can pay the co-pay and the poorest do not have to under the low-income Extra Help subsidy, middle-income patients get stuck with a bill that many cannot pay.[140] Such an "irrational application" of the Medicare Part D scheme, Pfizer said, violates the equal protection principles of the Fifth Amendment's Due Process Clause.[141] On September 30, 2021, the U.S. District Court for the Southern District of New York dismissed Pfizer's complaint, holding that HHS' action was "not contrary to law,"

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[135] *Id.*

[136] Konnath, *supra* note 12.

[137] *Id.*

[138] Complaint for Declaratory Judgment at 7, Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs., No. 20-cv-04920 (S.D.N.Y. June 26, 2020).

[139] *See id.*

[140] *See id.* at 8.

[141] *Id.*

and that the court "cannot declare that the Direct Program will not violate the Anti-Kickback Statute as Pfizer requests."[142]

IV. LEGISLATIVE PROPOSALS TO DATE

In light of this high-stakes litigation, lawmakers have suggested reforms that would greatly alter Medicare's operation or obviate the need for patient assistance programs altogether. A broad range of policy options have been considered, including allowing the federal government to negotiate the price of prescription drugs on the behalf of Medicare Part D beneficiaries.[143] That policy was proposed by several democratic lawmakers, each involving the "noninterference clause" of Medicare Part D, which states that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or impose a price structure for the reimbursement of covered part D drugs."[144] Currently, prescription drug benefits are provided through a marketplace of private plans which each negotiate drug prices with pharmaceutical companies, establish formularies, and control costs.[145] Proponents of consolidating negotiating power in the Secretary of HHS believe that this fundamental change to Medicare reimbursement would provide leverage to reduce drug costs, especially for high-priced, no-competitor drugs, the prices for which private plans currently have little negotiating power.[146] Pharmaceutical companies argue that such a change would disincentivize the research and development crucial to the United States' pharmaceutical industry prowess.[147]

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[142] Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs., No. 20-cv-04920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021), at *15.

[143] Juliette Cubanski et al., *What's the Latest on Medicare Drug Pricing Negotiations?*, KAISER FAM. FOUND. (July 23, 2021), https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations.

[144] *See id* (quoting 42 U.S.C. § 1860D-11).

[145] *See id.*

[146] *Id.*

[147] *See id.*

A. Proposed Reforms

A bill introduced by Speaker Nancy Pelosi, that passed the House of Representatives but stalled in the Senate, H.R. 3, Elijah Cummings Lower Drug Costs Now Act of 2019, amends the noninterference clause by adding an exception that allows for the negotiation of drug prices of at least 25 and up to 250 brand-name drugs that lack generic or biosimilar competitors. The bill prioritizes the 125 drugs with the highest Medicare Part D spending and the 125 drugs with the highest net spending in the United States.[148] The legislation would require the Secretary of HHS to consider "research and development costs, market data, production and distribution costs, and existing therapeutic alternatives" in setting the maximum price for a drug.[149] Interestingly, this legislation would establish the upper limit for a drug's price at 120% of the "Average International Market" ("AIM") price paid by six "economically prosperous countries," and establishes maximum drug prices for which there is no AIM price available at 85% of the average manufacturer price ("AMP").[150] Drug companies that do not comply with negotiations would be subject to financial penalties under the Act, and manufacturers who "fail to negotiate successfully" would face increasing excise taxes on the previous year's gross sale of the drug whose price was unsuccessfully negotiated. The taxes would rise by 10% each quarter up to a maximum of 95%.[151]

Another proposed bill strikes the noninterference clause altogether. The Doggett-Brown bill (H.R. 1046/S. 377) would circumvent patent exclusivity rights by granting a competitive license to another manufacturer to produce a generic or biosimilar version of the drug to Part D plans, should negotiations between the drug company and the Secretary of HHS fail.[152] In addition to

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[148] *See id.*

[149] *Id.*

[150] *Id.* (Countries include Australia, Canada, Japan, France, Germany, and the United Kingdom).

[151] *Id.*

[152] Meredith Freed et al., *A Look at Recent Proposals to Control Drug Spending by Medicare and its Beneficiaries*, KAISER FAM. FOUND. (Nov. 26,

the obvious drawbacks of potentially limiting a major source of U.S. intellectual property, detractors from this proposal also raise concerns about supply delay when negotiations stall.[153]

The Cummings-Sanders bill (H.R. 448/S. 99) contains many of the same proposals as the Doggett-Brown bill, but it specifically targets the most costly drugs.[154] This bill would also curb the inflation of drug prices by targeting drugs with the highest year-to-year price increases.[155] The proposal includes parameters for determining a negotiated price, including "clinical and cost effectiveness, the budgetary impact of covering a certain drug, the number of therapeutic alternatives with similar effectiveness, and the unmet need for the drug."[156] If negotiations fail, this proposal provides a mechanism to establish a fallback price, determined based on the lowest price paid by other federal programs such as Medicaid and Veteran's Affairs, or, if lower, the price paid by Organization for Economic Cooperation and Development ("OECD") countries.[157]

It should be noted that for all of the above proposals that alter or strike the noninterference clause, the Congressional Budget Office has predicted negligible savings because the Secretary of HHS would have "insufficient leverage" to secure price concessions.[158] The only bill with the potential to give the Secretary sufficient leverage is H.R. 3; there, leverage for negotiation comes from the potential imposition of increasing excise taxes for the failure to negotiate or unsuccessful negotiations.[159] Without such pressure available to the Secretary, there is little hope for cost savings on the government or the consumer's part.[160]

2019), https://www.kff.org/report-section/a-look-at-recent-proposals-to-control-drug-spending-by-medicare-and-its-beneficiaries-issue-brief/.

[153] *Id.*

[154] *Id.*

[155] *Id.*

[156] *Id.*

[157] *Id.*

[158] *Id.*

[159] *Id.*

[160] *Id.*

Conservative detractors from the proposed reforms point to the Veterans Health Administration ("VHA") as an example of the rationing that occurs when government gets involved in drug pricing.[161] The government is responsible for negotiating drug prices for the VHA, which, critics argue, forces exclusions to the drugs available to veterans due to the government's lack of bargaining power against competing private insurers.[162] In 2016, the VHA only covered three out of twenty-five newly-approved, "first-in-class" therapies, and excluded one in five of the top 200 drugs included in privately negotiated Part D plans.[163] This stark reality faced by nine million veterans, they argue, would also apply to forty-two million Medicare Part D beneficiaries, should any of the Democrats' proposals pan out, crushing the pharmaceutical industry's will to innovate along the way.[164] Surely, this point is valid: why would anyone spend $2.6 billion to develop a new drug if the government prevents forty-two million people from taking it?[165]

Other lawmakers have stopped short of introducing legislation but wrote a letter that called for the Office of the Inspector General of HHS to increase regulatory scrutiny of patient assistance programs, specifically by "(1) prohibiting pharmaceutical company donors from earmarking their donations for disease-specific funds; (2) requiring public disclosure of the treatments the funds cover and justification for any FDA-approved treatments not covered; and (3) requiring PAPs to cover generic alternatives."[166] The letter, written by Senators Elizabeth Warren (D-Mass.) and Sheldon

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[161] *See* Sally Pipes, *Keep Big Government Out of Medicare Drug Pricing Negotiations*, THE HILL (Dec. 11, 2017, 3:20 PM), https://thehill.com/opinion/healthcare/364297-keep-big-government-out-of-medicare-drug-pricing-negotiations.

[162] *See id.*

[163] *Id.*

[164] *Id.*

[165] *Id.*

[166] Press Release, Sheldon Whitehouse, Senators Whitehouse & Warren Call for Reforms to Eliminate Big Pharma Kick-Back Schemes Via Patient Assistance Programs (Dec. 5, 2019), https://www.whitehouse.senate.gov/news/release/senators-whitehouse-and-warren-call-for-reforms-to-eliminate-big-pharma-kick-back-schemes-via-patient-assistance-programs-.

Whitehouse (D-R.I.), claims that "it is impossible for patients, the public, and HHS-OIG to know whether drug assistance decisions correlate with donor's interests and whether PAPs are complying with HHS-OIG guidance" with such little transparency required of industry- and independently-run patient assistance programs.[167]

Despite lawmakers' apparent focus on drug price negotiations, little has been proposed to curb the influence of PAPs beyond the OIG's ongoing issuance of guiding commentary. As indicated by Pfizer's suit for declaratory judgment, such commentary does not provide pharmaceutical companies with sufficient notice that they may be in violation of the anti-kickback statutes.[168] In an article in Brooklyn Law Review, titled *Pharmaceutical Philanthropy or Resisting Regulations?: Why Pharmaceutical Donations Do Not Violate the Anti-Kickback Statute*, author Tino Illiparambil suggests using a "direct causal link test" to determine whether or not the anti-kickback statute has been violated.[169] This test would require courts to ask "whether, but for the donation to the PAP, the patient would not have chosen to participate in that specific PAP."[170] Under the test, the court would first determine whether the patient chose a PAP because they knew the charity receives donations from a drug maker; then determine whether the pharmaceutical company donor knew that patients chose that specific PAP due to its donations; and finally determine whether the company "*then* knowingly and willfully acted on this information with the intent of inducing patients' dependency on the product, resulting in future sales."[171] While this test strives to provide a system for courts to apply, it is likely to simply pile on to the OIG's existing guidance, adding complexity to a law that demands straightforward, uncomplicated application.

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[167] *Id.*

[168] *See* Complaint for Declaratory Judgment, Pfizer, Inc. v. U.S. Dep't of Health and Hum. Servs. No. 1:20-cv-04920-MKV (S.D.N.Y. June 26, 2020).

[169] Tino Illiparambil, *Pharmaceutical Philanthropy or Resisting Regulations?: Why Pharmaceutical Donations Do Not Violate the Anti-Kickback Statute*, 85 BROOK. L. REV. 571, 596 (2020).

[170] *Id.*

[171] *Id.*

B. An Alternative Approach

In light of failed attempts to overhaul Medicare, endless litigation over the use of PAPs to fill gaps in coverage, and complicated guidance promulgated by the OIG of HHS on proper PAP dealings, it is clear that more definitive, course-setting measures must be taken to curb PAP's "triple boon" for the pharmaceutical industry.[172]

This Note proposes a legislative bill to amend the Medicare Modernization Act and Internal Revenue Code that phases out all PAPs whose donations come primarily from pharmaceutical industry donors—both independent- and industry-run—in favor of a single, consolidated patient assistance fund administered by the Centers for Medicare & Medicaid Services ("CMS"). The bill would encourage an early shift in pharmaceutical donations to the consolidated patient assistance fund through tax incentives that reduce the available corporate tax deductions for pharmaceutical charity to PAPs and, in turn, create a higher available tax deduction for donations to the CMS-administered fund. The bill's third measure would eliminate prior OIG guidance on the proper administration of PAPs in favor of a strict reading of the anti-kickback statute. The new guidance would instruct the DOJ and OIG of DHHS to fully prosecute violations of the anti-kickback statute as written after a ten-to-fifteen-year safe harbor period, with the express direction that all PAPs who receive a majority of their funding from the pharmaceutical industry are de facto violators.

The proposed bill's first provision would establish a single, consolidated patient assistance fund administered by CMS. The fund would be supported by pharmaceutical industry donations encouraged by tax incentives and legal disincentives, as described below, and would be used to expand access to the Medicare Extra Help program by increasing the maximum yearly income and "other sources" threshold to qualify for extra financial assistance to bridge the gap for those too "wealthy" to receive extra help but not poor enough to currently receive co-pay assistance through Extra Help.[173] The fund would also serve as funding for a separate

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[172] *See* Hiltzik, *supra* note 64.

[173] *See* MEDICARE & YOU 2021, *supra* note 8, at 87–89.

program aimed at patients whose illness only has one available treatment, like Walter Feigenson, whose tafamidis therapy is the only available treatment for his heart condition.[174] Such patients would apply via standard application to CMS for a rare disease discount, instead of applying to a pharmaceutical company directly. As industry- and independently-run PAPs are currently among the largest 501(c)(3) organizations in the United States, a shift in these funds to a more evenly-distributed discount would help more low-income patients and patients with rare diseases more equally than current PAPs. Instead of the disparate eligibility requirements across current PAPs that are often hidden from public scrutiny, a single, consolidated patient assistance fund would offer straightforward eligibility criteria based on income alone, without the opportunity for pharmaceutical companies to target their contributions toward patients taking their own drugs.[175] Under this proposal, patients in need of support would either automatically qualify for co-pay assistance or apply via a standard application to CMS, in which they would indicate their financial and medical level of need for a non-generic drug.

The proposed program would also avoid the major pitfall that other proposed measures fail to address: the potential removal of popular drugs from Medicare Part D formularies due to cost.[176] With the infusion of potentially billions of dollars into a consolidated patient assistance fund, those who truly need specialized medicine can apply to CMS for help if they do not fall below the proposed expansion of the Extra Help program, and would not be forced to go to the black market for desired, non-covered drugs. The ability to negotiate drug prices would still be in the more able hands of insurers, while the ability to help those who have a demonstrated need would be the responsibility of CMS, which, as a government agency, has no incentive to approve or deny particular patient populations.[177]

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[174] *See* Laise, *supra* note 1.

[175] *See* Choudhry et al., *supra* note 45, at 831–32.

[176] *See* Pipes, *supra* note 161.

[177] *See generally* MEDICARE & YOU 2021, *supra* note 8 (discussing CMS procedures); s*ee generally* Pipes, *supra* note 161 (discussing the ability of insurance companies to negotiate).

The proposed bill's second provision would shift tax incentives away from pharmaceutical industry donations to patient assistance programs and towards the CMS-administered fund. To do so, the bill would amend the Internal Revenue Code's available corporate tax deduction for pharmaceutical company donations to PAPs from 10% to 5% in the first ten years after implementation, then reduce that available deduction from 5% to zero in the subsequent five-year period. As the limit for deductible contributions to PAPs decline, the available corporate tax deduction for contributions to the CMS fund will rise, beginning at the standard 10% in the first ten years and rising to 15% thereafter. This structure would gradually encourage pharmaceutical companies to shift donations away from non-CMS funds and towards the CMS fund.

Finally, the bill would impose a fifteen-year safe harbor period for pharmaceutical companies to comply with a strict interpretation of the anti-kickback statute without regard to OIG's past guidance. A strict interpretation of the anti-kickback statute is required because attempts by the OIG to offer guidance on the "problematic features" of patient assistance programs have failed to prevent litigation.[178] Instructions that warn against donations to PAPs with "narrowly defined disease groups," funds defined by the "stage of disease," or that are limited to a "subset of available products," have clearly been too vague or non-inclusive of PAPs that are clearly in violation.[179] The OIG itself notes that these factors are not dispositive in the anti-kickback statute determination—a "wholistic review" of the charities' operation is required.[180] This guidance has not prevented pharmaceutical companies from making complicated arrangements in attempt to skirt the anti-kickback statute, such as the third-party pharmacy scheme at issue in Pfizer's $23.5 million settlement agreement.[181] That kind of settlement, and years of required oversight by the OIG, could be avoided altogether if PAPs were strictly regulated to forbid pharmaceutical companies from becoming majority donors. Such a

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[178] *See generally* Complaint for Declaratory Judgment, *supra* note 125.

[179] *See* Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 104 at 31122.

[180] *Id.*

[181] *See generally* Press Release, U.S. Dep't of Just., *supra* note 107.

strict reading of the anti-kickback statute could actually benefit pharmaceutical companies in the form of reduced legal fees. No longer will the Pfizers of the world need to obtain declaratory judgments to question the validity of their beneficence.[182] They would simply be able to donate to the CMS-administered fund. Those funds would then be spread to address the needs of all pharmaceutical consumers, many of whom, to be sure, would benefit from expanded access to non-generic pharmaceuticals (though none would feel the great financial need to take its drug over another generic or competing drug due).

This proposal would likely have detractors: pharmaceutical companies would be loath to give up their patient-funneling cash cows of PAPs, and many patients, too, would likely be adversely impacted by the legislative drying up of pharmaceutical industry-funded PAPs. However, these downsides pale in comparison to the impacts of drug market manipulation that pharmaceutical companies currently engage in via patient assistance programs. This proposal would not fundamentally change the overall ability of private insurers to negotiate with drug companies, thereby preserving patient choice in the healthcare equation while offering discounts to only those who truly need it for lack of a generic alternative or insurmountable financial burden. It would widen the pool of patients eligible for assistance under Medicare Extra Help, preventing patients from sifting through the veiled eligibility criteria of patient assistance programs, while simultaneously providing the pharmaceutical industry with goodwill. Additionally, with the anti-kickback statute revived to its original interpretation, industry, charity, and the government alike would have appropriate notice when assessing compliance.

CONCLUSION

Patient assistance programs offer Medicare beneficiaries like Walter Feigenson the opportunity to take life-saving drugs they could otherwise not afford. While pharmaceutical donors insist that their goal is strictly altruistic, the reality is that many of these programs offer a financial windfall for drug makers because they

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[182] *See generally* Complaint for Declaratory Judgment, *supra* note 125.

help funnel patients towards new pharmaceuticals with generic alternatives while collecting the drug's market price at the expense of taxpayers. To preserve a safety net of assistance while discouraging illegal activity, a CMS-administered fund should be established for the appropriate disbursement of pharmaceutical industry charity, opening up access to costly, life-saving medications to a broader population of needy patients in a manner uninfluenced by corporate bottom lines.