CORRUPT OR CHARITABLE? PATIENT ASSISTANCE PROGRAMS AND THE CASE FOR NARROWING THE BREADTH OF THE FEDERAL ANTI-KICKBACK STATUTE

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INTRODUCTION

Consider the following hypothetical involving two fictional pharmaceutical companies: LifeSaving Devices Inc. and FormulaOne Services, Inc.[1] LifeSaving Devices specializes in medical devices that treat a rare spinal disorder. Physicians have been reluctant to recommend these devices due to the availability of more effective alternatives on the market. In addition, physicians have expressed concerns about the safety of these devices in treating patients. In hopes of increasing its profits, LifeSaving Devices decides to reach out directly to certain physicians and present them with a lucrative offer. The company will offer these physicians consideration, such as paid travel expenses, fees, and other items of value, under the condition that the physicians purchase and recommend the devices to their patients. Several physicians who have previously declined to recommend the devices to patients are now inclined to accept the offer. These physicians recommend the devices to their patients despite the potential risks and the physicians' beliefs that there are safer treatment options available.

FormulaOne Services, Inc., on the other hand, has recently developed a prescription medication that treats rare cardiac conditions that often result in heart disease and death.[2] However, due to the nature of the healthcare market and its impact on price, the medication is prohibitively expensive.[3] The company has recently learned that many patients covered by Medicare Part D are underinsured and unable to

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1 These facts are partly inspired by a settlement involving a French medical device manufacturer, but they have been modified for purposes of the hypothetical. Press Release, U.S. Att'y's Off., E. Dist. of Pa., French Medical Device Manufacturer to Pay $2 Million to Resolve Alleged Kickbacks to Physicians and Related Medicare Open Payments Program Violations (May 19, 2021), https://www.justice.gov/usao-edpa/pr/french-medical-device-manufacturer-pay-2-million-resolve-alleged-kickbacks-physicians [https://perma.cc/9ERK-QWTA].

2 These facts are partly inspired by the facts involved in Pfizer's suit for declaratory judgment to declare their Patient Assistance Program legal. *See* Complaint for Declaratory Judgment, Pfizer Inc. v. U.S. Dep't of Health & Hum. Servs., No. 20-cv-4920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021).

3 *See infra* Section I.A.

afford this potentially vital treatment.[4] The company designs a subsidy program to assist Medicare Part D patients with their out-of-pocket costs, removing this barrier to accessing the medication. The patients would be required to get a prescription from a physician and qualify for the program.

Obviously, LifeSaving Devices' arrangement is culpable and is a clear example of physicians being bribed to the point of corrupted decision-making. On the other hand, FormulaOne Services' conduct could prove to be quite useful in ensuring that underinsured patients are able to access life-saving treatment. Despite this distinction, under current federal law, both companies would be subject to penalties under the Federal Anti-Kickback Statute (AKS).[5] FormulaOne's program would not only likely be enjoined, but the company could potentially face severe treble damages.[6] The prosecution of FormulaOne would be due to the financial benefit FormulaOne stands to gain by providing subsidies that are reimbursable by the federal government.[7] Despite assisting underinsured patients with access to life-saving prescription medication, FormulaOne's program would almost certainly fall under the AKS.[8]

Retail prescription drug costs for the average American senior citizen taking four to five prescription drugs monthly is $31,000 per year, while the average annual income for Medicare beneficiaries is $29,650.[9] American spending on prescription drugs has increased by 76% between 2000 and 2017.[10] Despite initiatives taken to provide federal aid in the

4 *See generally* Cathy Schoen, Claudia Solís-Román, Nick Huober & Zachary Kelchner, *On Medicare but at Risk: A State-Level Analysis of Beneficiaries Who Are Underinsured or Facing High Total Cost Burdens*, COMMONWEALTH FUND, May 2016, at 1, https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2016_may_1874_schoen_on_medicare_but_at_risk_v5.pdf [https://perma.cc/9GDX-JQNG].

5 *See infra* Section I.C.

6 *See* 31 U.S.C. § 3729(a).

7 Robert N. Rabecs, *Health Care Fraud Under the New Medicare Part D Prescription Drug Program*, 96 J. CRIM. L. & CRIMINOLOGY 727, 746–47 (2006). The reasoning is that pharmaceutical manufacturers will want to incentivize using their product to trigger full coverage of the costs by the patient's insurance plan. This will allow manufacturers and pharmacies to seek reimbursement directly from the federal government—a reliable strategy to reap maximum profits. *Id.* at 742.

8 *See infra* Section II.B.2.

9 Dena Bunis, *Prescription Drug Price Increases Continue to Outpace Inflation*, AARP (June 7, 2021), https://www.aarp.org/politics-society/advocacy/info-2021/prescription-price-increase-report.html [https://perma.cc/2RPW-AXAQ].

10 Press Release, RAND Corp., Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries (Jan. 28, 2021), https://www.rand.org/news/press/2021/01/28.html [https://perma.cc/2CVM-9LVN].

healthcare market,[11] millions of Americans remain underinsured by their government-sponsored healthcare program due to the high costs of prescription drugs.[12] Absent comprehensive legislative solutions to address the prescription medication market, major U.S. pharmaceutical manufacturers operate Patient Assistance Programs (PAPs) to assist uninsured and underinsured individuals with high drug costs.[13] This assistance often comes in the form of direct-drug–discount coupons or cost-sharing payments.[14] These PAPs have proven to be quite impactful, and there is evidence that they mitigate the burden of healthcare costs on individuals.[15]

Since the implementation of Medicare Part D, PAPs have come under increased scrutiny by the federal government due to the potential for fraud and abuse.[16] The Medicare Part D program provides coverage for certain outpatient prescription drugs.[17] However, there is a question as to whether pharmacies and drug manufacturers can assist Part D beneficiaries with their cost-sharing obligations.[18] The federal government has stated that any pharmaceutical manufacturer sponsoring a PAP that subsidizes the cost of its products for Medicare Part D recipients is likely receiving kickbacks and is criminally liable under the AKS.[19] Because of the broad reach of the AKS, many PAPs that may be helpful in reducing healthcare costs are now subject to criminal penalties.[20]

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11 *See generally* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 42 U.S.C.); Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 42 U.S.C.).

12 Reshma Ramachandran, Tianna Zhou & Joseph S. Ross, *Out-of-Pocket Drug Costs for Medicare Beneficiaries Need to Be Reined In*, STAT (Jan. 7, 2022), https://www.statnews.com/2022/01/07/out-of-pocket-drug-costs-for-medicare-beneficiaries-need-to-be-reined-in [https://perma.cc/2K6B-TYV6].

13 Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) [hereinafter OIG Special Advisory Bulletin].

14 SUZANNE M. KIRCHHOFF, CONG. RSCH. SERV., R44264, PRESCRIPTION DRUG DISCOUNT COUPONS AND PATIENT ASSISTANCE PROGRAM (PAPS) 1 (2017).

15 *See The Impact of Patient Assistance on Access, Medication Adherence and Quality of Life*, PAN FOUND. (Mar. 1, 2019), https://www.panfoundation.org/app/uploads/2019 [https://perma.cc/H5S4-GB2Q]; *see also* Limin Gao, Jivin Joseph, Marcelle Santoro-Levy, Alan S. Multz & Vladimir K. Gotlieb, *Utilization of Pharmaceutical Patient and Prescription Assistance Programs via a Pharmacy Department Patient Assistance Program for Indigent Cancer Patients*, 51 HOSP. PHARMACY 572 (2016) (finding that a pharmacy-based PAP resulted in a total cost savings of $1.7 million in one year in addition to increasing patients' compliance with chemotherapy protocols).

16 *See generally* OIG Special Advisory Bulletin, *supra* note 13, at 70624.

17 42 U.S.C. § 1395w-101(a)(1)(A).

18 *See* OIG Special Advisory Bulletin, *supra* note 13, at 70624.

19 *Id.*

20 *See* 42 U.S.C. § 1320a-7b(b)(1).

This Note will argue that PAPs demonstrate the problems involved with the AKS's emphasis on inducement.[21] Any subsidy, even if intended to help a patient with cost-sharing obligations, could be seen as an illegal inducement if it removes financial barriers that would otherwise prevent the patient from receiving the medication.[22] Because of this, courts should interpret the AKS in the spirit of its original purpose: to prohibit remuneration to an individual with the corrupt intention of improperly influencing a physician's decision-making.[23] Thus, PAPs should not be prosecuted pursuant to the AKS unless there is a clear indication that remuneration was offered in exchange for something of value. In other words, there should be clear proof that a physician was improperly induced to prescribe the medication due to the presence of remuneration. Under this scheme, PAPs would not be unfairly characterized simply because they remove a financial impediment to patients accessing drugs prescribed to them by a qualified physician.

Part I of this Note gives background on the prescription drug price crisis, along with an account of the various structures of PAPs and relevant background on Medicare Part D.[24] Part I then provides the legislative history of the AKS and its traditional enforcement mechanisms.[25] Finally, Part I looks at how PAPs implicate kickback concerns when operating within the Medicare Part D program.[26] Part II analyzes the problems federal courts have in determining the breadth of the AKS and how the court-adopted one-purpose test unfairly prohibits many harmless PAP arrangements.[27] Part III proposes a safe harbor solution that narrows the one-purpose test, making it more akin to the gratuity test articulated in *United States v. Sun-Diamond Growers of California*.[28] Part III also demonstrates how the test for gratuity, despite

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21 In the context of the AKS, "induce" is defined as "to bring on or about, to affect, cause, to influence to an act or course of conduct, lead by persuasion or reasoning, incite by motives, prevail on." Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995) (quoting *Induce*, BLACK'S LAW DICTIONARY (6th ed. 1990)).

22 Off. of the Inspector Gen., U.S. Dep't of Health & Hum. Servs., Advisory Opinion No. 20-05, at 15 (Sept. 18, 2020) [hereinafter OIG Advisory Opinion].

23 Richard P. Kusserow, *The Medicare and Medicaid Anti-Kickback Statute and the Safe Harbor Regulations—What's Next?*, 2 HEALTH MATRIX 49, 52 (1992); *see also* Guilfoile v. Shields, 913 F.3d 178, 192–93 (1st Cir. 2019) ("[T]he heartland of what the AKS is intended to prevent—the use of payments to improperly influence decisions on the provision of health care that lead to claims . . . to federal health care programs.").

24 *See infra* Part I.

25 *See infra* Part I.

26 *See infra* Part I.

27 *See infra* Part II.

28 526 U.S. 398 (1999); *see infra* Part III.

certain complications in its application, will taper the AKS so that it applies to conduct that inherently corrupts medical decision-making.[29]

I. BACKGROUND

A. *State of Prescription Drug Prices in the United States*

It is no secret that prescription drug prices can be prohibitively expensive in the United States.[30] Americans spend more on prescription drug costs than residents of any other country.[31] While Medicare and Medicaid have helped Americans decrease out-of-pocket costs for prescription medication, these programs have not guaranteed affordable costs for prescription drugs.[32] In fact, a recent RAND study found that American spending on prescription drugs has increased by 76% between 2000 and 2017.[33] In addition, unlike private health insurers, Medicaid and Medicare administrators are prohibited from negotiating prescription drug prices.[34] As a result, millions of Americans who are covered by insurance are "functionally uninsured" and cannot afford their prescription medication despite being covered by Medicare or Medicaid.[35]

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29 *See infra* Part III.

30 *See* Samantha McGrail, *US Prescription Drug Prices 256% Higher Than Other Countries*, PHARMA NEWS INTEL. (Feb. 3, 2021), https://pharmanewsintel.com/news/us-prescription-drug-prices-256-higher-than-other-countries [https://perma.cc/P6S6-7GAZ]; Christopher Curley, *Prescription Drug Prices in the U.S. Are Twice as High: Here's Why*, HEALTHLINE (Feb. 2, 2021), https://www.healthline.com/health-news/prescription-drug-prices-in-the-u-s-are-twice-as-high-heres-why [https://perma.cc/BM2F-8BXD].

31 *See* Press Release, RAND Corp., *supra* note 10.

32 Mark Duggan & Fiona Scott Morton, *The Effect of Medicare Part D on Pharmaceutical Prices and Utilization*, 100 AM. ECON. REV. 1 (2010); John DeFuria, Note, *The Patient Assistance Problem* 1, HEALTH L. OUTLOOK (Mar. 16, 2021), https://scholarship.shu.edu/cgi/viewcontent.cgi?article=1025&context=health-law-outlook [https://perma.cc/FR39-8EY4] ("Due to increasingly high healthcare costs, the reality of how insurance companies cover the cost of prescription medicines has left many Americans 'functionally uninsured' meaning that their health insurance either does not cover certain medications or requires them to pay out-of-pocket costs that they simply cannot afford."); *see also* Yuting Zhang, Judith R. Lave, Joseph P. Newhouse & Julie M. Donohue, *How the Medicare Part D Drug Benefit Changed the Distribution of Out-of-Pocket Pharmacy Spending Among Older Beneficiaries*, 65B J. GERONTOLOGY: SOC. SCIS. 502, 505 (2010).

33 Press Release, RAND Corp., *supra* note 10.

34 42 U.S.C. § 1395w-111(i); Dennis Thompson, *What's Behind the Sharp Rise in Prescription Drug Prices?*, CBS NEWS (Aug. 24, 2016, 11:17 AM), https://www.cbsnews.com/news/whats-behind-the-sharp-rise-in-prescription-drug-prices [https://perma.cc/T5GV-T6MV].

35 *The Need for Patient Assistance and Access Programs*, PATIENTS RISING NOW, https://patientsrisingnow.org/the-need-for-patient-assistance-and-access-programs [https://perma.cc/MWM5-RTHH].

This is partly attributable to the cost-sharing nature of health insurance in the United States.[36] An individual's coverage for a prescription drug treatment does not guarantee full coverage of the cost, and cost-sharing requirements often mean the individual is required to pay for a portion as an out-of-pocket cost.[37] More importantly, patients who are covered by Medicare Part D are also responsible for the full out-of-pocket costs during a coverage gap known as the "doughnut hole."[38]

While there is a national debate over whether pharmaceutical manufacturers are to blame for the recent rise in drug costs,[39] the inherent structure of the healthcare market makes it difficult to conclude that a single entity is to blame.[40] The market for pharmaceutical drugs is "inelastic" in that there will always be high demand for prescription medication as long as people are afflicted with illness.[41] Thus, the high price of prescription drugs will usually not deter healthcare consumers, but rather will lead to many consumers suffering economic harm due to their participation in the market.[42] Congress has debated and proposed a multitude of legislative solutions for this problem to no avail.[43] As long as pharmaceutical companies remain for-profit industries, the economic

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36 Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 318 (2010). In the United States, patients covered by health insurance must still pay a portion of the costs for their healthcare out-of-pocket. This can be in the form of deductibles, copayments, or coinsurance. These payments are often referred to as cost-sharing mechanisms because the cost of the healthcare is shared by the patient and the insurance company. It is important to note that insurance premiums, which are monthly payments made to retain health insurance coverage, are not considered cost-sharing amounts or out-of-pocket costs. *Cost Sharing*, HEALTHINSURANCE.ORG, https://www.healthinsurance.org/glossary/cost-sharing [https://perma.cc/7WF5-FUZJ].

37 *Cost Sharing*, *supra* note 36.

38 Tironi, *supra* note 36, at 318. The structure of doughnut holes and how PAPs assist with meeting this coverage gap is discussed in more detail *infra* Section I.D.

39 *See, e.g.*, Danial E. Baker, *High Drug Prices: So Who Is to Blame?*, 52 HOSP. PHARMACY 5 (2017); Avik Roy, *Drug Companies, Not 'Middlemen,' Are Responsible for High Drug Prices*, FORBES (Oct. 22, 2018, 11:02 PM), https://www.forbes.com/sites/theapothecary/2018/10/22/drug-companies-are-responsible-for-high-drug-prices-not-middlemen/?sh=64cf3f434947 [https://perma.cc/JFE6-M9YD]; Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set*, TIME (Apr. 19, 2019, 10:00 AM), https://time.com/5564547/drug-prices-medicine [https://perma.cc/GCL8-57X3].

40 Nick Sawicki, *Pointing Fingers: Why No Singular Entity Is to Blame for Rising Drug Costs*, BROWN POL. REV. (Apr. 9, 2020), https://brownpoliticalreview.org/2020/04/pointing-fingers-why-no-singular-entity-is-to-blame-for-rising-drug-costs [https://perma.cc/TA8N-ZJBD].

41 DeFuria, *supra* note 32, at 2.

42 *Id.* ("Everything that economics textbooks tell us about the ordinary forces that drive product markets, like supply and demand[,] suddenly become irrelevant and all that matters is keeping someone alive or improving their quality of life, no matter what the cost." (footnote omitted)).

43 *Prescription Drugs and the Affordable Care Act, 10 Years Later*, BU QUESTROM SCH. OF BUS. (Feb. 27, 2020), https://www.bu.edu/questrom/2020/02/27/the-acas-effect-on-the-prescription-drug-market-and-what-might-come-next [https://perma.cc/KF2H-RTH8].

complexities will remain a barrier to efficient solutions to prescription drug pricing.[44] In the meantime, U.S. drug manufacturers have developed programs designed to help insured patients gain access to drugs they need but cannot afford.[45]

B. *Structure and Impact of Patient Assistance Programs*

The origin of PAPs can be traced to 1987 when Congress earmarked funding for certain charitable programs that provided prescription medication to low-income people with HIV/AIDS.[46] Since then, pharmaceutical manufacturers have created their own PAPs by creating nonprofit private foundations, which distribute the manufacturer's products to low-income patients.[47] The benefits received, along with the structure of the program, often vary depending on the program and the sponsoring manufacturer.[48] Often, the manufacturer sets up a nonprofit private foundation that is managed in-house to distribute the products.[49] Other proposed arrangements involve a third-party vendor that would administer the cost-sharing program.[50] These programs are normally limited to providing free drugs to Medicare patients outside of the Part D program.[51]

Another distinct type of PAP involves the set-up of an independent foundation to receive donations from a pharmaceutical manufacturer on the express condition that the donations are used to subsidize

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44 *See generally* Steven G. Morgan, Hannah S. Bathula & Suerie Moon, *Pricing of Pharmaceuticals Is Becoming a Major Challenge for Health Systems*, BMJ (Jan. 13, 2020), https://www.bmj.com/content/368/bmj.l4627 [https://perma.cc/62MF-QXA8].

45 Lauren Chase, *What Are Patient Assistance Programs?*, GOODRX HEALTH (Apr. 28, 2022), https://www.goodrx.com/healthcare-access/patient-advocacy/what-are-patient-assistance-programs [https://perma.cc/8Q7F-38PF].

46 Sheng Liu, Jonathan J. Darrow & Aaron S. Kesselheim, *Patient Assistance Programs for Prescription Drugs: Charities or Kickbacks?*, 15 J. HEALTH & LIFE SCIS. L. 68, 71 (2021).

47 Chronic Disease Fund Inc., *A Guide to Patient Assistance Programs: What You Need to Know to Promote Patient Advocacy and Maximize Charitable Contributions*, DOCPLAYER, https://docplayer.net/28450580-A-guide-to-patient-assistance-programs-what-you-need-to-know-to-promote-patient-advocacy-and-maximize-charitable-contributions.html [https://perma.cc/LSQ5-UZEF].

48 *See* Chase, *supra* note 45.

49 Chronic Disease Fund Inc., *supra* note 47.

50 OIG Advisory Opinion, *supra* note 22, at 5–6.

51 Liu, Darrow & Kesselheim, *supra* note 46, at 72. In this context, operating "outside of the Part D Program" means that any assistance provided to beneficiaries would not count towards TrOOP costs. Memorandum from Cynthia Tudor, Dir., Medicare Drug Benefit Grp., Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Hum. Servs., to All Part D Sponsors (Oct. 4, 2006), https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/MemoPAPsOutsidePartDBenefit_100406.pdf [https://perma.cc/A5WK-YP59].

prescription drug costs.[52] Commonly referred to as independent charity PAPs,[53] these programs are run independently by the foundation, which has full discretion as to patient eligibility and the amount of cost-sharing assistance provided.[54] Pharmaceutical manufacturers are permitted to make donations to these PAPs, but these donations must not be intended to exert any influence over the charity or subsidy program.[55]

While the enrollment process of any type of PAP will vary depending on the program,[56] a typical application would require a documented medical diagnosis showing a need for the drug.[57] The prescribing physician would have to certify that the medication is necessary, and the patient would have to certify their financial status.[58] After this, depending on the type of PAP involved, either the charity running the PAP or the third-party foundation working with the manufacturer would investigate the patient's insurance coverage to determine the amount it will pay in subsidies.[59]

Overall, PAPs have had a positive impact on healthcare in the United States, and there is demonstrated evidence that these programs have provided relief to underinsured patients.[60] In general, PAPs have helped patients access high-cost medications, and healthcare providers are not impacted by unpaid bills.[61] In fact, there is evidence that PAPs have encouraged patients to consistently stick to their treatment regimens. In 2019, a study undertaken by the Pan Foundation found that after receiving financial assistance from a PAP, patients were much more likely to finish their course of treatment.[62] A 2016 study revealed that a

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52 *See* OIG Special Advisory Bulletin, *supra* note 13, at 70624.

53 *Id.* at 70626.

54 *See* Liu, Darrow & Kesselheim, *supra* note 46, at 73.

55 *See* OIG Special Advisory Bulletin, *supra* note 13, at 70626.

56 Marie A. Chisholm & Joseph T. DiPiro, *Pharmaceutical Manufacturer Assistance Programs*, 162 ARCHIVES INTERNAL MED. 780, 781 (2002).

57 Nat'l Council on Patient Info. & Educ., *Understanding Prescription Assistance Programs (PAPs)* 2, BEMEDWISE (2019), https://www.bemedwise.org/wp-content/uploads/2019/12/paps.pdf [https://perma.cc/YRP6-FTPW].

58 *Id.*

59 *See* Chisholm & DiPiro, *supra* note 56, at 781.

60 Niteesh K. Choudhry, Joy L. Lee, Jessica Agnew-Blais, Colleen Corcoran & William H. Shrank, *Drug Company-Sponsored Patient Assistance Programs: A Viable Safety Net?*, 28 HEALTH AFFS. 827, 827 (2009) ("Pharmaceutical Research and Manufacturers of America (PhRMA) estimates that its Partnership for Prescription Assistance (PPA) program, which it launched in 2005 to bring together a variety of private and public programs, has helped 5.5 million Americans.").

61 Curtis E. Haas, *Patient Assistance Programs Are the Good, the Bad, and the Ugly*, PHARMACY TIMES (Sept. 27, 2020), https://www.pharmacytimes.com/view/patient-assistance-programs-are-the-good-the-bad-and-the-ugly [https://perma.cc/QTT7-Q6L2].

62 *The Impact of Patient Assistance on Access, Medication Adherence and Quality of Life*, *supra* note 15.

pharmacy-based PAP for cancer patients not only helped with the expenses of chemotherapy, but resulted in an increase in compliance with chemotherapy protocols.[63] Thus, from a purely public health perspective, the benefits of PAPs in providing assistance to underinsured patients are clear.[64] However, from a legal perspective, the form of these arrangements takes priority over their function. Because the arrangements involve subsidizing patients who are enrolled in a federal healthcare program, the AKS presents an obstacle to their existence.

C. *Anti-Kickback Statute*

1. Legislative History

The AKS imposes criminal and civil liability[65] on anyone who willfully solicits or receives remuneration in return for a service or item that is reimbursable by a federal healthcare program.[66] The AKS was originally implemented in an amendment to the Social Security Act of 1965.[67] Initially, the purpose of the statute was to provide an enforcement mechanism to prevent practices that were regarded as unethical, including the acceptance of bribes.[68] Congress had two primary concerns when passing this statute, and both are tied to the threat of overutilization of healthcare services. The first was that these corrupt practices would

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63 Gao, Joseph, Santoro-Levy, Multz & Gotlieb, *supra* note 15, at 572.

64 *See, e.g.*, David H. Howard, *Drug Companies' Patient Assistance Programs—Helping Patients or Profits?*, 371 NEW ENG. J. MED. 97, 97 (2014) (discussing Biogen's generous program covering a significant amount of costs for its treatment therapy for multiple sclerosis).

65 A violation of the AKS is punishable by up to ten years of imprisonment and a fine of up to $100,000. 42 U.S.C. § 1320a-7b(b)(1). The elements required to bring civil penalties and criminal penalties remain the same. *See id.* §§ 1320a-7a, 1320a-7b.

66 *Id.* § 1320a-7b(b)(1). Specifically, the statute provides that:

> Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . .
>
> . . . in return for referring 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 . . .
>
> . . . .
>
> shall be guilty of a felony . . . .

Id.

67 *See* Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419–20 (1972) (codified at 42 U.S.C. § 1395nn). The original statute states that any person "who solicits, offers, or receives any . . . kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment . . . shall be guilty of a misdemeanor . . . ." *Id.* at 1420.

68 H.R. REP. NO. 92-231, at 5007 (1971).

dramatically increase the cost of Medicare to consumers and the government.[69] Because healthcare is a commercial enterprise in the United States, there is a financial incentive to induce referrals if it results in an increase in the flow of business.[70] Thus, with arrangements geared towards inducing referrals, physicians may be prescribing or providing services that are not medically necessary, leading to an unnecessary increase in the cost of those services.[71] The second primary concern is related to the first in that Congress wanted to prevent this financial inducement from corrupting a physician's decision-making.[72]

In 1977, Congress amended the statute to include "any remuneration"[73] to address healthcare fraud and activities such as "steering" patients to a particular pharmacy or "ping-ponging" patients from one practitioner to another for no medical reason.[74] The elements of a violation of the AKS remain unchanged since this amendment, but Congress has consistently revised the statute to address its breadth by authorizing the issuance of advisory opinions and providing for "safe harbor" provisions by the Secretary of Health and Human Services (HHS).[75]

2. Enforcement Apparatus of the Anti-Kickback Statute

With increased federal funding for healthcare fraud enforcement and steep statutory penalties associated with the AKS, the Act on its own poses a dramatic threat to conduct that may defraud the healthcare

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69 *See* Tamsen Douglass Love, *Toward a Fair and Practical Definition of "Willfully" in the Medicare/Medicaid Anti-Kickback Statute*, 50 VAND. L. REV. 1029, 1035 (2019).

70 Richard P. Kusserow, *The Medicare and Medicaid Anti-Kickback Statute and Safe Harbor Regulations—What's Next?*, 2 HEALTH MATRIX 49, 52 (1992).

71 *Id.*

72 *Id.*; *see also* H.R. REP. NO. 95-393 (II), at 47–48 (1977).

73 Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175, 1175–76.

74 H.R. REP. NO. 95-393 (II), at 39, 45. This policy concern is really a supplement to the larger concern of increasing overall healthcare costs. *See id.* at 48 (stating that one of the primary goals of the amendments is to prevent activity where healthcare actors "operate in a manner inconsistent with accepted, sound medical or business practices resulting in excessive and unreasonable financial cost to either medicare or medicaid" and that "[i]ncluded in the area of abuse are the provision of unnecessary health services and the provision of necessary care in unnecessarily costly settings").

75 Omnibus Reconciliation Act of 1980, H.R. REP. NO. 96-1167, at 59 (1980) ("The Committee is concerned that criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent."); 42 U.S.C. § 1320a-7b(b)(3)(E) (authorizing Secretary of HHS to issue "safe harbor" exceptions).

system.[76] In order to assess the full weight of penalties associated with the AKS, one must explore how the statute works in tandem with enforcement of the False Claims Act (FCA).[77] The FCA imposes civil liability on those who submit false or fraudulent claims to the United States.[78] Naturally, the FCA authorizes the United States to bring a civil cause of action against those found in violation.[79] However, it also allows private citizens to bring *qui tam* actions against those alleged to be in violation.[80] In this scenario, a private party will bring a complaint setting forth the claims, and the DOJ will intervene and fully prosecute the claim.[81]

The penalties for violations of the FCA are often severe. If the government successfully prosecutes an FCA action, it is awarded a penalty of $5,000 to $10,000 for each false claim submitted, in addition to treble damages and attorneys' fees and costs.[82] Often, the government brings actions under both the AKS and FCA on the theory that a claim for payment made as a result of an unlawful kickback also constitutes a false claim.[83] The argument is that submission of a Medicare claim requires express certification that the requestor has complied with the AKS.[84] Thus, many AKS charges are the result of a private party bringing a *qui tam* action against a defendant.[85] So long as the government can continue to rely on *qui tam* actions that bring FCA claims based on violations of the AKS, it can broadly enforce the AKS and recover substantial treble damages. The government can also exclude healthcare providers who violate the AKS from federal healthcare programs, which

76 *See* § 1320a-7b(b)(2)(B) (setting a maximum $100,000 fine and/or maximum prison term of ten years for violation of the statute).

77 *See* 31 U.S.C. §§ 3729–3733.

78 *Id.* § 3729.

79 *Id.* § 3730(a).

80 *Id.* § 3730(c).

81 Robert Salcido, *Mixing Oil and Water: The Government's Mistaken Use of the Medicare Anti-Kickback Statute in False Claims Act Prosecutions*, 6 ANNALS HEALTH L. 105, 106 (1997).

82 31 U.S.C. § 3729(a).

83 Neither statute authorizes these combined enforcement actions. However, there is a split among the district courts on whether dual enforcement of the AKS and FCA in this manner is permitted. *See* Salcido, *supra* note 81, at 107.

84 United States *ex rel.* Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 95 (3d Cir. 2009) ("Falsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a federally funded insurance program is actionable under the FCA.").

85 *See generally* Klaczak v. Consol. Med. Transp., 458 F. Supp. 2d 622 (N.D. Ill. 2006); United States *ex rel.* Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39 (D. Mass. 2011); United States *ex rel.* Bartlett v. Ashcroft, 39 F. Supp. 3d 656 (W.D. Penn. 2014).

risks putting the healthcare provider in financial ruin.[86] Thus, there is a lot at stake for healthcare providers, which makes careful navigation of the healthcare market and federal healthcare programs more important than ever.[87]

3. Common Arrangements Prosecuted Under the AKS

While the key analysis of whether conduct violates the AKS hinges on whether something of value was offered to induce healthcare referrals, the most sinister arrangements prosecuted under the AKS typically involve either the bribery of physicians and hospitals or laboratory fraud.[88]

The prosecution of physicians and medical service companies under the AKS typically involves a physician entering an agreement with a manufacturer in which the manufacturer will pay the physician a fee every time she prescribes the manufacturer's product to a patient.[89] The most recent notable case involved the prosecution of thirty telemedicine executives who conspired to pay doctors and nurses to order their medical equipment and testing kits when it was often unnecessary.[90] In 1989, the First Circuit sustained the convictions of several hospital executives for accepting payments from an ambulance company in return for use of its ambulance service.[91] In 2013, eleven individuals, including

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86 42 U.S.C. § 1320a-7; *see also* Pamela H. Bucy, *The Path from Regulator to Hunter: The Exercise of Prosecutorial Discretion in the Investigation of Physicians at Teaching Hospitals*, 44 ST. LOUIS U. L.J. 3, 38–39 (2000).

87 There is also a persuasive argument that there is an inherent conflict in applying the AKS and FCA in tandem because the FCA only requires "reckless disregard" or "deliberate ignorance," while the AKS, as discussed, requires that the actor "'knowingly and willfully' engaged in the prohibited conduct." *See* Salcido, *supra* note 81, at 130–32 (first quoting 31 U.S.C. § 3729(b)(1)(A)(iii); and then quoting 42 U.S.C. § 1320a-7b(b)(1)(A)).

88 Marc S. Raspanti & Douglas E. Roberts, *A Practitioner's Primer on the History and Use of the Federal Anti-Kickback Statute*, AHLA CONNECTIONS 16, 18–20 (2017), https://www.pietragallo.com/wp-content/uploads/2017/03/msr_der_-_a_practitioners_primer_on_history_and_use_of_federal_anti-kickback_statute.pdf [https://perma.cc/AC8A-C3KW].

89 This hypothetical is inspired by the facts of *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995).

90 Press Release, U.S. Att'y's Off., S. Dist. of Ga., Operation Rubber Stamp: Major Health Care Fraud Investigation Results in Significant New Charges (Oct. 7, 2020), https://www.justice.gov/usao-sdga/pr/operation-rubber-stamp-major-health-care-fraud-investigation-results-significant-new [https://perma.cc/35CN-YMZA].

91 United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20 (1st Cir. 1989).

five physicians, were prosecuted under the statute.[92] In that case, the government alleged that the CEO of Sacred Heart Hospital paid physicians to refer their patients for hospital services that would be reimbursed by Medicare and Medicaid.[93]

In a similar vein, laboratory fraud cases often involve labs providing something of value to physicians who refer patients to their often medically unnecessary testing services.[94] *Hanlester Network v. Shalala* is a notable example of this type of conduct.[95] In 2013, the United States indicted several individuals and lab entities for paying physicians certain "processing and handling" fees in exchange for referrals for blood testing.[96] Defendants submitted claims for kickbacks and unnecessary medical services and collected millions from Medicare reimbursement.[97]

Both types of conduct share a common theme: healthcare providers being financially induced to prescribe potentially unnecessary services and subsequently reimbursed by the federal government for those services. In these examples, there is heightened concern of how these payments could potentially influence and corrupt how a practitioner decides to treat a patient's medical condition. In the context of PAPs, these concerns are certainly still present, but the federal government's scrutiny of PAPs only increased with the advent of Medicare Part D.[98]

D. *Medicare Part D's Coverage Gap*

Before discussing the legal ramifications of PAPs and their interaction with the AKS, a brief explanation of the structure of Medicare Part D is necessary. The Medicare Part D Program provides coverage to certain individuals for outpatient prescription drugs.[99] When Medicare was first implemented in 1965, there were few concerns over the cost of prescription drugs compared to the cost of hospital services.[100] Soon after,

92 Press Release, U.S. Att'y's Off., N. Dist. of Ill., Owner and Executives Convicted in Medicare Referral Kickback Conspiracy at Closed Sacred Heart Hospital (Mar. 19, 2015), https://www.justice.gov/usao-ndil/pr/owner-and-executives-convicted-medicare-referral-kickback-conspiracy-closed-sacred [https://perma.cc/SQ8V-AZ6V].

93 *Id.*

94 *See generally* Douglas E. Roberts, Marc S. Raspanti & Pamela C. Brecht, *A New Era of Laboratory Fraud, Part 1: Operation LabScam Redux*, COMPLIANCE TODAY, Sept. 2016, at 22, 22–25.

95 *See infra* Section II.A.2.

96 United States v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 487, 496 (D.S.C. 2016).

97 *Id.*

98 *See* OIG Special Advisory Bulletin, *supra* note 13.

99 *See generally* 42 U.S.C. § 1395w-102.

100 Thomas R. Oliver, Philip R. Lee & Helene L. Lipton, *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK Q. 283, 291–92 (2004).

lawmakers became concerned about the rise in costs of prescription drugs and it became evident that, under its current structure, Medicare was not designed to address the issue of costly outpatient prescription drugs.[101] Congress began to report findings that few Medicare beneficiaries had coverage for their prescription drugs outside of the hospital.[102] In 2003, after decades of congressional gridlock, President Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act, which established the new Medicare Part D Program.[103]

Under Part D, any individual eligible for Medicare can obtain Part D coverage for outpatient prescription drugs.[104] Most Medicare Part D plans have a coverage gap, commonly referred to as the "donut hole."[105] A patient must pay 100% of the cost of covered prescription drugs until a certain amount is spent, after which the patient will enter the donut hole.[106] Once a patient enters the donut hole, they will pay no more than 25% of the cost for their plan's covered prescription drugs.[107] More importantly, while in the donut hole, the full price of the drug and what the patient and manufacturer pay will count toward True Out of Pocket Costs (TrOOP).[108] A patient must then incur a certain amount of TrOOP before activating catastrophic coverage.[109] Once catastrophic coverage is triggered, Medicare will cover a majority of additional costs of covered prescription drug costs.[110]

While Medicare Part D has helped uninsured and underinsured patients gain access to prescription drug medications, the coverage gap has proven to be an obstacle in obtaining truly affordable costs by those covered by Medicare Part D.[111] In addition, because Medicare Part D necessarily involves federal funds, any attempt by a pharmaceutical

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101 *Id.*

102 *Id.* at 293.

103 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

104 42 U.S.C. § 1395w-101(a)(3)(A).

105 *What Is the Medicare Part D "Donut Hole"?*, UNITED HEALTHCARE, https://www.uhc.com/news-articles/medicare-articles/what-is-the-medicare-part-d-coverage-gap [https://perma.cc/65T3-WMQW].

106 *Id.*

107 *Id.*

108 Rabecs, *supra* note 7, at 735.

109 *Id.* at 742.

110 *An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 19, 2022), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit [https://perma.cc/DFH3-KPDV].

111 Zhang, Lave, Newhouse & Donohue, *supra* note 32, at 506 ("Only 4% of beneficiaries overall . . . had out-of-pocket drug spending high enough . . . to put them in the catastrophic coverage region where they paid only 5% of drug costs.").

manufacturer or healthcare provider to assist Medicare Part D recipients could be prosecuted under the AKS.[112]

E. *The Legal Ramifications of PAPs and Medicare Part D*

In a special bulletin published after the implementation of Medicare Part D, the Office of the Inspector General for HHS (OIG) articulated its view that manufacturer-sponsored subsidies to Medicare Part D beneficiaries would be prohibited by the AKS.[113] Particularly, Medicare Part D poses potential for abuse and fraud because pharmaceutical manufacturers have an incentive to assist Part D beneficiaries with their TrOOP.[114] Once the beneficiaries enter their catastrophic coverage, manufacturers can seek reimbursement for medications directly from the insurance plans.[115] As a result, there are questions as to whether direct PAPs, in which a manufacturer directly assists beneficiaries with the costs of the manufacturer's own product, constitute unlawful kickbacks, in which the manufacturer would be giving something of value to beneficiaries in exchange for their use of its product.[116]

OIG made several clarifications in its bulletin in order to address manufacturers' interests in continuing to help Medicare Part D enrollees with their prescription drug costs.[117] While acknowledging that PAPs have provided an "important safety net" for underinsured or uninsured patients, OIG's bulletin explains that PAP subsidies tied to a pharmaceutical manufacturer's products would likely be prohibited by the statute because the manufacturer would be giving something of value to beneficiaries to induce them to use its product.[118] OIG's primary policy concerns with manufacturer-sponsored PAPs include (1) the potential to steer beneficiaries to the manufacturer's drugs when there are cheaper alternatives available; (2) insulating beneficiaries from the economic effects of drug pricing, thus leading to price inflation, which could increase Medicare costs; and (3) reducing incentives for beneficiaries to find alternative prescription drugs that are less expensive.[119] The publication does concede the benefits that PAPs can provide to those who

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112 *See* OIG Special Advisory Bulletin, *supra* note 13, at 70624.

113 *Id.*

114 Rabecs, *supra* note 7, at 742.

115 *Id.*

116 *See* OIG Special Advisory Bulletin, *supra* note 13, at 70624.

117 *Id.*

118 *Id.* at 70623–25.

119 *Id.* at 70625–26.

are underinsured.[120] Acknowledging this, the bulletin provides certain guidelines companies must follow to avoid federal scrutiny into their arrangements.[121]

Since the publication of OIG's special bulletin, the DOJ began to increase its enforcement actions against PAP arrangements.[122] In most of these cases, depending on the structure of the program, the primary target for prosecution is the pharmaceutical company that sponsors the program.[123] Under this theory, the manufacturer is offering remuneration to induce or refer a person to use its product.[124] PAP foundations can also be found in violation of the statute if the foundations colluded with a manufacturer to promote its product.[125] In order to critique the government's application of the law to PAPs, a discussion is needed on how the judicially created one-purpose test has broadened the AKS dramatically since its passage.

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120 *Id.* at 70623–24 ("Patient assistance programs (PAPs) have long provided important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs.").

121 *Id.* at 70626–27. According to OIG, Independent PAPs may pass muster under the AKS if certain conditions are met. For example, no manufacturer can exert any control or influence over the charity or subsidy program, and the "charity awards assistance [must be] in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary." *Id.* at 70626.

122 Liu, Darrow & Kesselheim, *supra* note 46, at 75 tbl.2.

123 *See, e.g.*, Press Release, U.S. Dep't of Just., Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks (Dec. 20, 2017) [hereinafter United Therapeutics Press Release], https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability [https://perma.cc/8D5D-JZ8M] (announcing a $210 million settlement with a pharmaceutical company for unlawful copay assistance for expensive medications); Press Release, U.S. Dep't of Just., Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations (Sept. 22, 2017), https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and [https://perma.cc/B4R8-3NJ4] (announcing Aegerion's agreement to settle criminal and civil violations after being charged with funneling funds to a third-party foundation in order to subsidize patients' copayment obligations).

124 *See, e.g.*, United Therapeutics Press Release, *supra* note 123.

125 *See* Press Release, U.S. Dep't of Just., Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients (Oct. 25, 2019), https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare [https://perma.cc/K2AL-UH28] (stating that third-party organizations were accused of collaborating with pharmaceutical companies in funneling money to patients specifically taking the companies' drugs).

II. ANALYSIS

A. *Anti-Kickback Statute in the Courts and the One-Purpose Test*

Overall, federal courts have interpreted the AKS broadly.[126] Notwithstanding this trend, there are several instances of courts attempting to limit the breadth of the statute.[127] In doing so, courts have clearly demonstrated an understanding that the statute may be overinclusive, potentially criminalizing conduct that is desirable.[128] Before Congress amended the statute to include "any remuneration," the most common difficulty courts faced was determining what type of conduct constituted a kickback.[129] Courts were split on how to distinguish conduct that constituted a kickback and conduct that simply constituted a payment for services rendered.[130]

While this split was eventually resolved by Congress, it serves as an early illustration of federal courts' hesitancy to apply the AKS to conduct that may not be highly culpable. For example, in *United States v. Porter*, the Fifth Circuit analogized kickbacks to bribes and held that absent factors that make a payment illegitimate and corrupt, a payment for services rendered that otherwise meets statutory requirements is lawful under the AKS.[131] Clearly, the Fifth Circuit was hesitant to read the statute so as to criminalize arrangements that were not necessarily sinister or otherwise plainly problematic.[132] Absent further guidance from Congress, most courts preferred to uphold prosecutions under the AKS only when inherently corrupt payments were made.[133] This particular construction

126 *See, e.g.*, United States v. Greber, 760 F.2d 68, 72 (3d Cir. 1985); Pfizer Inc. v. U.S. Dep't of Health & Hum. Servs., No. 20-cv-4920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021).

127 *See generally* Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995); United States *ex rel.* Ruscher v. Omnicare, Inc., 663 F. App'x 368 (5th Cir. 2016).

128 *See infra* Section II.A.3.

129 Love, *supra* note 69, at 1035–37.

130 *Compare* United States v. Porter, 591 F.2d 1048, 1053–54 (5th Cir. 1979) (holding that because legitimate services were performed, the payments did not constitute corrupt kickbacks), *with* United States v. Tapert, 625 F.2d 111, 121 (6th Cir. 1980) (finding that payments made to physicians in return for sending samples to a lab constituted kickbacks).

131 *Porter*, 591 F.2d at 1053–54.

132 *Id.* at 1054 ("If the meaning of the 1972 version of 42 U.S.C. § 1395nn(b) was not clear and precise to the Congress and to United States Attorneys charged with enforcing the law, then we are hard put to say, with that degree of confidence required in a criminal conviction, that these defendants were given clear warning by that statute that their conduct was prohibited by it, thus amounting to a criminal act.").

133 *See, e.g.*, United States v. Zacher, 586 F.2d 912 (2d Cir. 1978). *But see Tapert*, 625 F.2d at 121.

was foreclosed when Congress amended the statute to include "any remuneration" to induce referrals.[134]

1. *United States v. Greber*

Despite Congress's best efforts, the federal judiciary's woes in determining the breadth of the AKS continued. When Congress amended the statute in 1980, it inserted a provision requiring that the criminal defendant "knowingly and willfully" violated the statute.[135] Federal courts proceeded to struggle to define this level of mens rea.[136] The challenge mainly focused on judicial construction of the term "knowingly and willfully" in the statute, and whether Congress intended to narrow the mens rea to include only specific intent to violate the statute.[137]

One of the first cases that dealt with this issue was *United States v. Greber*.[138] In this case, Dr. Greber was convicted of violating the AKS when he billed Medicare for his diagnostic services and sent a portion of the reimbursement to the physician that referred the patient to his services.[139] Dr. Greber argued that the government had to prove that the only purpose behind the fees paid to the prescribing physician was to induce future referrals.[140] In his view, he was not only paying the physicians for referrals but also for legitimate services rendered.[141]

The Third Circuit rejected this argument and held that even if the physician had performed a service for which he was compensated, the inducement factor was still met.[142] The court further held that the government need only prove that "*one* purpose of the payment" was to induce the individual to use a service for which payment is made under a federal healthcare program.[143] In other words, if inducement is one of several purposes in making a payment, that is sufficient to find liability

134 Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, §§ 4(b)(1)–(2), 91 Stat. 1175, 1180 (1977).

135 Omnibus Reconciliation Act of 1980, Pub L. No. 96-499, § 917, 94 Stat. 2599 (1980).

136 An in-depth analysis of the various levels of intent potentially required to violate the AKS as it applies to all healthcare conduct is outside the scope of this Note. Nevertheless, a brief overview of some of the major cases wrestling with this issue is required to provide a basis for analyzing the issue as it relates to PAPs. For an in-depth discussion of requisite intent required to violate the AKS, along with a similar argument for narrowing the breadth of the statute in a more general context, see Love, *supra* note 69, at 1042–58.

137 *Id.* at 1050.

138 United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

139 *Id.* at 69–70.

140 *Id.* at 71.

141 *Id.*

142 *Id.* ("The statute is aimed at the inducement factor.").

143 *Id.* at 69.

under the AKS.[144] This is now known as the "one-purpose test." The test is effectively the current law today regarding the burden of proof in an AKS violation, and the majority of circuit courts have adopted a version of this test.[145] The one-purpose test, in combination with the broad sweep of the text of the statute, implies that the AKS could apply to many kinds of conduct, unbeknownst to the actors involved, in an increasingly complex healthcare marketplace. However, in adopting the one-purpose test, several courts have attempted to limit the AKS to address the breadth of the holding in *Greber*.[146] While the holdings still retain some version of the one-purpose test, courts are sensitive to the problems posed by its wide reach.[147]

2. *Hanlester Network v. Shalala*

While the central holding of *Hanlester Network v. Shalala* largely implicates the level of intent associated with the AKS,[148] the Ninth Circuit's seemingly contradictory holding reveals a larger issue with the one-purpose test. The case involved several arrangements structured by Hanlester Network, a general partnership.[149] Hanlester offered limited partnership interests to physicians who were willing to refer patients to Hanlester's lab tests.[150] In addition, Hanlester Network entered into an agreement with Smithkline BioScience Laboratories (SKBL).[151] Under this agreement, SKBL would manage and operate Hanlester's labs and Hanlester would send lab tests that physicians had ordered to SKBL labs.[152] After OIG alleged that this conduct violated the AKS, the Ninth Circuit found that the majority of defendants lacked the requisite intent to prove a violation.[153] The court construed "knowingly and willfully" as requiring a showing that (1) defendants knew that the statute prohibited offering something of value to induce referrals, and (2) defendants

144 *Id.*

145 *See, e.g.*, United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989); United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998); United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000); United States v. Borrasi, 639 F.3d 774, 782 (7th Cir. 2011).

146 *See infra* Section II.A.2.

147 *See infra* Sections II.A.2–II.A.3.

148 Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995).

149 *Id.* at 1394–95.

150 *Id.* at 1394.

151 *Id.*

152 *Id.* at 1395.

153 *Id.* at 1400–01.

specifically intended to violate the statute.[154] The court further held that proof of quid pro quo is not required to find a violation of the AKS.[155]

Thus, the court's construction of the statute is both broad and narrow. On one hand, the court held that proof of quid pro quo is not required and implicitly applied *Greber*'s one-purpose test.[156] On the other hand, the court heightened the mens rea required by the statute to criminalize conduct that was done in knowing violation of the statute.[157] The contradictory nature of this two-fold holding illustrates the problem posed by the AKS. The statute criminalizes any intent to *induce* a referral, which, as defined by the *Hanlester* court, means to "bring on or about, to affect, cause, to influence to an act or course of conduct, [or] lead by persuasion or reasoning."[158] Under the one-purpose test, any good-faith attempt to remove an economic barrier that would otherwise prevent someone from purchasing a prescription drug could be seen as influencing someone to engage in a certain course of conduct. With the prohibitively high costs of prescription medication, this test is unworkable absent a legislative solution.[159] While *Hanlester*'s holding on specific intent has not been adopted by other circuits, the one-purpose test is still the prevailing law.[160] Nonetheless, other circuits have recognized limiting principles to the one-purpose test, which is useful in viewing the legality of PAPs.[161]

3. *United States ex rel. Ruscher v. Omnicare*

The Fifth Circuit has recently recognized an inherent difficulty in applying the one-purpose test to certain conduct.[162] In 2016, in an unpublished opinion, the court granted summary judgment in favor of Omnicare after a *qui tam* suit was brought alleging violations of the False

154 *Id.* at 1400.

155 *Id.* at 1396–97.

156 The *Hanlester* court did not expressly discuss the one-purpose test, but the Ninth Circuit adopted the test several years earlier. *See* United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989).

157 *Hanlester Network*, 51 F.3d at 1400.

158 *Id.* at 1398 (quoting *Induce*, BLACK'S LAW DICTIONARY (6th ed. 1990)).

159 Which, based on Congress's current gridlock, is increasingly unlikely.

160 In addition, the *Hanlester* court's specific intent holding was expressly overruled by Congress. The Patient Protection and Affordable Care Act of 2010 amended the AKS to add a provision that states that "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]." Patient Protection and Affordable Care Act, Pub L. No. 111-148, § 6402(f)(2), 124 Stat. 119, 759 (2010) (codified as amended at 42 U.S.C. § 1320a-7b).

161 *See infra* Section II.A.3.

162 *See generally* United States *ex rel.* Ruscher v. Omnicare, Inc., 663 F. App'x 368 (5th Cir. 2016).

Claims Act and the AKS.[163] The realtor-plaintiff alleged that Omnicare had offered benefits to nursing home facilities in exchange for referrals to Medicare and Medicaid by essentially offering favorable payment options to several of its nursing home clients whose debts were past due.[164]

The Fifth Circuit held that the plaintiff failed to establish evidence that these billing practices were designed for the purpose of inducing the facilities to make Medicare and Medicaid referrals to Omnicare.[165] The court further reasoned that Omnicare may have hoped for Medicare referrals, but without evidence showing that the practice's *purpose* was to induce these referrals, there was no AKS violation.[166] The Fifth Circuit's holding is a more practical reading of the AKS. Particularly, it shows that the court recognizes the breadth of the one-purpose test and attempts to limit it by heightening the purpose element of the statute, making it more akin to corrupt intent.[167] By distinguishing purpose from hope for results, the court implicitly acknowledged that application of the AKS should be limited to inherently corrupt conduct that necessarily has a negative impact on the functionality of the healthcare system.

The court's holding illustrates the importance of inquiring into the state of mind of all parties involved in these arrangements. As the court acknowledged, an entity may knowingly benefit from an arrangement that involves referrals to Medicare and Medicaid, but that knowledge should not immediately convert into corrupt intent.[168] Rather, the proper inquiry should focus on the *primary purpose* of such an arrangement.[169] Adopting this framework could potentially help to better identify inherently corrupt arrangements with the proper mens rea. However, while illustrating the practical difficulties in applying the one-purpose test, the Fifth Circuit's distinction between hope for referrals and purpose to induce referrals[170] may be difficult to determine in many instances. The court in *Omnicare* did not provide any guidelines in helping to distinguish a hope for a referral from a purpose to induce a referral.

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163 *Id.* at 370.

164 *Id.* at 373.

165 *Id.* at 374.

166 *Id.* at 374–75.

167 *Id.* at 374 ("None of the evidence, however, shows that Omnicare designed its settlement negotiations and debt collection practices to induce SNF clients to continue making Medicare and Medicaid referrals to Omnicare.").

168 *Id.*

169 *Id.* ("There is no AKS violation, however, where the defendant merely hopes or expects referrals from benefits that were designed wholly for other purposes.").

170 *Id.* at 374–75.

Nevertheless, it is a reassuring signal that there ought to be limiting principles to the one-purpose test.[171]

B. *How the One-Purpose Test Unfairly Impacts PAPs*

Despite the signaling of certain limiting principles of the one-purpose test, the federal government has maintained that it will apply the test broadly to pharmaceutical-company–sponsored PAPs.[172] In addition, while the case law is limited, federal courts have not yet indicated any willingness to limit the one-purpose test as applied to PAPs.[173] To be clear, the AKS is essential when scrutinizing many kinds of kickback schemes that clearly pose a threat to efficient healthcare, and it is important to be vigilant in prosecuting conduct that is meant to induce a referral. Notwithstanding this consideration, as applied to PAPs, the one-purpose test's use of inducement is simply too sweeping. As a result, programs that are designed to help patients with chronic illnesses are not being implemented because of the broad definition of inducement as applied to the AKS.

1. OIG's Application of the One-Purpose Test to PAPs

Recognizing the far reach of the AKS, Congress authorized the issuance of advisory opinions on whether certain arrangements would violate the statute.[174] These advisory opinions provide helpful insight into how the one-purpose test is applied to PAPs and how the results are often arbitrary at best. As these opinions show, the potential government scrutiny into these arrangements can come at a direct cost to Medicare patients with rare, chronic diseases.[175]

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171 Scholars have also recognized how the breadth of the one-purpose test can impact other healthcare arrangements that may be beneficial to managing costs. *See* Timothy J. Aspinwall, *The Anti-Kickback Statute Standard(s) of Intent: The Case for a Rule of Reason Analysis*, 9 ANNALS HEALTH L. 155, 177 (2000) (discussing how the one-purpose test prohibits certain gainsharing arrangements in which a physician is incentivized to effectively limit treatment costs by allowing the physician to share cost savings with the hospital).

172 *See* Tino Illiparambil, *Pharmaceutical Philanthropy or Resisting Regulations?: Why Pharmaceutical Donations Do Not Violate the Anti-Kickback Statute*, 85 BROOK. L. REV. 571, 594 (2020).

173 *See, e.g.*, United States v. Teva Pharmaceuticals, 560 F. Supp. 3d 412 (D. Mass. 2021); Pfizer Inc. v. U.S. Dep't of Health & Hum. Servs., No. 20-cv-4920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021).

174 42 U.S.C. § 1320a-7c(a)(1)(D).

175 *See generally* OIG Advisory Opinion, *supra* note 22.

On September 23, 2020, OIG published an advisory opinion finding that a proposed subsidy program sponsored by a pharmaceutical manufacturer likely violated the AKS.[176] Under the program, a Medicare beneficiary would be eligible for a subsidy card that could be used to subsidize the costs of a prescription drug designed to treat a progressive, rare disease that could lead to heart failure.[177] The government found that under this arrangement, the subsidy program would operate as a quid pro quo in which the beneficiary received something of value in return for purchasing the medication.[178] OIG reasoned that by removing an economic barrier to purchasing the medication, the pharmaceutical company had induced the beneficiary to purchase their product, thus violating the statute.[179] Notably, OIG found it irrelevant that the medication covered by the program was the only approved treatment for the disease.[180]

Due to the broad reach of the one-purpose test, the opinion is likely consistent with current interpretations of what kind of conduct qualifies under the statute. The key intervening fact is that the patient in this context is still required to obtain a prescription from a physician before purchasing this medication.[181] This fact is especially vexing because the crux of the advisory opinion is based on the beneficiary being induced by the manufacturer.[182] Thus, the conduct in this instance lacks the more serious concerns that could arise from physician bribery or laboratory fraud.[183] OIG acknowledged this argument but still reasoned that because the physician must work with the beneficiary to enroll them in the subsidy program, the physician's awareness of the program would influence their decision in prescribing the medication since it may impact their income.[184] In other words, because the physician would want to help reduce the substantial costs of prescription medication, the physician's clinical decision-making would be impacted.[185] Unlike physicians who are unduly influenced by corrupt payments or gratuities, physicians who

176 *Id.* at 2.

177 *Id.* at 5–6.

178 *Id.* at 14 ("[T]he . . . [p]rogram would operate as a quid pro quo—Requestor would offer remuneration (the Subsidy Card) to the beneficiary in return for the beneficiary purchasing one of the Medications.").

179 *Id.* at 15, 24 ("[T]he Subsidy Card would be offered to beneficiaries to induce them to purchase a covered item by removing what would otherwise be an impediment that would deter such purchase.").

180 *Id.* at 21.

181 *Id.* at 22.

182 *Id.* at 20.

183 *See supra* Section I.C.3.

184 OIG Advisory Opinion, *supra* note 22, at 20.

185 *Id.* at 22.

make the neutral clinical decision to prescribe a medication that a patient would be able to afford should not, as a matter of law, meet the requisite standard of being corruptly induced to prescribe such medication. The conduct simply lacks the corrupt element that the AKS was intended to prevent.[186] While this advisory opinion is not binding, OIG makes it clear that good faith efforts to assist Medicare Part D patients with out-of-pocket costs will be scrutinized and likely prosecuted despite the conduct not being nearly as culpable as the examples provided.[187]

2. Recent Federal Court Decisions Regarding PAPs

While there is not yet a substantial body of appellate case law applying the AKS to PAPs, federal courts appear ready to adopt OIG's reasoning and will likely continue applying the one-purpose test to PAPs.[188] Two recent district court decisions illustrate the futility of these programs' ability to assist Medicare recipients as demonstrated by their holdings that the programs are unlawful under the AKS. In *United States v. Teva Pharmaceuticals* and *Pfizer v. United States*, both courts found that proposed arrangements violated the AKS, and both courts rejected arguments that the conduct alleged was not sufficiently corrupt to constitute a violation of the AKS.[189]

The District Court of Massachusetts denied Teva's motion to dismiss with respect to the government's claim that Teva's PAP violated the AKS.[190] The government's complaint alleged that Teva had collaborated with two charity funds to ensure that its donations to the charities were used for copay assistance of Teva's product, Copaxone, a prescription drug used to treat multiple sclerosis.[191] Teva argued that the government failed to allege any agreement between the parties that made any donations by Teva contingent on the charity funds promoting Copaxone.[192] In addition, Teva argued that the government had only alleged that Teva had hoped or expected its donations be used for

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186 *See* H.R. REP. NO. 95-393(II), at 3048 (1977) (identifying the most common arrangements targeted by the AKS to be steering patients to a specific pharmacy, billing for services not rendered, referring patients to a facility when there is no reason to do so, and billing for a service more extensive than actually provided).

187 *See supra* Section I.C.3.

188 *See* United States v. Teva Pharmaceuticals USA Inc., 560 F. Supp. 3d 412, 419 (D. Mass. 2021); Pfizer Inc. v. U.S. Dep't of Health & Hum. Servs., No. 20-cv-4920, 2021 WL 4523676, at *14 (S.D.N.Y. Sept. 30, 2021).

189 *See generally Teva Pharmaceuticals*, 560 F. Supp. 3d 412; *Pfizer Inc.*, 2021 WL 4523676.

190 *See Teva Pharmaceuticals*, 560 F. Supp. 3d at 423.

191 *Id.* at 416–17.

192 *Id.* at 419–20.

Copaxone.[193] Relying on the holding in *Omnicare*, Teva argued that while they had hoped their donations would be used for patients using Copaxone, the donations were not *contingent* on any agreement to purchase their products.[194] The court found that because the complaint alleged that Teva had tailored its donations to ensure that it was the exact amount necessary to cover the copays of certain Copaxone patients, it showed a purpose of inducement.[195] Notably, the court referenced the *Omnicare* argument and acknowledged that hope for referrals may be expected in certain arrangements,[196] but that here the government adequately alleged that Teva's conduct was specifically intended to induce purchases of its product.[197] Therefore, no such contingent agreement was necessary to state a claim in the criminal complaint.

Pfizer advanced a similar argument in defense of its program. In 2020, Pfizer filed suit seeking a declaratory judgment that its proposed PAP was lawful after OIG issued an advisory opinion to the contrary.[198] In Pfizer's defense, the company attempted to insert an element of corrupt intent into the statute and argued that proof of quid pro quo is required under the AKS.[199] The Southern District of New York rejected this argument.[200] The court found that corruption is irrelevant and that the AKS only requires an intent to influence a decision about medical care to find a violation.[201] The court acknowledged that the prescription drug price crisis likely requires a legislative or policy solution, but that the court's hands are tied by the statute.[202] The decision's application of the one-purpose test is broad and is consistent with OIG's position that intent to remove an economic barrier to receiving prescription medication may violate the AKS, regardless of the actual impact on the decision-making

193 Defendant's Memorandum of Law in Support of Motion to Dismiss at 2, 24, *Teva Pharmaceuticals*, 560 F. Supp. 3d 412 (No. 20-cv-11548).

194 *Id.* at 2 ("To violate the AKS, a donation must be contingent on the charity's agreement to recommend or otherwise promote the donor or its product. There is no such agreement alleged here.").

195 *Teva Pharmaceuticals*, 560 F. Supp. 3d at 420–21.

196 *Id.* at 420.

197 *Id.* at 421.

198 *See generally* Pfizer Inc. v. U.S. Dep't of Health & Hum. Servs., No. 20-cv-4920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021).

199 Memorandum of Law in Support of Plaintiff's Motion for Summary Judgment at 10, *Pfizer Inc.*, 2021 WL 4523676 (No. 20-cv-4920).

200 *See generally Pfizer Inc.*, 2021 WL 4523676.

201 *Id.* at *11–12.

202 *Id.* at *15 ("While there may be an administrative or legislative remedy to the problems Pfizer seeks to correct here, the remedy does not lie with the Court.").

of the prescribing physician.[203] Thus, corrupt inducement is not relevant in the court's analysis.

Both decisions show the threat that the one-purpose test poses to PAPs. As long as the government and courts continue to apply the test to these programs, arrangements that may genuinely help Part D patients afford life-saving medications will be undermined. Thus, OIG should issue a safe harbor to help narrow the breadth of the statute to this conduct.

III. PROPOSAL

As discussed, Congress had two primary concerns when passing the AKS: halting practices that would dramatically increase the costs of Medicare and preventing financial inducement from corrupting a physician's decision-making.[204] In its initial bulletin, OIG's reasoning for subjecting PAPs to scrutiny is certainly consistent with the former concern.[205] There is a valid argument that cost subsidies could lead to an increase in demand, which could be used to increase profits to pharmaceutical companies.[206] That being said, it is questionable whether this is a fair criticism. While the pharmaceutical companies making profit in a for-profit healthcare market may not be the best policy outcome, low-

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203 *Compare id.* ("As Pfizer describes the Direct Program, it is aimed to allow individuals who otherwise may not purchase tafamidis (through economic hardship, personal choice, or both) to purchase it. Because the stated intent of the payments Pfizer proposes here are to increase the number of Medicare beneficiaries who purchase the drug, the Court is unable to issue the declaratory judgment . . . ." (citation omitted)), *with* OIG Advisory Opinion, *supra* note 22, at 15 ("Accordingly, where a Medicare beneficiary otherwise may be unwilling or unable to purchase the Medications due to his or her cost-sharing obligations, which are driven by the list price of the Medications, the Subsidy Program would induce that beneficiary to purchase the Medications by removing the financial impediment, and the Medicare program would bear the costs for the Medications.").

204 *See* Love, *supra* note 69, at 1035; Kusserow, *supra* note 23, at 52. In the context of PAPs, OIG has also indicated another remunerative concern: whether the subsidy would influence the *patient's* decision-making. *See* OIG Advisory Opinion, *supra* note 22, at 15 & n.36. Addressing this concern, previous proposals have exclusively focused on the patient instead of the physician. *See* Illiparambil, *supra* note 172, at 593. However, the patient's agency in picking a prescription drug is often necessarily limited at the discretion of the prescribing physician. Thus, focusing on the physician is more effective to ensure adequate functionality of the arrangement.

205 OIG Special Advisory Bulletin, *supra* note 13, at 70626 ("[W]e are concerned about the use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices.").

206 *But see* David M. Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 COLUM. L. REV. 1861 (1989) (arguing that antifraud Medicare statutes are inherently paradoxical because they are applied to a for-profit healthcare industry and that issues of economic efficiency and utilization of healthcare services are not implicated by payments among healthcare providers).

income patients are able to access prescription medications that are necessary for survival.[207] In addition, several solutions have been proposed for this that would alleviate this concern.[208]

As to the concern of corrupt medical decision-making, OIG's Special Bulletin, its advisory opinions, and its application of the one-purpose test fail to fully address how PAPs implicate this primary concern. While the Special Bulletin and subsequent court decisions do express concern that patients' decision-making would be influenced by the subsidy,[209] they fail to explain how this copay assistance would lead to an overutilization of healthcare services. Instead, the Special Bulletin is more concerned that patients would use one medication over cheaper alternatives.[210] Since one only needs to show any intent to influence under the AKS, the statute is being weaponized to address conduct that does not respond to the primary concerns Congress had when passing the statute.[211]

A. *Safe Harbor Regulation Akin to* Sun-Diamond

A legislative solution to the impact of the AKS is likely not realistic. However, OIG could issue a safe harbor that modifies the "one-purpose" inducement test as originally articulated in *Greber*.[212] In addition to proving the elements of knowingly and willfully giving, receiving, or soliciting a remuneration in return for patient referrals in connection with a federal healthcare program, the government, in the context of PAPs, should only focus on how the subsidy program impacts the physician's decision-making. In other words, whether the subsidy induces the beneficiary should not be analyzed under the context of the AKS. Instead, when evaluating PAPs, the safe harbor should require *corrupt* inducement of a decisionmaker. Of course, this begs the question of what this approach would look like.

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207 Illiparambil, *supra* note 172, at 595.

208 *See, e.g.*, DeFuria, *supra* note 32, at 17 (proposing a federal law making it illegal for a manufacturer-PAP to provide copay assistance towards a drug for which there is an FDA-approved generic equivalent).

209 OIG Special Advisory Bulletin, *supra* note 13, at 70626.

210 *Id.*

211 *See* H.R. REP. NO. 95-393(II), at 3048 (1977).

212 United States v. Greber, 760 F.2d 68, 72 (3d Cir. 1985).

1. How *Sun-Diamond* Can Redefine Corrupt Inducement

A helpful tool in defining the parameters of this safe harbor is a Supreme Court case that defined the level of intent required to be convicted of bribery and gratuity.[213] In *United States v. Sun-Diamond Growers of California*, the Supreme Court grappled with the question of what counts as a gratuity and a bribery under the Federal Bribery Statute.[214] The Court clarified that a gratuity requires a showing that value was given to a public official because of an act performed or to be performed by the official.[215] A bribery, according to the Court, constitutes giving something of value to a public official to influence an official act.[216] A bribery would require an intent to give something of value in exchange for an act in the form of an explicit quid pro quo,[217] while a gratuity is giving a reward to a public official for a future or past act.[218] The Court concluded that in order to prove an illegal gratuity, the government must prove a connection between the gratuity and a *specific* official act.[219] Otherwise, the statute could criminalize a high school principal's giving of a baseball cap to the Secretary of Education upon visiting the school.[220] Under the Supreme Court's holding, the value given must be intended to influence official conduct.[221]

The *Sun-Diamond* holding was well received by lobbyists who advocated for narrowing the breadth of a statute that could subject innocuous conduct to severe criminal sanctions.[222] The Supreme Court's hesitancy to apply criminal sanctions to conduct that may be harmless is applicable in the AKS context.[223] HHS could implement a safe harbor that is similar to the gratuity test defined in *Sun-Diamond*.[224] OIG has

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213 United States v. Sun-Diamond Growers of Cal., 526 U.S. 398 (1999).

214 *Id.* at 398; 18 U.S.C. § 201(c).

215 *Sun-Diamond*, 526 U.S. at 404–05.

216 *Id.*

217 *Id.*

218 *Id.* at 405.

219 *Id.* at 405–08.

220 *Id.* at 407.

221 *Id.* at 406–08.

222 Steven M. Levin, *Illegal Gratuities in American Politics: Learning Lessons from the* Sun-Diamond *Case*, 33 LOY. L.A. L. REV. 1813, 1822 (2000).

223 Especially considering that a violation of the AKS gives rise to treble damages under the FCA as well. 31 U.S.C. § 3729(a)(1).

224 While a valid argument could be made that the safe harbor should reflect the even narrower test for bribery articulated in *Sun-Diamond*, this would likely be a step too far. Based on legislative history and amendments made, it is clear Congress intended the AKS to have *some* breadth. It is likely that a safe harbor applying the bribery test would directly go against congressional intent. *See*

expressed concern that a manufacturer's subsidy program could improperly influence patient and physician decision-making.[225] The former is easily dispensed with because a patient requires a prescription before purchasing medication covered by Medicare Part D and does not necessarily have wide discretion in choosing prescription medication.[226] The latter, while largely speculative, is a valid concern, and the *Sun-Diamond* test can apply here.

A safe harbor requiring a but-for causal connection between the removal of an economic benefit and the physician's official act would help resolve this possibility and would effectively focus government scrutiny on corrupt conduct that the AKS was designed to prevent. The Court in *Sun-Diamond* explained that "[a]n illegal gratuity . . . may constitute merely a reward for some future act that the public official will take (and may already have determined to take)."[227] Thus, consistent with *Sun-Diamond*, the common test for gratuity is assessing whether, when a gift or remuneration was made, the giver or donor expected that a public official would perform or had performed a *specific* act.[228] When applying the AKS to PAPs, HHS should consider adopting this gratuity test and only find an unlawful kickback when the donor-manufacturer intended to influence a specific physician to prescribe specific drugs because of the subsidy. However, physicians ought to be allowed to reasonably consider the patient's insurance coverage and the economic burden that a prescription may pose. If a physician considers these burdens, an argument could be made that the physician made a decision based on the subsidy, bringing us back to the overbreadth issue. Therefore, there must be a framework to define when influencing a physician's decision-making goes from reasonable to improper.

This framework can be difficult to establish. Even in *Sun-Diamond*'s aftermath, scholars have pointed out the difficulty of showing just when conduct crosses from ethical to unethical.[229] Some have pointed out that

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Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub L. No. 95-142, §§ 4(b)(1)–(2), 91 Stat. 1175, 1180 (1977) (codified as amended at 42 U.S.C. § 1395) (congressional amendments adding "any remunerations" as elements of the AKS).

225 OIG Special Advisory Bulletin, *supra* note 13, at 70626.

226 Nat'l Council on Patient Info. & Educ., *supra* note 57; OIG Advisory Opinion, *supra* note 22, at 23.

227 United States v. Sun-Diamond Growers of Cal., 526 U.S. 398, 405 (1999).

228 *See generally* Charles B. Klein, *What Exactly Is an Unlawful Gratuity After* United States v. Sun-Diamond Growers*?*, 68 GEO. WASH. L. REV. 116 (1999).

229 Karen M. Linder, *When Does Unethical Become Criminal?: Interpreting the Gratuity Provision of 18 U.S.C. Sec. 201.* United States v. Sun-Diamond Growers of California, 7 MO. ENV'T L. & POL'Y REV. 161 (2000); Klein, *supra* note 228, at 117; George D. Brown, *Putting Watergate Behind Us*—Salinas*,* Sun-Diamond*, and Two Views of the Anticorruption Model*, 74 TUL. L. REV. 747, 769 (2000).

this very ambiguity may protect instances of innocent conduct, but only at the expense of preventing effective prosecution of bribery.[230] Complicating matters further, there is a circuit split regarding the meaningful distinction between bribery and gratuity as articulated in *Sun-Diamond*.[231] Nevertheless, this ambiguity does not outweigh the public policy advantage of shifting the focus from mere inducement to a more narrow inquiry of corrupt intent to influence physician conduct in the context of PAPs. While the one-purpose test makes the inquiry a much simpler matter for the government to make its case, it does so at the cost of subjecting manufacturers to criminal and civil sanctions for actions that help patients afford potentially life-saving treatment.[232] In addition, like in prosecutions for bribery, circumstantial evidence could be key to showing when inducement becomes improper.[233] This could include a showing of evidence that alternative, more efficient medication is available or expert testimony regarding the wisdom of a doctor's particular course of action. Either way, this circumstantial evidence can serve to help build a better picture of whether an improper healthcare decision has been made. That way, the act of making prescription medication more affordable will not be immediately presumed suspect under the AKS.

CONCLUSION

Under the current standard, any attempt by a manufacturer to make its product affordable will trigger punitive fines and potential prison time that ought to be associated with highly culpable and corrupt activity.[234] With the current state of the healthcare market, its economic complexities, and its competitive nature, the far-reach of the AKS creates

230 Linder, *supra* note 229, at 168.

231 Some circuit courts have required a direct relationship between the payment and the official act. *See* United States v. Espy, 23 F. Supp. 2d 1, 7 (D.D.C. 1998). Other circuit courts have applied a less rigorous test that would recognize an illegal gratuity where a payment was made solely because of the "status" of the official and not because of an "act." United States v. Jennings, 160 F.3d 1006, 1013 (4th Cir. 1998).

232 Leah L. Zullig, Steven Wolf, Lisa Vlastelica, Veena Shankaran & S. Yousuf Zafar, *The Role of Patient Financial Assistance Programs in Reducing Costs for Cancer Patients*, 23 J. MANAGED CARE & SPECIALTY PHARMACY 407, 410 (2017) (finding that "PAPs may reduce [out-of-pocket] costs for select patients who can prove financial need and are filling prescriptions for certain high-priced drugs," while noting that costs are often shifted to health insurers).

233 *See* United States v. Standefer, 610 F.2d 1076, 1081 (3d Cir. 1979); United States v. Schaffer, 183 F.3d 833, 840 (D.C. Cir. 1999).

234 31 U.S.C. § 3729(a) (penalties for violation of FCA).

an unworkable legal landscape.[235] Innovative market solutions are often a cornerstone of industries that operate on a for-profit basis. When those solutions also serve the public by lowering the burden in accessing prescription drugs, it ought to be encouraged by our legal institutions.

Absent any dramatic overhaul of the healthcare market, U.S. healthcare spending will continue to increase.[236] So far, federal courts are reluctant to assess these policy considerations when applying the AKS to these arrangements.[237] This is understandable considering the strong hold that the one-purpose test has on judicial construction of the AKS.[238] However, the impact this standard has on the functioning of certain subsidy programs should raise fundamental questions regarding the breadth of the AKS and how it could be impacting conduct that may have a positive impact on people's lives.

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235 *See generally* David A. Hyman & Joel V. Williamson, *Fraud and Abuse: Regulatory Alternatives in a "Competitive" Health Care Era*, 19 LOY. U. CHI. L.J. 1133 (1988) (arguing that fraud and abuse laws that constrain arrangements and incentive programs are inappropriate as the healthcare industry begins to evolve into a more competitive, market-based industry).

236 *NHE Fact Sheet*, CMS.GOV, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet [https://perma.cc/FZC3-2YUC] (showing a 9.7% increase in healthcare spending in 2020); *see also* Yusra Murad, *CMS Estimates Annual U.S. Health Care Spending to Hit $5.96 Trillion by 2027*, MORNING CONSULT (Feb. 20, 2019, 5:05 PM), https://morningconsult.com/2019/02/20/cms-estimates-annual-u-s-health-care-spending-to-hit-5-96-trillion-by-2027 [https://perma.cc/6YCY-NN9B].

237 *See supra* Section II.B.2.

238 *See* United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989); United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998); United States v. McClatchey, 217 F.3d 823, 834–35 (10th Cir. 2000); United States v. Borrasi, 639 F.3d 774, 781–82 (7th Cir. 2011).