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Are Good Deeds Being Punished?: Independent Charity Patient Assistance Programs and the Anti-Kickback Statute

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ARE GOOD DEEDS BEING PUNISHED?: INDEPENDENT CHARITY PATIENT ASSISTANCE PROGRAMS AND THE ANTI-KICKBACK STATUTE

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Abstract

Largely funded by the pharmaceutical industry, Independent Charity Patient Assistance Programs (PAPs) dispense billions of dollars of aid annually to help financially vulnerable patients afford their prescription drugs. Recently, these charitable entities and their drug company donors have faced mounting legal scrutiny for allegedly funneling illegal kickbacks to Medicare beneficiaries. This Note examines Independent Charity PAPs and the issues they raise under the Anti-Kickback Statute (AKS). It explores the uncertain legal environment in which Independent Charity PAPs operate and concludes that a new AKS regulatory safe harbor may be necessary to preserve the viability of the safety net assistance that Independent Charity PAPs provide.

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INTRODUCTION

"It's terrifying . . . I am going to die without this," was Irene Adkins's reaction to the prospect of losing financial support from Caring Voice Coalition, Inc. (CVC).[1] Like many Medicare beneficiaries, Irene relied upon aid from CVC—an Independent Charity Patient Assistance Program (PAP)—to afford her cost-sharing responsibility for the drugs necessary to treat her pulmonary hypertension condition.[2] In early 2018, Irene's fear was realized when CVC announced that it would no longer offer financial assistance to patients.[3]

CVC based its decision on a move by the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) to rescind a favorable advisory opinion that had approved of the aid CVC provided to Medicare beneficiaries.[4] CVC's announcement also came on the heels of a $210 million settlement agreement between pharmaceutical manufacturer United Therapeutics Corp. (UT) and the U.S. Department of Justice (DOJ) to resolve claims that UT had illegally "used [CVC] as a conduit to pay the copay obligations of thousands of Medicare patients . . . and to induce those patients' purchases" of UT's "[P]ulmonary [A]rterial [H]ypertension" (PAH) drugs.[5]

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1. Robert Langreth & Ben Elgin, *'I Am Going to Die Without This': Regulators Target a Health-Care Lifesaver*, BLOOMBERG BUSINESSWEEK (Dec. 21, 2017), https://www.bloomberg.com/news/articles/2017-12-21/-i-am-going-to-die-without-this-regulators-target-a-health-care-lifesaver [https://perma.cc/BZH4-F83X].

2. *Id.*

3. *See* Greg Smiley, *A Decision on 2018 Financial Assistance*, CARING VOICE COALITION (Jan. 4, 2018), http://www.caringvoice.org/ decision-2018-financial-assistance/ [https://perma.cc/QP47-WXKH]; Langreth & Elgin, *supra* note 1.

4. *See* Smiley, *supra* note 3; Office of the Inspector Gen., U.S. Dep't of Health & Human Servs., Final Notice of Rescission of OIG Advisory Opinion No. 06-04 (Nov. 28, 2017) [hereinafter OIG Rescission of Adv. Op. No. 06-04], https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf [https://perma.cc/4GMA-EQ3S]; Langreth & Elgin, *supra* note 1.

5. Settlement Agreement at 1, 2 (Dec. 19, 2017), https://www.justice.gov/usao-ma/press-release/file/1019336/download [https://perma.cc/2AC2-SHDU]; *see* Press Release, Office of Pub.

On the same day that CVC announced it would be suspending financial aid indefinitely, the OIG took extraordinary action to open another avenue of aid for patients like Irene and sent an urgent letter to a pharmaceutical trade association representative promising that the agency:

> [would] not pursue administrative sanctions against any Drug Company for providing free drugs during 2018 to Federal health care program beneficiaries who were receiving cost sharing support for those drugs from CVC as of November 28, 2017, as long as the Drug Company complie[d] with the safeguards described in [the] letter.[6]

The CVC saga is representative of the mounting scrutiny that Independent Charity PAPs and their pharmaceutical industry benefactors face.[7] It also illustrates the chilling effect this scrutiny has had upon the charities and their donors.[8] CVC ceased operations on May 1, 2019,[9] and late last year federal prosecutors announced that another drug maker, Actelion Pharmaceuticals, had agreed to pay $360 million to settle allegations that it too had used CVC to illegally funnel kickbacks to Medicare beneficiaries.[10]

Such deterrence may be warranted. Critics contend that Independent Charity PAPs undermine the economic benefits of cost-sharing and result in "hidden costs for insurers and taxpayers."[11] However, proponents of

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Affairs, Dep't of Justice, Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks (Dec. 20, 2017), https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability [https://perma.cc/NCQ8-27D3].

6. Letter from Gregory E. Demske, Chief Counsel to the Inspector Gen., U.S. Dep't Health & Human Servs., to James C. Stansel, Exec. Vice President & Gen. Counsel, Pharm. Research & Mfrs. of Am. (Jan. 4, 2018), https://oig.hhs.gov/compliance/alerts/guidance/stansel-letter.pdf [https://perma.cc/8X3G-TFMX].

7. *See* Langreth & Elgin, *supra* note 1.

8. *See id.*

9. *See* CaringVoiceCoalition (@CVCinc), TWITTER (May 1, 2019, 7:40 AM), https://twitter.com/CVCinc/status/1123598130098864128 [https://perma.cc/33V9-CJFR] (announcing that CVC would cease operations after May 1, 2019); *see also* CARING VOICE COALITION, http://www.caringvoice.org/ [https://perma.cc/VN3L-QY2R] ("Caring Voice Coalition's last full day of operation was May 1, 2019.").

10. *See, e.g.*, Katie Thomas, *Drug Maker Pays $360 Million to Settle Investigation into Charity Kickbacks*, N.Y. TIMES (Dec. 6, 2018), https://www.nytimes.com/2018/12/06/health/actelion-johnson-and-johnson-kickback-medicare.html [https://perma.cc/EY4X-G42D].

11. David H. Howard, *Drug Companies' Patient-Assistance Programs—Helping Patients or Profits?*, 371 NEW ENG. J. MED. 97, 99 (2014); *see also* Peter A. Ubel & Peter B. Bach, *Copay Assistance for Expensive Drugs: A Helping Hand That Raises Costs*, 165 ANNALS INTERNAL MED. 878, 878 (2016) (arguing that "copay assistance is part of the [drug] price problem, not a solution to it").

Independent Charity PAPs argue that "[c]ausing companies to stop offering PAPs would leave many patients with chronic conditions out in the cold with respect to prescription drug access."[12] Moreover, limiting access to prescription drugs could increase utilization of high-cost health care interventions, such as hospitalizations.[13]

The OIG, the federal agency tasked with civil enforcement of the Anti-Kickback Statute (AKS), has long recognized the potential benefits of Independent Charity PAPs.[14] Yet, the OIG's frenetic response to CVC's abrupt decision to halt its provision of financial assistance illuminates a critical challenge: How can the OIG protect the integrity of federal health care programs, such as Medicare Part D, from abusive uses of Independent Charity PAPs without cutting down the seemingly critical pharmaceutical safety net that these entities provide to financially vulnerable patients?

This Note explores the challenge of identifying a balanced regulatory approach to Independent Charity PAPs, and it proceeds in three parts. Part I explains how Independent Charity PAPs work, traces their history, and analyzes their impact. Part II provides a thumbnail sketch of the AKS and an overview of the OIG's AKS guidance related to Independent Charity PAPs. It also reviews recent legal scrutiny of Independent Charity PAP donors. Part III explains how this recent scrutiny has precipitated an uncertain legal environment for Independent Charity PAPs and analyzes whether a new AKS safe harbor is warranted to clarify the AKS implications of pharmaceutical manufacturer donations made to Independent Charity PAPs. This Note concludes by suggesting that if Independent Charity PAPs are worth preserving, the OIG should promulgate an AKS regulatory safe harbor for Independent Charity PAPs and their industry donors.

I. INDEPENDENT CHARITY PAPS: A PRIMER

Pharmaceutical PAPs dispense billions of dollars of free drugs and financial assistance annually to help qualifying individuals defray the cost of prescription drugs.[15] This Part defines and describes these entities,

12. *See* Myrl Weinberg, *Reforming Patient Assistance Programs: Perfect World Meets Real World*, 28 HEALTH AFF. 839, 840 (2009).

13. Judy T. Chen & Kent H. Summers, *Pharmaceutical Manufacturer Prescription Assistance Programs: Are They Worth It?*, 13 J. MANAGED CARE PHARMACY 611, 613 (2007).

14. *See, e.g.*, Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,624–25 (Nov. 22, 2005).

15. CONG. RESEARCH SERV., R44264, PRESCRIPTION DRUG DISCOUNT COUPONS AND PATIENT ASSISTANCE PROGRAMS (PAPS) 1 (2017). This Note focuses exclusively on PAPs that target patient access to pharmaceuticals, but it is worth noting that similar programs exist in other sectors of the health care industry. *See, e.g.*, Brad M. Beall, Note, *Investing in the Ill: The Need to Curb Third-Party Payment of Qualified Health Plan Premiums*, 69 FLA. L. REV. 1339, 1353

explains their origins, and examines their controversial relations with pharmaceutical industry donors.

A. *Pharmaceutical PAP Typology*

Two of the most common forms of Pharmaceutical PAPs are "Pharmaceutical Manufacturer PAPs" and "Independent Charity PAPs."[16] Pharmaceutical Manufacturer PAPs are directly associated with specific pharmaceutical manufacturers.[17] They include pharmaceutical companies' "own 501(c)(3) organizations, which often are set up as private foundations."[18] Pharmaceutical companies use these PAPs to supply "drugs directly to patients who cannot afford them."[19] The scale of Pharmaceutical Manufacturer PAP funding is substantial. The Foundation Center, an organization that tracks philanthropic giving, counts ten Pharmaceutical Manufacturer PAPs among the twenty largest charitable foundations in the United States as measured by total giving in 2015.[20] The annual giving of many Pharmaceutical Manufacturer PAPs

(2017) (discussing payments made by "provider-affiliated nonprofits" to help defray the cost of Qualified Health Plans (QHPs) for individuals demonstrating financial need).

16. CONG. RESEARCH SERV., *supra* note 15, at 15; *see* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,624 ("Some PAPs are affiliated with particular pharmaceutical manufacturers; others are operated by independent charitable organizations . . . without regard to any specific donor or industry interests."); RAMSEY BAGHDADI, HEALTH AFFAIRS, HEALTH POLICY BRIEF: PATIENT FINANCIAL SUPPORT 2 (2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000176/full/ [https://perma.cc/TM2F-AP4J] ("Manufacturers may either sponsor their own PAPs . . . or donate to independent foundations that then provide patients with financial assistance."); Austin Frerick, *The Cloak of Social Responsibility: Pharmaceutical Corporate Charity*, 153 TAX NOTES 1151, 1157 (2016) (discussing the differences between Manufacturer PAPs and Independent Charity PAPs).

17. *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,624 n.3 (defining Pharmaceutical Manufacturer PAPs as "any PAP that is directly or indirectly operated or controlled in any manner by a pharmaceutical manufacturer or its affiliates").

18. CONG. RESEARCH SERV., *supra* note 15, at 15, 17 ("Private foundations often are tightly controlled, receive significant portions of their funds from a small number of donors, and make grants to other organizations rather than directly carry out charitable activities.").

19. Frerick, *supra* note 16, at 1157; *see also Application for HUMIRA® (adalimumab)*, MYABBVIE ASSIST (Sept. 2019), https://www.abbvie.com/content/dam/abbvie-dotcom/uploads/PDFs/pap/humira-patient-assistance-application.pdf [https://perma.cc/8LHP-FWRE] ("myAbbVie Assist provides free medicine to qualifying patients.").

20. *See Fiscal Totals of the 50 Largest Foundations in the U.S. by Total Giving, 2015*, FOUND. CTR., http://data.foundationcenter.org/#/foundations/all/nationwide/top:giving/list/2015 [https://perma.cc/4V5G-DU5J].

surpasses that of "more well-known foundations such as the Ford Foundation."[21]

Independent Charity PAPs, on the other hand, are operated by charitable entities that are separate from pharmaceutical manufacturers.[22] These entities are typically organized as public charities,[23] which tend to "have broad public support and tend to provide charitable services directly to the intended beneficiaries."[24] However, Independent Charity PAPs are often largely funded by donations made by pharmaceutical manufacturers.[25] This drug maker largesse is of such a grand scale that two Independent Charity PAPs—Patient Access Network Foundation (PAN Foundation) and Good Days—rank among the 100 largest not-for-profit organizations in the United States.[26]

Independent Charity PAPs "offer aid such as financial assistance to uninsured consumers or underinsured consumers who cannot meet their health plans' premiums or cost sharing, such as co-payments, coinsurance, and deductibles."[27] Common aid eligibility criteria include:

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21. Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in Pharmaceutical Markets* 29 (Hutchins Ctr., Working Paper No. 30, 2017), https://www.brookings.edu/wp-content/uploads/2017/05/wp30_scottmorton_competitioninpharma1.pdf [https://perma.cc/VS2G-MBF5]; *see also Fiscal Totals of the 50 Largest Foundations in the U.S. by Total Giving, 2015*, *supra* note 20 (ranking the total giving of charitable foundations in 2015).

22. *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,624 (noting that Independent Charity PAPs operate "without regard to any specific donor or industry interests").

23. *See, e.g.*, *Publication 78 Data for Patient Access Network Foundation*, TAX EXEMPT ORG. SEARCH, https://apps.irs.gov/app/eos/ (select search by "Organization Name"; then search organization name "Patient Access Network Foundation"; then follow "Patient Access Network Foundation" hyperlink) (listing "Deductibility Code: PC [(Public Charity)]") [https://perma.cc/WG8S-6CZJ].

24. CONG. RESEARCH SERV., *supra* note 15, at 16.

25. *See* Jonathan D. Rockoff, *U.S. Probe Sheds Light on Charities' Role in Boosting Drug Sales*, WALL ST. J., https://www.wsj.com/articles/u-s-probe-sheds-light-on-charities-role-in-boosting-drug-sales-1497000601 [https://perma.cc/FJC4-DCFG] (last updated June 11, 2017, 9:24 PM) ("The eight biggest [Independent Charity PAPs] got more than $1.1 billion in donations mostly from drug companies in 2014 . . . ."); *see also* Ben Elgin & Robert Langreth, *How Big Pharma Uses Charity Programs to Cover for Drug Price Hikes*, BLOOMBERG (May 19, 2016, 6:00 AM), https://www.bloomberg.com/news/articles/2016-05-19/the-real-reason-big-pharma-wants-to-help-pay-for-your-prescription [https://perma.cc/Z43P-7WDM] (reporting that Novartis contributed "just over half" of Independent Charity PAP Patient Services, Inc.'s 2014 funding and that "[a]bout 95 percent" of Independent Charity PAP PAN Foundation's contributions are provided by pharmaceutical companies).

26. *See NPT Top 100 (2019): An In-Depth Study of America's Largest NonProfits*, NONPROFIT TIMES (Nov. 4, 2019), https://www.thenonprofittimes.com/report/npt-top-100-2019-an-in-depth-study-of-americas-largest-nonprofits/ [https://perma.cc/FQ6G-C44P] (ranking PAN Foundation thirty-eighth and Good Days eighty-ninth based on 2018 revenues of $540,784,733 and $240,058,988, respectively).

27. CONG. RESEARCH SERV., *supra* note 15, at 15.

"(1) annual income, (2) insurance status, (3) physician endorsement, (4) prescription information, and (5) proof of U.S. citizenship or legal residence."[28] Patient income eligibility limits are often tied to the Federal Poverty Level (FPL).[29] However, many Independent Charity PAPs adjust income limits according to drug prices, raising income eligibility limits for more expensive drugs.[30] The financial support these entities provide is usually limited to a specific time period.[31]

B. *A Brief History of Independent Charity PAPs*

Independent Charity PAPs arose in response to high out-of-pocket costs associated with novel pharmaceutical and biologic treatments.[32] In contrast to Pharmaceutical Manufacturer PAPs, which often target uninsured patients and limit aid to company-specific products, the flexibility of Independent Charity PAPs offered a way for insured patients to maintain their coverage and defray the out-of-pocket costs of multiple treatments, regardless of manufacturer.[33] Founded in 1989, Patient Services Inc. (PSI) is often credited as the first Independent Charity PAP.[34] PSI's President, Dana Kuhn, a former hospital counselor, started the charity after seeing chronic disease patients "taking drastic steps to get [health insurance] coverage, including one couple who got divorced so the mother and child could go on Medicaid."[35] Many Independent Charity PAPs, like PSI, see themselves as offering a lifeline to patients "who make too much money to qualify for a free drug program" but nonetheless cannot afford their steep co-payments.[36] According to Kuhn, these financially vulnerable patients might otherwise get caught in a

28. *Id.* at 17.

29. *Id.*

30. *See id.*

31. *Id.*

32. *See* Tina Shah, *Copayment Foundations: Help for the Underinsured*, 5 BIOTECHNOLOGY HEALTHCARE 41, 41 (2008); *see also* Geeta Anand, *Through Charities, Drug Makers Help People—and Themselves*, WALL ST. J., https://www.wsj.com/articles/SB113339802749110822 [https://perma.cc/VZQ8-WGV9] (last updated Dec. 1, 2005, 12:01 AM) ("To cope with rising medical costs, insurers are requiring patients to pay higher premiums and co-payments for drugs. While poor uninsured patients can often get expensive medicine free from drug companies, people with insurance are increasingly finding it difficult to afford these drugs. In response, drug companies are giving money to charities that are specifically set up to help patients pay such costs.").

33. *See* Shah, *supra* note 32, at 41.

34. *See id.* at 42.

35. Jayne O'Donnell et al., *Drug Co-Pay Groups: Critical Patient Charities or Fronts for Drugmakers?*, USA TODAY (Apr. 26, 2018, 7:09 AM), https://www.usatoday.com/story/news/politics/2018/04/26/drug-co-payments-groups-patient-charities-drugmakers-affordable-care-act/485524002/ [https://perma.cc/K5B2-AYZ4].

36. *Id.*

tragic cycle where they "stop taking their drugs, their conditions become exacerbated so they go to emergency rooms where they can't be denied their drug and can get stabilized for little or no money."[37]

Since the late 1980s, an increasingly broad array of Independent Charity PAPs has developed.[38] These not-for-profit organizations offer similar assistance but "vary in size, disease focus, and other forms of aid."[39] During the past few decades, Independent Charity PAPs have grown in scale.[40] A study of tax data found that, between 2004 and 2014, giving by Independent Charity PAPs rose from $11 million to $868 million,[41] and "surged" to $1.35 billion in 2015.[42] The PAN Foundation—the largest Independent Charity PAP[43]—"increased its annual grants and donations from about $38 million in 2010 to $496 million in 2014 and $942 million in 2015."[44] Among the Independent Charity PAPs analyzed in a 2019 study, "total revenue in 2017 ranged from $24 million to $532 million, and expenditures on patient assistance programs ranged from $24 million to $353 million, representing, on average, 86% of their revenue."[45]

The rapid rise in spending by Independent Charity PAPs has likely been driven by "the expansion of publicly funded insurance and [the proliferation of] specialty drugs."[46] The Medicare Modernization Act of 2003[47] created the Medicare Part D program, "a voluntary outpatient drug benefit" for Medicare beneficiaries.[48] By 2016, "nearly forty-two million people" had enrolled in Part D.[49] The federally subsidized program "pays

37. *Id.*

38. *See* Shah, *supra* note 32, at 42.

39. *Id.*

40. *Id.* ("Since the [HealthWell Foundation (HWF) and the [PAN] Foundation's] inception in 2003, these organizations have helped more than 50,000 and 25,000 patients, respectively." (citation omitted)).

41. Frerick, *supra* note 16, at 1158.

42. Austin Frerick, Letter to the Editor, *An Update on Pharmaceutical Corporate Charity*, TAX NOTES, May 8, 2017, at 857.

43. *Id.* at 858 (noting that PAN Foundation "represented 70 percent of all independent charity giving in 2015").

44. CONG. RESEARCH SERV., *supra* note 15, at 21–22.

45. So-Yeon Kang et al., *Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs*, 322 JAMA 422, 424 (2019).

46. Frerick, *supra* note 16, at 1159.

47. Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 26 and 42 U.S.C.).

48. MEDICARE PAYMENT ADVISORY COMM'N, PART D PAYMENT SYSTEM 1 (2018), http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_18_partd_final_sec.pdf?sfvrsn=0 [https://perma.cc/Y2RF-KA9T].

49. MICHAEL MCCAUGHAN, PRESCRIPTION DRUG PRICING: MEDICARE PART D, at 1 (2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000172/full/ [https://perma.cc/S9EA-UH5L].

for almost two billion prescriptions annually, representing nearly $90 billion in spending."[50]

The AKS prohibits pharmaceutical manufacturers from providing financial assistance or discounts to patients for products paid for by federal health insurance programs.[51] However, OIG guidance indicates that a pharmaceutical manufacturer may donate to Independent Charity PAPs—without implicating the AKS—provided that the charity and the assistance it allocates are sufficiently insulated from the manufacturer.[52] Hence, as Medicare beneficiaries increasingly enrolled in Part D plans, pharmaceutical manufacturers were likely motivated to boost donations to Independent Charity PAPs because Pharmaceutical Manufacturer PAPs could no longer be relied upon to address this population.[53]

Another potential driver of the growth of Independent Charity PAPs may be the recent rise in spending on specialty drugs.[54] There is no common definition of specialty drugs, but the category often includes expensive drugs "used to treat complex diseases including multiple sclerosis, cancer, and hepatitis C" as well as some biologics and orphan drugs.[55] In recent years, "spending for specialty drugs has grown faster than spending for other pharmaceuticals."[56] In addition, these high price drugs are causing more Medicare Part D beneficiaries to reach the catastrophic phase of their benefit.[57] As a result, many Part D beneficiaries, particularly those who do not qualify for the program's Low-Income Subsidy (LIS),[58] bear steep cost-sharing responsibilities.[59] In 2015, the average annual out-of-pocket spending among high-cost Part D beneficiaries who did not qualify for the LIS was $2,958.[60] Many of these beneficiaries turn to Independent Charity PAPs to meet their cost-

50. *Id.*

51. *See* 42 U.S.C. § 1320a-7b(b) (2012); *infra* Section II.A.

52. *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005); *infra* Section II.C.

53. *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,624 ("[W]e conclude that pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts present heightened risks under the antikickback statute.").

54. *See* Frerick, *supra* note 16, at 1159.

55. SUZANNE M. KIRCHHOFF, CONG. RESEARCH SERV., R44132, SPECIALTY DRUGS: BACKGROUND AND POLICY CONCERNS 1 (2015).

56. Frerick, *supra* note 16, at 1159.

57. *See* MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 421 (2018).

58. *See* 42 U.S.C. § 1395w-114 (2012) (providing subsidies for qualifying low-income Medicare beneficiaries).

59. *See* MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 57, at 424.

60. *See id.*

sharing requirements.[61] Indeed, specialty pharmacies that dispense specialty drugs often connect patients with Independent Charity PAPs.[62]

C. *The Impacts of PAPs*

Little is known about how effectively PAPs improve patient access to drugs.[63] A 2009 study of PAPs highlighted "the lack of transparency that exists surrounding drug company-sponsored PAPs"[64] and concluded that it is unclear how effectively PAPs promote access to medications.[65] Similarly, recently published research has found that Independent Charity PAPs typically disclose neither drug maker donations "nor . . . the actual allocation of financial assistance across specific drugs."[66]

Despite the dearth of information available about PAPs, some evidence suggests that they are beneficial to patients. A literature review found that "PAP enrollment assistance plus additional medication services (e.g., counseling, free samples) is associated with improved disease indicators for patients with chronic diseases" but stressed that "few inferences" about "the effectiveness, use, or value of PAPs" could be drawn from existing research on PAPs due to "limitations in the studies' designs."[67] A 2014 study of uninsured patients found that Pharmaceutical Manufacturer "PAPs were successful in providing significant medication cost savings for patients" but provided only "brand name prescription drugs, which are typically more expensive" than generic drugs.[68] Likewise, the authors of a study published in 2017 noted that PAPs are a useful tool to "help patients bridge their cancer care costs" and "may reduce [out-of-pocket] costs for select patients who can prove financial need and are filling prescriptions for certain high-priced drugs"

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61. *Cf.* Joseph Walker, *Patients Struggle with High Drug Prices*, WALL ST. J., https://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981 [https://perma.cc/R7G9-BSPU] (last updated Dec. 31, 2015, 10:38 AM) (describing middle-class Medicare patients' struggles to afford the out-of-pocket costs associated with expensive prescription drugs and their reliance upon Independent Charity PAPs for financial assistance).

62. *See* MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 57, at 414.

63. *See* CONG. RESEARCH SERV., *supra* note 15, at 22.

64. Niteesh K. Choudhry et al., *Drug Company-Sponsored Patient Assistance Programs: A Viable Safety Net?*, 28 HEALTH AFF. 827, 832 (2009).

65. *Id.* at 833.

66. Kang et al., *supra* note 45, at 427 (noting that "[t]his lack of transparency" impedes efforts to assess whether "the activities of [Independent Charity PAPs] are aligned with their charitable missions").

67. Tisha M. Felder et al., *What is the Evidence for Pharmaceutical Patient Assistance Programs?: A Systematic Review*, 22 J. HEALTH CARE FOR POOR & UNDERSERVED 24, 44, 45 (2011).

68. Yelba M. Castellon et al., *The Impact of Patient Assistance Programs and the 340B Drug Pricing Program on Medication Cost*, 20 AM. J. MANAGED CARE 146, 148 (2014).

but cautioned that "PAPs may do so by shifting cost to health insurers."[69] The study analyzed oncology prescriptions filled by an academic cancer center's specialty pharmacy and found that among the "[t]welve percent of prescriptions . . . that received PAP assistance, the median amount of financial assistance provided per prescription was $411.10 . . . which amounted to 15% of the median prescription cash price."[70]

A descriptive study of specialty pharmacy patients who received assistance from an Independent Charity PAP found that "[t]he mean annual per capita income was $19,159" and that "all [of the] patients had an income at or below 500% of the FPL based on household size."[71] The patients were predominately insured by Medicare Part B or Medicare Part D and most of the patients were at least sixty-five years old.[72] The overwhelming majority of the patients "were receiving assistance for oncology medications."[73] The patients faced an "average initial co-pay of $728 per patient per year" and received "an average of $722 in financial assistance" from the Independent Charity PAP.[74]

D. *Controversial Donor Relations*

It is an "open secret" that Independent Charity PAPs are largely funded by contributions made by pharmaceutical companies.[75] It has also

69. Leah L. Zullig et al., *The Role of Patient Financial Assistance Programs in Reducing Costs for Cancer Patients*, 23 J. MANAGED CARE & SPECIALTY PHARMACY 407, 410 (2017) (concluding that "PAPs played a relatively small role in reducing the cost of [oral anticancer medication] prescriptions" because "[f]ew patients received PAP assistance, and among those who did, PAPs covered only a small proportion of [out-of-pocket] costs"). The study did not distinguish between Pharmaceutical Manufacturer PAPs and Independent Charity PAPs. *See id.*

70. *Id.* at 408–10. The study defined "cash price" as "[a] reduced price offered to patients paying cash on the day of their prescription fills." *Id.* at 408.

71. Julia Zhu et al., *A Descriptive Study of Patients Receiving Foundational Financial Assistance Through Local Specialty Pharmacies*, 24 AM. J. MANAGED CARE S80, S81–S82, S83 (2018) (noting that patients often abandon drug therapies when their out-of-pocket expenses exceed $250 and speculating that the reduction in co-pays among the study population "might have helped decrease the medication abandonment rate").

72. *Id.* at S82.

73. *Id.*

74. *Id.*

75. Andrew Pollack, *Drug Maker's Donations to Co-Pay Charity Face Scrutiny*, N.Y. TIMES (Dec. 18, 2013), https://www.nytimes.com/2013/12/19/business/shake-up-at-big-co-pay-fund-raises-scrutiny-on-similar-charities.html [https://perma.cc/5X3U-6P8A]; *see also* HEALTHWELL FOUND., WHEN HEALTH INSURANCE IS NOT ENOUGH: HOW CHARITABLE COPAYMENT ASSISTANCE ORGANIZATIONS ENHANCE PATIENT ACCESS TO CARE 5 (2012), https://www.healthwellfoundation.org/wp-content/uploads/legacy/files/HWF-white%20paper%20for%20printing.pdf [https://perma.cc/W3MK-N3BB] (noting that the providing of financial assistance to patients "would not be possible without the generous support of pharmaceutical and biotechnology industry donors"); *PAN Facts & Stats*, PAN FOUND., https://panfoundation.org/

been reported that many Independent Charity PAPs solicit donations directly from pharmaceutical manufacturers.[76] Moreover, one Independent Charity PAP has reportedly pitched pharmaceutical industry donations as a "win-win situation" whereby companies "make a small contribution to help the patient and get much more money back when the insurer pays for the drug."[77]

Perhaps unsurprisingly, pharmaceutical companies' donations to Independent Charity PAPs have raised eyebrows.[78] Dr. David Howard suggests that Independent Charity PAPs are a "triple boon for manufacturers" because "[t]hey increase demand, allow companies to charge higher prices, and provide public-relations benefits."[79] According to Dr. Howard, pharmaceutical manufacturers can use donations to Independent Charity PAPs as a way to "blunt the impact of drug copayments and coinsurance on patients" and thereby increase demand for expensive drugs among price-conscious patients who would otherwise opt not to take an expensive drug.[80] Dr. Howard also contends that, by reducing patients' price sensitivity, Independent Charity PAPs "may lead to higher drug prices" because pharmaceutical companies are relieved of the economic effects of patient cost-sharing that help keep prices in check.[81]

Similarly, Dr. Peter Ubel and Dr. Peter Bach argue that Independent Charity PAPs will increase overall health care costs by "reduc[ing] public outcry over outrageous drug prices" and enabling pharmaceutical manufacturers to "sidestep" insurer price negotiations—keeping the costs borne by patients low, "even when insurers are aiming to keep them high."[82] So-Yeon Kang and her colleagues echo this concern. Concluding that the drugs covered by the Independent Charity PAPs they studied

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index.php/en/about-us/media-room/pan-facts-stats [https://perma.cc/BVD8-LFLW] ("The majority of PAN's funding comes from pharmaceutical companies.").

76. *See* Anand, *supra* note 32 ("Patient Services developed the concept of soliciting drug-company money to pay insurance premiums, the National Organization for Rare Disorders, a Connecticut nonprofit, recently began performing the same kind of middleman role.").

77. *Id.*

78. *See* Alex Berenson, *In Drug-Aid Foundations, a Web of Corporate Interests*, N.Y. TIMES (Apr. 8, 2006), https://www.nytimes.com/2006/04/08/business/in-drugaid-foundations-a-web-of-corporate-interests.html [https://perma.cc/G5XE-78UL] (noting that critics of Independent Charity PAPs "worry that they are little more than ways for drug makers to sustain their high prices by funneling patients enough money to meet their co-payments, while letting insurers pick up most of the bill"); *see also* Anand, *supra* note 32 ("[Critics] argue that by paying patients' premiums or co-payments, drug companies are shifting most of the price of these medicines to the patients' insurers, who in turn spread the cost onto the other people they cover.").

79. Howard, *supra* note 11, at 97.

80. *Id.*

81. *Id.* at 98.

82. Ubel & Bach, *supra* note 11, at 878.

"were generally more expensive than those that were not covered," Kang and her colleagues caution that Independent Charity PAPs "can desensitize beneficiaries to the total price of the drug and thus undermine the purpose of co-payments and coinsurance."[83] This is especially problematic for the Medicare Part D program because beneficiaries who choose higher cost drugs will reach catastrophic coverage faster.[84]

The story of a Medicare beneficiary named Vivian illustrates how Independent Charity PAPs can simultaneously help patients gain access to drugs and generate revenue for pharmaceutical manufacturers. When Vivian's "rare gastrointestinal tumor recurred," she was prescribed an expensive cancer drug.[85] Although Vivian and her husband Ronald qualified for prescription drug coverage under Medicare,[86] their "income of $2,000 a month put them in a group required to pay $3,600 a year before being eligible for the drug benefit" and also required them "to pay 5% of each prescription."[87] To afford those cost-sharing requirements and gain access to the drug, Vivian and her husband turned to an Independent Charity PAP that was funded by the manufacturer of the cancer drug.[88] The Independent Charity PAP reported assisting 1,255 cancer patients through programs funded by the manufacturer.[89] If each of those patients, like Vivian, used the aid to purchase the manufacturer's cancer drug through drug benefits that covered a significant portion of the $37,000 annual average wholesale price of the drug,[90] the Independent Charity

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83. Kang et al., *supra* note 45, at 427, 429 ("The [study's] finding [that Independent Charity PAPs offer] preferential coverage of high-priced specialty and brand-name drugs over generic equivalents adds to a growing body of literature suggesting that co-payment assistance programs may motivate physicians and patients to choose treatment options with a lower out-of-pocket cost burden despite the higher total cost and the availability of lower-cost alternatives.").

84. *Id.* at 427.

85. Anand, *supra* note 32.

86. The couple was covered "under a pilot Medicare program" similar to the Medicare Part D program. *Id.* Generally, under the Medicare Part D:

> Medicare beneficiaries can purchase drug coverage subject to a deductible of $250 per year, 25% co-pays on the next $2,000 spent, no coverage for the next $2,850 spent (a gap referred to as the "doughnut hole"), and 5% co-pays on any additional amounts spent during the year (so-called "catastrophic" coverage) . . . . The program relies on private insurers to offer seniors a variety of options (differing primarily in the lists of drugs covered, which can change monthly while beneficiaries could only change plans once a year).

LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 883 (4th ed. 2017).

87. Anand, *supra* note 32.

88. *See id.*

89. *Id.*

90. Medicare Part D plans cover 75% of drug costs during the initial phase of the benefit and, during the catastrophic phase of the benefit, the plans cover "15 percent of the cost of drugs

PAP could have facilitated "tens of millions of dollars" of sales of the drug among patients who otherwise would not have been able to afford it.[91]

II. AN OVERVIEW OF THE ANTI-KICKBACK STATUTE AND ITS APPLICATION TO INDEPENDENT CHARITY PAPS

In 2015, the DOJ began to closely scrutinize pharmaceutical manufacturer donations to Independent Charity PAPs.[92] Since then, federal prosecutors have announced settlements with at least ten pharmaceutical manufacturers[93] and at least three Independent Charity PAPs.[94] The settlements resolve allegations of False Claims Act (FCA)[95] violations premised upon the theory that donations made to Independent

over the catastrophic limit, with the beneficiary paying 5 percent and the federal subsidy (known as reinsurance) paying the remaining 80 percent." *See* MCCAUGHAN, *supra* note 49, at 2, 3.

91. Anand, *supra* note 32.

92. *See* Rockoff, *supra* note 25.

93. *See* Press Release, U.S. Attorney's Office, Dep't of Justice, Actelion Pharms. Agrees to Pay $360 Million to Resolve Allegations that It Paid Kickbacks Through a Co-Pay Assistance Found. (Dec. 6, 2018), https://www.justice.gov/usao-ma/pr/actelion-pharmaceuticals-agrees-pay-360-million-resolve-allegations-it-paid-kickbacks [https://perma.cc/B4AY-D22F]; Press Release, Office of Pub. Affairs, Dep't of Justice, Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More than $35 Million to Resolve Criminal Charges & 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/WL2K-AYEE]; Press Release, Office of Pub. Affairs, Dep't of Justice, Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks (May 24, 2018), https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks [https://perma.cc/BR9R-GRCU]; Press Release, Office of Pub. Affairs, Dep't of Justice, *supra* note 5; Press Release, Office of Pub. Affairs, Dep't of Justice, Three Pharm. Cos. Agree to Pay a Total of Over $122 Million to Resolve Allegations that They Paid Kickbacks Through Co-Pay Assistance Founds. (Apr. 4, 2019), https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid [https://perma.cc/MXR2-3W4X]; Press Release, Office of Pub. Affairs, Dep't of Justice, Two Pharm. Cos. Agree to Pay a Total of Nearly $125 Million to Resolve Allegations that They Paid Kickbacks Through Copay Assistance Founds. (Apr. 25, 2019), https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid [https://perma.cc/C53X-W9PW]; Press Release, U.S. Attorney's Office, Dep't of Justice, Sanofi Agrees to Pay $11.85 Million to Resolve Allegations That it Paid Kickbacks Through a Co-Pay Assistance Foundation (Feb. 28, 2020), https://www.justice.gov/usao-ma/pr/sanofi-agrees-pay-1185-million-resolve-allegations-it-paid-kickbacks-through-co-pay [https://perma.cc/ZS4A-HQ5S].

94. *See* Press Release, Office of Pub. Affairs, Dep't of Justice, Patient Servs. Inc. Agrees to Pay $3 Million for Allegedly Serving as a Conduit for Pharm. Cos. to Illegally Pay Patient Copayments (Jan. 21, 2020), https://www.justice.gov/opa/pr/patient-services-inc-agrees-pay-3-million-allegedly-serving-conduit-pharmaceutical-companies [https://perma.cc/KBR9-LLEK]; Press Release, U.S. Attorney's Office, Dep't of Justice, Founds. Resolve Allegations of Enabling Pharm. Cos. 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/R59H-GK8X].

95. Ch. 67, 12 Stat. 696 (1863) (codified as amended at 31 U.S.C. §§ 3729–3733 (2012)).

Charity PAPs by pharmaceutical manufacturers violate the AKS by serving as "a conduit to pay kickbacks to Medicare patients taking [the manufacturers'] drugs."[96] Additionally, several courts have considered *qui tam* FCA actions against pharmaceutical companies predicated upon allegations that donations made to Independent Charity PAPs violated the AKS.[97] This Part reviews this recent legal scrutiny of pharmaceutical manufacturer donations made to Independent Charity PAPs; it begins by providing a thumbnail sketch of the AKS and an overview of AKS regulatory guidance related to Independent Charity PAPs.

A. *The AKS: A Thumbnail Sketch*

Under the AKS it is unlawful to "knowingly and willfully" solicit, receive, offer, or pay "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" to reward or induce the referral or purchase of "any item or service" paid for, at least in part, "under a Federal health care program."[98] Violating the AKS is a felony that is punishable by a maximum fine of $100,000 and ten years of imprisonment.[99] The AKS is enforced by the DOJ, which has authority over criminal prosecutions, and by the OIG, which has authority to "initiate administrative proceedings to exclude a person from Federal health care programs or to impose civil monetary penalties for kickback violations."[100] The AKS was amended by the Patient Protection and Affordable Care Act (ACA)[101] to clarify that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" under the FCA.[102] Hence, the government and

96. Press Release, U.S. Attorney's Office, Dep't of Justice, *supra* note 94.

97. *See* United States *ex rel.* Greenfield v. Medco Health Sols., 880 F.3d 89, 94 (3d Cir. 2018); United States *ex rel.* Vitale v. MiMedx Grp., Inc., 381 F. Supp. 3d 647, 651 (D.S.C. 2019); United States *ex rel.* Brown v. Celgene Corp., 226 F. Supp. 3d 1032, 1057 (C.D. Cal. 2016).

98. 42 U.S.C. § 1320a–7b(b) (2012).

99. *Id.*

100. Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120, 31,121 (May 30, 2014); *see* Thomas N. Bulleit, Jr. & Joan H. Krause, *Kickbacks, Courtesies, or Cost-Effectiveness?: Application of the Medicare Antikickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 FOOD & DRUG L.J. 279, 282 (1999).

101. Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of 26 and 42 U.S.C.).

102. 42 U.S.C. § 1320a-7b(g). The FCA imposes a civil penalty 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; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . .

qui tam relators can pursue a FCA action based upon an AKS violation.[103] The ACA also reduced the intent requirement of the AKS such that a person can violate the AKS despite either a lack of "actual knowledge" of the AKS or the "specific intent" to violate it.[104]

Courts have interpreted the AKS expansively.[105] In *United States v. Greber*,[106] the U.S. Court of Appeals for the Third Circuit established the "one purpose" test for AKS violations.[107] The Third Circuit held that payments the defendant made to a physician to induce referrals violated the AKS "even if the payments were also intended to compensate for professional services."[108] The court ruled that "if one purpose of the payment was to induce future referrals, the [AKS] has been violated."[109] It reasoned that Congress intended the AKS to have a "deterrent effect" that would counter financial incentives to order unnecessary services.[110]

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31 U.S.C. § 3729(a)(1) (2012). The penalties and damages awarded under the FCA can be massive, especially where a high volume of false claims for Medicare reimbursement are involved. *See, e.g.*, United States *ex rel.* Drakeford v. Tuomey, 792 F.3d 364, 370 (4th Cir. 2015) (affirming a $237,454,195 judgment against a hospital found to have "knowingly submitted 21,730 false claims to Medicare for reimbursement").

103. *See* United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 95 (3d Cir. 2018); *cf.* United States *ex rel.* King v. Solvay Pharm., Inc., 871 F.3d 318, 324 n.1 (5th Cir. 2017) ("The AKS provides no private right of action; therefore, a private plaintiff may not sue a health care provider under the AKS alone." (quoting United States *ex rel.* Ruscher v. Omnicare, Inc., 663 F. App'x 368, 371 n.2 (5th Cir. 2016))), *cert. denied*, 138 S. Ct. 2030 (2018).

104. Pub. L. 111-148, § 6402(f), 124 Stat. at 759 (codified as amended at 42 U.S.C. § 1320a-7b(h)); *see also* Laura G. Hoey et al., *Is the Current Anti-Kickback Enforcement Environment Stifling Innovation in Health Care?*, BNA'S HEALTH L. REP., Aug. 10, 2017, at 1, 2 (noting that the ACA "lessened the intent standard" of the AKS).

105. *See, e.g.*, Bulleit & Krause, *supra* note 100, at 283 ("The [AKS] has been held applicable to a wide variety of financial relationships that are quite different from an obvious kickback for a patient referral or a bribe to recommend the purchase of specific products or services."); *see also* Hoey et al., *supra* note 104, at 2 (noting that the AKS is "both nebulous and broad").

106. 760 F.2d 68 (3d Cir. 1985).

107. *See id.* at 69.

108. *Id.* at 72.

109. *Id.* at 69. The "one purpose" test espoused in *Greber* has been adopted widely. *See, e.g.*, United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 30 (1st Cir. 1989); United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989); Bulleit & Krause, *supra* note 100, at 283. However, "it may be a defense that an improper purpose was 'incidental,' 'minor,' or not 'material.'" Bulleit & Krause, *supra* note 100, at 283. Moreover, a "collateral hope for referrals" does not violate the AKS but "it may be difficult for a jury to distinguish between a motivating factor and a collateral hope or expectation." *See* United States v. McClatchey, 217 F.3d 823, 834 & n.7 (10th Cir. 2000).

110. *Greber*, 760 F.2d at 70–71. However, courts have acknowledged that:

> [T]he [AKS] does not make increased cost to the government the sole criterion of corruption. In prohibiting "kickbacks," Congress need not have spelled out the obvious truisms that, while unnecessary expenditure of money earned and

The court also ruled that the statute's reference to "'any remuneration' . . . includes not only sums for which no actual service was performed but also those amounts for which some professional time was expended" because "the potential for unnecessary drain on the Medicare system remains."[111]

At least one circuit court has suggested that defraying the cost of Medicare patients' prescription drug co-pays is proscribed by the AKS. Writing for the U.S. Court of Appeals for the Seventh Circuit in *United States ex rel. Grenadyor v. Ukrainian Village Pharmacy, Inc.*,[112] Judge Richard Posner offered a colorful explanation as to why co-pay discounts offered to Medicare beneficiaries by a pharmacy could violate the AKS:

> [W]hat is wrong with offering an inducement that reduces a product's cost to the consumer? The answer is that a discount or refund can become a 'kickback' . . . [where] it artificially inflates the price that the government pays pharmacies for prescription drugs for Medicare or Medicaid beneficiaries. . . .
>
> [A] refund to [a pharmacy] customer would thus have been a "kickback" in an appropriately pejorative sense because it would have increased the pharmacy's sales (and presumably its profits, as otherwise it wouldn't provide refunds) at the government's expense. . . . It would have done so either by diverting customers from other pharmacies or by inducing customers to purchase drugs that they would not have been willing to purchase had they been responsible for the copay.[113]

> contributed by taxpaying fellow citizens may exacerbate the result of the crime, kickback schemes can freeze competing suppliers from the system, can mask the possibility of government price reductions, can misdirect program funds, and, when proportional, can erect strong temptations to order more drugs and supplies than needed. Nor need Congress have spelled out duties, beyond the duty of avoiding receipt and payment of kickbacks.

United States v. Ruttenberg, 625 F.2d 173, 177 n.9 (7th Cir. 1980); *see also* Bulleit & Krause, *supra* note 100, at 282 ("[T]he main purpose of the [AKS] . . . [is to] prevent[] inappropriate financial considerations from influencing the amount, type, cost, or selection of the provider of medical care received by a federal health care program beneficiary.").

111. *Greber*, 760 F.2d at 71; *see also* Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995) ("Congress introduced the broad term 'remuneration' in the 1977 amendment of the statute to clarify the types of financial arrangements and conduct to be classified as illegal under Medicare and Medicaid. The phrase 'any remuneration' was intended to broaden the reach of the law which previously referred only to kickbacks, bribes, and rebates." (citations omitted)).

112. 772 F.3d 1102 (7th Cir. 2014).

113. *Id.* at 1104–05. The *Grenadyor* court ultimately held that the relator's FCA allegations, which were premised in part upon the alleged kickbacks the defendant pharmacies made to

B. *AKS Safe Harbors and OIG Guidance*

In recognition of the vast and perplexing breadth of the AKS,[114] Congress has enacted several statutory exceptions[115] and has required the OIG to promulgate regulations "specifying payment practices that shall not be treated as a criminal offense . . . and shall not serve as the basis for an exclusion under [the AKS]."[116] These safe harbors offer an affirmative defense: "Once the government establishes the elements of a violation of the [AKS], the burden shifts to a defendant to demonstrate by a preponderance of the evidence that her conduct fell within the safe harbor provision of the statute."[117]

The OIG promulgated the first AKS safe harbor regulations in 1991[118] and is required to annually solicit proposals for modifications and additions.[119] Among the factors that the OIG considers when making changes to the safe harbors are the effects the change would have upon

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Medicare beneficiaries, were not pleaded with enough specificity. *See id.* at 1107 ("Grenadyor would have had to allege either that the pharmacy submitted a claim to Medicare (or Medicaid) on behalf of a specific patient who had received a kickback, or at least name a Medicare patient who had received a kickback (presumably if the pharmacy provided a drug to a Medicare patient it billed Medicare for the cost of the drug minus the copay).").

114. *See* S. REP. NO. 100-109, at 27 (1987) ("It is the understanding of the Committee that the breadth of this statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed."); *see also* Bulleit & Krause, *supra* note 100, at 285 ("[I]t may be difficult to think of a financial relationship in the health care industry that is *not* at risk for violation.").

115. *See* 42 U.S.C. § 1320a-7b(b)(3) (2012).

116. Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93, § 14(a), 101 Stat. 680, 697 (codified as amended at 42 U.S.C. § 1320a-7b(b)(3)(E)); *see also* Hoey et al., *supra* note 104, at 2 ("Congress has provided for certain statutory exceptions and authorized the [OIG] to promulgate additional safe harbors to protect innocuous, or even potentially beneficial, business and payment practices.").

117. United States v. George, 900 F.3d 405, 413 (7th Cir. 2018); *see also* MedPricer.com, Inc. v. Becton, Dixon & Co., 240 F. Supp. 3d 263, 275 (D. Conn. 2017) (holding that a defendant "cannot claim an exemption" under a regulatory safe harbor for a business arrangement that implicates the AKS without a showing that the arrangement "'fit squarely' within the safe harbor"), *adhered to on reconsideration by* 2017 WL 1234102 (D. Conn. Apr. 3, 2017).

118. *See* Bulleit & Krause, *supra* note 100, at 288.

119. *See* 42 U.S.C. § 1320a-7d(a)(1)(A). Congress explained that the annual solicitation of safe harbor proposals is intended to promote:

> Greater public involvement in the process for identifying changes or additions to safe harbors, and fraud alerts will stimulate more timely and responsive information for assisting providers and suppliers in understanding Medicare requirements, as well as, enabling federal and state criminal justice agencies to focus on the most deliberate cases of fraudulent and abusive practices.

H.R. REP. NO. 104-496, at 84 (1996).

the accessibility, quality, and cost of health care services as well as the amount of "competition among health care providers."[120] No statutory or regulatory AKS safe harbor currently addresses financial assistance provided to Medicare beneficiaries by Independent Charity PAPs.

The OIG is also required to issue advisory opinions pertaining to the AKS.[121] In doing so, the OIG "provide[s] guidance on what constitutes prohibited remuneration under the [AKS], whether an arrangement satisfies the criteria for a statutory exception or safe harbor, and whether an activity constitutes grounds for the imposition of sanctions."[122] Advisory opinions can help provide clarity for businesses considering business arrangements that do not clearly fit an existing AKS safe harbor.[123] To receive an advisory opinion, requestors must: "be a party to the arrangement, or proposed arrangement, that is the subject of the request";[124] must submit detailed information about themselves, the arrangement, and "other . . . parties to the arrangement";[125] and must certify to the truth and completeness of all of the information submitted.[126] However, the opinions are applicable only to the requestor, bind only the OIG, and do not "limit[] the investigatory or prosecutorial authority of the OIG, DOJ or any other agency of the Government."[127] Moreover, the OIG retains the right to "rescind, terminate, or modify [an] advisory opinion."[128] Importantly, "OIG advisory opinions do not establish rules of decision, and are not to receive judicial deference."[129]

120. 42 U.S.C. § 1320a-7d(a)(2).

121. *See id.* § 1320a-7d(b).

122. Bulleit & Krause, *supra* note 100, at 293.

123. *Id.* at 293.

124. 42 C.F.R. § 1008.11 (2018).

125. *Id.* § 1008.36; *see id.* §§ 1008.37, .39 (discussing disclosure of other information).

126. *See id.* § 1008.38.

127. *Id.* § 1008.1; *see id.* §§ 1008.53, .59.

128. *Id.* § 1008.45. A rescinded advisory opinion "is revoked retroactively to the original date of issuance with the result that the advisory opinion will be deemed to have been without force and effect," *id.* § 1008.45(b)(1), a terminated advisory opinion "is revoked as of the termination date and is no longer in force and effect after the termination date," *id.* § 1008.45(b)(2), and a modified advisory opinion "continues in full force and effect in modified form thereafter," *id.* § 1008.45(b)(3).

129. United States *ex rel.* McDonough v. Symphony Diagnostic Servs., Inc., 36 F. Supp. 3d 773, 780 (S.D. Ohio 2014) ("OIG advisory opinions, by regulation 'have no application to any individual or entity that does not join in the request for the opinion.'" (quoting 42 C.F.R. § 1008.53)). In *Christensen v. Harris County*, the U.S. Supreme Court held that agency "interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference," but may be "entitled to respect" as a persuasive authority. 529 U.S. 576, 587 (2000) (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)); *see also* Deborah Thompson Eisenberg, *Regulation by* Amicus: *The Department of Labor's Policy Making in the Courts*, 65 FLA. L. REV. 1223, 1239 (2013)

The OIG also issues guidance related to the AKS in the form of advisory bulletins.[130] However, the interpretive guidance provided by these bulletins also lacks "the force of authoritative law."[131]

C. *OIG Guidance Related to Independent Charity PAPs*

The OIG has issued two advisory bulletins addressing AKS concerns related to Independent Charity PAPs.[132] Additionally, the agency has published several advisory opinions that analyze the AKS implications of Independent Charity PAPs and protect certain structures from the imposition of administrative sanctions.[133]

1. Special Advisory Bulletins

In 2005, in anticipation of the implementation of the Medicare Part D program, the OIG issued an advisory bulletin in response to pharmaceutical manufacturers' "interest in continuing to assist Medicare Part D enrollees of limited means who do not qualify for the low-income subsidy" and concerns that financial assistance provided by Pharmaceutical Manufacturer PAPs to Medicare beneficiaries for drugs covered by Part D would implicate the AKS.[134] The OIG noted the importance of the long-standing "safety net assistance" provided by PAPs and expressed support for the "efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not" violate the AKS.[135] The agency concluded that "[M]anufacturer PAPs that subsidize Part D cost-sharing amounts present heightened risks under the [AKS]" but found that properly structured "cost-sharing subsidies provided by *bona fide*,

(discussing the Supreme Court's evolving perspective "on the degree of deference to give an informal agency interpretation").

130. *See, e.g.*, Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,628 (Nov. 22, 2005) (noting that "the OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by OIG" as part of its effort to further the goals of "prevent[ing] fraud and abuse" under the Health Insurance Portability and Accountability Act of 1996).

131. United States *ex rel.* Jamison v. McKesson Corp., 784 F. Supp. 2d 664, 677 n.10 (N.D. Miss. 2011) (ruling that an "OIG Special Advisory Opinion" was an "agency interpretation[]" that did not bind the court).

132. *See* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,623–24; Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120, 31,120–21 (May 30, 2014).

133. *See, e.g.*, Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. at 70,627 n.17.

134. *Id.* at 70,624.

135. *Id.* at 70,623–24.

independent charities unaffiliated with pharmaceutical manufacturers should not raise [AKS] concerns, even if the charities receive manufacturer contributions."[136]

The OIG reasoned that cost-sharing subsidies provided by a pharmaceutical manufacturer to Medicare Part D beneficiaries for the manufacturer's own drugs "would be squarely prohibited by the statute, because the manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product."[137] Moreover, the agency noted that Pharmaceutical Manufacturer PAPs that subsidize the manufacturer's own products:

> present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries[']s incentives to locate and use less expensive, equally effective drugs.[138]

In contrast, the OIG outlined parameters by which pharmaceutical manufacturers can donate to an Independent Charity PAP that provides cost-sharing assistance to Medicare Patients for Part D drugs without implicating the AKS.[139] The OIG stated that donations to an Independent Charity PAP "should raise few, if any, [AKS] concerns" if: (1) the pharmaceutical manufacturer and its affiliates do not "exert[] any direct or indirect influence or control over the charity or the subsidy program"; (2) the Independent Charity PAP provides assistance in a manner such that it "cannot be attributed to the donating pharmaceutical manufacturer"; (3) the Independent Charity PAP provides aid "without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan"; (4) the Independent Charity PAP employs "a reasonable, verifiable, and uniform measure of financial need that is

136. *Id.* at 70,624.

137. *Id.* at 70,625.

138. *Id.* In particular, the agency pointed to concerns that Pharmaceutical Manufacturer PAPs could increase Medicare outlays if used in a way that would "increase the number of beneficiaries using the manufacturer's product who reach the catastrophic benefit in any given coverage year and hasten the point . . . at which beneficiaries reach the catastrophic benefit." *Id.* at 70,625–26. Additionally, the OIG noted its concern that "cost-sharing subsidies" could be used to "shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices." *Id.* at 70,626. Furthermore, the OIG explained that Pharmaceutical Manufacturer PAPs that provide in-kind assistance can "have the practical effect of locking beneficiaries into the manufacturer's product" and that manufacturer-provided Medicare Part D cost-sharing subsidies would have a similar "steering effect." *Id.*

139. *Id.*

applied in a consistent manner"; and (5) the donating "pharmaceutical manufacturer does not solicit or receive data from the charity that would [enable] the manufacturer [to] correlat[e] the amount [and] frequency of its donations with the number of subsidized prescriptions for its products."[140]

In sum, the OIG explained that an "[I]ndependent [C]harity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices."[141] It expressed its apprehension that pharmaceutical manufacturers might seek to improperly influence Independent Charity PAPs "to ensure that the manufacturer's contributions only or primarily benefit patients using its products" and "to maximize the number of beneficiaries qualifying for cost-sharing subsidies."[142] The agency noted that "cost-sharing subsidies can be very profitable for manufacturers . . . . So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance" and suggested that this potential profitability creates "incentives for abuse."[143]

In 2014, the OIG issued another advisory bulletin with "additional guidance" related to Independent Charity PAPs.[144] The OIG again recognized the "important safety net assistance" that PAPs provide for patients unable to "afford their cost-sharing obligations for prescription drugs."[145] However, the agency pointed out that "[t]wo remunerative aspects of PAP arrangements require scrutiny under the [AKS]: donor contributions to PAPs (which can also be analyzed as indirect remuneration to patients) and PAPs' grants to patients."[146] The OIG explained that the AKS "could be violated" by donations "made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor's federally reimbursable items" and by financial assistance provided to a patient by a PAP with the intent "to influence the patient to

140. *Id.* The OIG further stipulated that "[n]o individual patient information may be conveyed to donors" and "neither patients nor donors may be informed of the donation made to the PAP by others." *Id.* at 70,626 n.16. Additionally, the OIG explained that "[r]eporting of data that is not in the aggregate or that is patient specific would be problematic, as would reporting of any data, whether or not in the aggregate, related to the identity, amount, or nature of subsidized drugs." *Id.*

141. *Id.* at 70,627.

142. *Id.* at 70,626.

143. *Id.*

144. *E.g.*, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120, 31,120 (May 30, 2014).

145. *Id.*

146. *Id.* at 31,121.

purchase (or induce the patient's physician to prescribe) certain items."[147]

The 2014 bulletin reiterated the OIG's prior guidance that "pharmaceutical manufacturers can effectively contribute to the safety net by making cash donations to independent, *bona fide* charitable assistance programs" and expanded upon the factors the agency "believe[s] are fundamental to a properly structured Independent Charity PAP."[148] In particular, the agency focused on "[d]isease funds, eligible recipients, and the conduct of donors."[149]

The OIG stated that "disease funds should be defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products; disease funds should not be defined for the purpose of limiting the drugs for which the Independent Charity PAP provides assistance."[150] The agency warned that Independent Charity PAPs with "narrowly defined disease funds may be subject to scrutiny if the disease funds result in funding exclusively or primarily the products of donors or if other facts and circumstances suggest that the disease fund is operated to induce the purchase of donors' products."[151] The OIG also cited concerns that narrow disease funds that limit cost-sharing support to "expensive or specialty drugs" might reduce the benefit of Independent Charity PAPs for patients and could "steer patients in a manner that is costly to Federal health care programs and may even facilitate increases in drug prices."[152] Hence, it cautioned that:

> a fund will be subject to more scrutiny if it is limited to a subset of available products, rather than all products approved by the Food and Drug Administration (FDA) for treatment of the disease state(s) covered by the fund or all products covered by the relevant Federal health care program when prescribed for the treatment of the disease states (including generic or bioequivalent drugs).[153]

Additionally, the OIG specified that "Independent Charity PAP[s] must determine [patient] eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner."[154] Moreover, it concluded that "the cost of the particular drug for which the patient is applying for assistance is not an appropriate stand-

147. *Id.*
148. *Id.*
149. *Id.*
150. *Id.* at 31,122.
151. *Id.* at 31,121.
152. *Id.* at 31,122.
153. *Id.*
154. *Id.*

alone factor in determining individual financial need."[155] The OIG also pointed out that "actions by donors to correlate their funding of PAPs with support for their own products . . . may be indicative of a donor's intent to channel its financial support to copayments of its own products, which would implicate the [AKS]."[156]

2. Advisory Opinions

The OIG has issued several favorable advisory opinions to Independent Charity PAPs.[157] Under these favorable advisory opinions, the OIG typically promises not to sanction the requestor even though the arrangement contemplated in the opinion could violate the AKS.[158] In its 2014 bulletin, the OIG noted that:

> [F]avorable [advisory] opinions related to PAPs typically are based upon the charity's certifications that: (1) No donor or affiliate of any donor has exerted or will exert any direct or indirect influence or control over the charity or any of the charity's programs; (2) the charity will define its disease funds in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (3) the charity's disease funds will not be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs.[159]

Moreover, since publishing its 2014 bulletin, the OIG has issued modifications to many favorable advisory opinions related to Independent Charity PAPs.[160] These modifications include additional certifications that the Independent Charity PAP requestors: (1) will define disease funds broadly to cover at least all FDA-approved drugs for the type of disease; (2) "will not maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or

155. *Id.* ("[G]enerous financial need criteria, particularly when a fund is limited to a subset of available drugs or the drugs of a major donor, could be evidence of intent to fund a substantial part of the copayments for a particular drug (or drugs) for the purpose of inducing the use of that drug (or those drugs), rather than for the purpose of supporting financially needy patients diagnosed with a particular disease.").

156. *Id.* at 31,123.

157. *See supra* note 133 and accompanying text.

158. *See, e.g.*, Office of Inspector Gen., U.S. Dep't. of Health & Human Servs., OIG Advisory Op. No. 07-06 (July 23, 2007), https://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-06.pdf [https://perma.cc/8AMR-YG2Y].

159. Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. at 31,121 n.8.

160. *See, e.g.*, Office of Inspector Gen., Dep't. of Health & Human Servs., Notice of Modification of OIG Advisory Op. No. 07-06 (Dec. 21, 2015), https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/mod-advopn0706.pdf [https://perma.cc/R9ZA-LFNS].

marketed by one manufacturer or its affiliates"; (3) will provide assistance, regardless of price, "for all prescription medications, including generic or bioequivalent drugs, approved by the FDA for treatment of the disease state(s) covered by the fund"; and (4) will make all patient eligibility decisions based upon "a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner."[161]

In November 2017, the OIG rescinded a favorable advisory opinion that had been issued to CVC, an Independent Charity PAP.[162] The OIG explained that it took the unprecedented step of rescinding the opinion[163] because CVC had:

> (i) provided patient-specific data to one or more donors that would enable the donor(s) to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products, and (ii) allowed donors to directly or indirectly influence the identification or delineation of Requestor's disease categories.[164]

The OIG reasoned that CVC's actions represented a failure to comply with certifications that "the arrangement interposed an independent, *bona fide* charitable organization between donors and patients."[165] Furthermore, the OIG stressed concerns that the failure "materially increased the risk that [CVC] served as a conduit for financial assistance from a pharmaceutical manufacturer donor to a patient, and thus increased the risk that the patients who sought assistance from [CVC] would be steered to federally reimbursable drugs that the manufacturer donor sold."[166]

D. *DOJ Investigations*

A notable example of the DOJ's recent scrutiny of pharmaceutical manufacturers' donations to Independent Charity PAPs is the $210 million agreement that UT, a manufacturer of PAH drugs, entered into with the DOJ to settle claims that UT had "violated the [FCA] by paying

161. *Id.* at 2–3.

162. *See* OIG Rescission of Adv. Op. No. 06-04, *supra* note 4, at 2–3.

163. *See* Robert Langreth & Ben Elgin, *Drug Charity May Shutter After U.S. Faults Pharma Influence*, BLOOMBERG (Nov. 29, 2017, 12:17 PM), https://www.bloomberg.com/news/articles/2017-11-29/pharma-charity-may-shut-after-u-s-faults-drugmakers-influence [https://perma.cc/5739-9CPF].

164. OIG Rescission of Adv. Op. No. 06-04, *supra* note 4, at 2.

165. *Id.*

166. *Id.*

kickbacks to Medicare patients" through an Independent Charity PAP.[167] The DOJ contended that UT had donated to and used a PAH disease fund operated by CVC "as a conduit to pay the copay obligations of thousands of Medicare patients taking [UT's PAH drugs], to eliminate price sensitivity of patients purchasing or physicians prescribing the [PAH] [d]rugs, and to induce those patients' purchases of the [PAH] [d]rugs."[168]

The DOJ further alleged that UT's donations to CVC were based upon "the revenue it would receive from prescriptions for Medicare patients who received assistance from CVC to cover their copays for [UT's PAH] [d]rugs."[169] Additionally, UT had purportedly collected and used data from CVC to determine how many and to what extent patients taking UT's PAH drugs received assistance from CVC and "to confirm that UT's revenue far exceeded the amount of UT's donations to CVC."[170] Moreover, the DOJ alleged UT had "referred Medicare patients prescribed [UT's PAH] [d]rugs to CVC, which resulted in claims to federal healthcare programs to cover the cost of the drugs."[171]

As part of the settlement agreement, UT entered into a Corporate Integrity Agreement (CIA) with the OIG.[172] In the CIA, UT committed to "vest sole responsibility and authority for budgeting and other donation related activities relating to Independent Charity PAPs" in an independent committee separate from its "sales, marketing, and similar commercial business units."[173] UT also agreed that in order to make a donation to an Independent Charity PAP it will not: (1) "influence or control" the creation of any of the Independent Charity PAP's "specific disease funds" or any changes thereto; (2) "influence or control . . . the Independent Charity PAP's" patient assistance eligibility criteria or determinations; (3) "solicit or receive . . . any data or information from the Independent Charity PAP that would enable it to correlate the amount or frequency of its donations with support for [UT's] products or

167. Press Release, U.S. Attorney's Office, Dep't of Justice, United Therapeutics Agrees to Pay $210 Million to Resolve Allegations that It Paid Kickbacks Through a Co-Pay Assistance Found. (Dec. 20, 2017), https://www.justice.gov/usao-ma/pr/united-therapeutics-agrees-pay-210-million-resolve-allegations-it-paid-kickbacks-through [https://perma.cc/Z3PK-2UHX].

168. Settlement Agreement, *supra* note 5, at 2.

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.* at 3; *see* OFFICE OF INSPECTOR GEN. OF THE DEP'T OF HEALTH & HUMAN SERVS. & UNITED THERAPEUTICS CORP., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND UNITED THERAPEUTICS CORPORATION 1 (Dec. 18, 2017), https://oig.hhs.gov/fraud/cia/agreements/United_Therapeutics_Corporation_12182017.pdf [https://perma.cc/3ATG-2MGW].

173. OFFICE OF INSPECTOR GEN. OF THE DEP'T OF HEALTH & HUMAN SERVS. & UNITED THERAPEUTICS CORP., *supra* note 172, at 18.

services"; or (4) "provide donations for a disease state fund that covers only a single product or that covers only [UT's] products."[174]

E. *FCA* Qui Tam *Cases Predicated on Independent Charity PAP Donations*

Three recent *qui tam* FCA suits have touched upon the AKS implications of Independent Charity PAP donations. In *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*,[175] the Third Circuit considered a *qui tam* relator's allegation that Accredo, a specialty pharmacy, had violated the FCA because donations Accredo made to an Independent Charity PAP were illicit kickbacks under the AKS.[176] The relator argued that Accredo's decision to to donate to the Independent Charity PAPs was based upon a belief that donating would have a favorable effect on the pharmacy's business.[177] The district court granted summary judgment in favor of the pharmacy after finding that the relator had "failed to provide evidence of even a single federal claim for reimbursement by Accredo that was linked to the alleged kickback scheme."[178] The Third Circuit affirmed the district court's judgment and notably declined to "express [a] view on whether Accredo's charitable contributions were illegal kickbacks under the [AKS]."[179]

In *United States ex rel. Brown v. Celgene Corp.*,[180] the U.S. District Court for the Central District of California held that Celgene, a pharmaceutical manufacturer, could not "be liable for giving money" to Independent Charity PAPs without "evidence that the[] donations were contingent on the foundation's agreement to purchase or recommend Celgene's drugs."[181] The FCA *qui tam* relator in *Brown* alleged that Celgene had violated the AKS by "directing money through [Independent Charity PAPs] to induce patients to buy its drugs."[182] The relator pointed to donations that Celgene had made to Independent Charity PAPs allegedly "for the purpose of helping patients (including those enrolled in Medicare) pay co-payments for [cancer] drugs."[183] However, the court reasoned that the relator's evidence suggested that the donations did not depend upon any "agreement to purchase or recommend Celgene's

174. *Id.* at 20.
175. 880 F.3d 89 (3d Cir. 2018).
176. *Id.* at 94.
177. *See id.* at 92.
178. *Id.* at 91.
179. *Id.* at 93 n.4, 100.
180. 226 F. Supp. 3d 1032 (C.D. Cal. 2016).
181. *Id.* at 1057.
182. *Id.*
183. *Id.*

drugs" because "one of the [Independent Charity PAPs] funded by Celgene, would reimburse ten different [cancer] drugs, only three of which were manufactured by Celgene."[184]

Most recently, in *United States ex rel. Vitale v. MiMedx Group, Inc.*,[185] the U.S. District Court for the District of South Carolina denied, in part, a pharmaceutical manufacturer's motion to dismiss as to a relator's FCA causes of action premised upon violations of the AKS stemming from donations the manufacturer had allegedly made to an Independent Charity PAP (PAN Foundation). Specifically, the relator alleged that the manufacturer had donated to PAN Foundation "while manipulating the submission of patient assistance applications to ensure its contributions fund[ed] only patients seeking [its] products."[186] The court reasoned, *inter alia*, that the FCA causes of action should survive the manufacturer's motion to dismiss because the relator alleged that the manufacturer "knowingly and willfully paid a remuneration," the cost-sharing responsibility of Medicare beneficiaries, "indirectly" through "correlated" donations to PAN Foundation "to induce" Medicare beneficiaries "to purchase [the manufacturer's] Products."[187]

III. WHY INDEPENDENT CHARITY PAPS MAY WARRANT SAFE HARBOR PROTECTIONS

The scrutiny of pharmaceutical manufacturer donations to Independent Charity PAPs by federal prosecutors and the reconsideration of favorable advisory opinions by the OIG have generated an uncertain legal environment for the charitable entities and their pharmaceutical industry donors. In light of this uncertainty, one Independent Charity PAP, CVC, has suspended its provision of financial aid, and pharmaceutical industry donations to Independent Charity PAPs have

184. *Id.* at 1057 & n.33.

185. 381 F. Supp. 3d 647 (D.S.C. 2019).

186. *Id.* at 651, 659.

187. *Id.* at 659. It was alleged that:

> [The manufacturer] would encourage sales representatives to identify patients of [the manufacturer's] medical provider clients who would be eligible for PAN [Foundation] funding to cover Medicare coinsurance and copays and prepare PAN [Foundation] applications for them. [The manufacturer] would then make charitable contributions to and fund PAN [Foundation] in an amount correlated with the number of patients [the manufacturer] had identified who would be seeking PAN [Foundation] funding. [The manufacturer] would next have its sales representatives, who had been told to hold applications until the PAN [Foundation] funds were funded, rush to submit applications.

Id. (citations omitted).

reportedly declined.[188] This Part explains the uncertain AKS implications of Independent Charity PAPs and analyzes whether a new AKS safe harbor is warranted to provide greater clarity for these entities and their donors.

A. *OIG Guidance Provides Limited Protection for Independent Charity PAP Donors*

In its guidance, the OIG has repeatedly recognized Independent Charity PAPs as an important safety net for financially vulnerable Medicare beneficiaries who face high prescription drug costs.[189] The agency has also stated that pharmaceutical manufacturers can lawfully contribute to Independent Charity PAPs through "properly structured" arrangements.[190] However, adherence to the OIG's guidelines does not guarantee that donations made by pharmaceutical manufacturers to Independent Charity PAPs will not trigger an AKS violation.[191] The OIG's bulletins and advisory opinions suggest how the OIG will exercise its prosecutorial discretion but do not offer legally binding protection from DOJ prosecutions or *qui tam* litigants.[192]

The DOJ highlighted this point in a Statement of Interest that it filed in *Vitale*.[193] In response to the defendant pharmaceutical manufacturer's motion to dismiss, the DOJ argued that OIG "advisory opinions issued to 501(c)(3) foundations and other guidance do not alter the elements of the AKS or represent an exhaustive list of considerations of AKS liability as to [the defendant]."[194] The DOJ asserted that, despite the OIG's guidance regarding donations to Independent Charity PAPs, "the AKS not only prohibits pharmaceutical companies from 'directly' paying Medicare copays to induce purchases of their products, the statute also prohibits

188. *See* Rockoff, *supra* note 25 (reporting that federal investigations into Independent Charity PAPs have spooked the pharmaceutical industry and led to a drop in manufacturer donations to Independent Charity PAPs); *supra* notes 3–4 and accompanying text.

189. *See, e.g.*, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120, 31,120 (May 30, 2014).

190. *Id.* at 31,121.

191. Indeed, the OIG itself acknowledged that "[a] determination regarding whether a particular arrangement violates the [AKS] requires an individualized evaluation of all of the relevant facts and circumstances, including the parties' intent." *Id.* Additionally, favorable advisory opinions issued to Independent Charity PAPs have focused "on the charities that requested the opinions—not the donors." *Id.* at 31,123.

192. *See* United States *ex rel.* McDonough v. Symphony Diagnostic Servs., Inc., 36 F. Supp. 3d 773, 780 (S.D. Ohio 2014); United States *ex rel.* Jamison v. McKesson Corp., 784 F. Supp. 2d 664, 677 n.10 (N.D. Miss. 2011).

193. *See* United States' Statement of Interest at 8, United States *ex rel.* Vitale v. MiMedx Grp., Inc., 381 F. Supp. 3d 647 (D.S.C. 2019) (No. 3:17-cv-00166-RBH).

194. *Id.*

them from using intermediaries to accomplish the same goal 'indirectly.'"[195] Moreover, the DOJ contended that the OIG's guidance "do[es] not create new conditions, the non-compliance with which must be specifically pled to sufficiently allege an AKS violation," but instead "represent[s] the conditions under which [the OIG] agreed to refrain from certain administrative enforcement action against [the Independent Charity PAP]."[196]

The DOJ softened its stance by noting that "strictly adher[ing] to the letter and spirit of the safeguards in an existing [OIG] advisory opinion . . . might provide [an] entity with a basis to assert that it did not possess the requisite intent to violate the AKS."[197] Notably, the *Brown* court appeared to apply similar logic in holding that a showing that a pharmaceutical manufacturer had donated to an Independent Charity PAP that provided financial assistance for a broad class of drugs, a minority of which were the manufacturer's, was insufficient to establish an AKS violation.[198] Indeed, the *Brown* court implicitly accepted the premise that adherence to OIG guidance favoring Independent Charity PAP arrangements that commit to "cover[ing] a broad spectrum of available products" could disprove the intent necessary to violate the AKS.[199]

However, the *Brown* court analyzed only the relationship between the manufacturer and the charity.[200] It did not address the relator's reference to testimony that Celgene "gave tens of millions of dollars per year to non-profit organizations for the purpose of helping patients (including those enrolled in Medicare) pay co-payments for [cancer] drugs."[201] Instead, the *Brown* court reasoned that, without evidence that the manufacturer's "donations were contingent on the foundation's agreement to purchase or recommend the [manufacturer's] drugs," the donations could not have violated the AKS.[202] This overlooks the DOJ's point that the AKS "also prohibits [manufacturers] from using intermediaries to . . . 'indirectly'" induce Medicare beneficiaries to purchase the manufacturer's drugs by defraying the beneficiaries' co-payments.[203]

Although *Brown* supports the theory that compliance with OIG

195. *Id.* at 6.

196. *Id.* at 8.

197. *Id.* at 9 n.4 ("Such an inquiry would involve a fact-specific, case-by-case determination.").

198. *See* United States *ex rel.* Brown v. Celgene Corp., 226 F. Supp. 3d 1032, 1057 & n.33 (C.D. Cal 2016).

199. Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120, 31,121 n.8 (May 30, 2014).

200. *See Brown*, 226 F. Supp. 3d at 1057.

201. *Id.*

202. *Id.*

203. United States' Statement of Interest, *supra* note 193, at 6.

guidelines may be sufficient to negate an inference that a pharmaceutical manufacturer's donations to an Independent Charity PAP were intended to induce Medicare beneficiaries to purchase the manufacturer's drugs, it does not stand for the proposition that compliance with OIG guidelines always shelters such donations from the AKS. Given the breadth of the AKS, a pharmaceutical manufacturer's donations to an Independent Charity PAP may yet run afoul of the AKS, despite strict compliance with OIG guidelines, where evidence—perhaps like the return on investment analysis referenced by the relator in *Greenfield*[204]—demonstrates that at least one purpose of a manufacturer's donations was to indirectly induce Medicare beneficiaries to purchase its drugs. Hence, as the DOJ's Statement of Interest in *Vitale* indicates, compliance with the OIG's guidelines may not be a reliable defense against allegations that donations made to an Independent Charity PAP violated the AKS.[205] This precipitates an uncertain legal environment[206] that may deter manufacturers from donating at all[207] and, in the case of CVC,[208] has deterred at least one charity from operating.

B. *Should the OIG Promulgate an AKS Safe Harbor Regulation for Independent Charity PAPs?*

In the face of this uncertainty, the pharmaceutical industry has called for the OIG to promulgate a new AKS safe harbor to "provide more concrete guardrails for companies in evaluating whether support of independent charitable foundations are appropriate in a given circumstance."[209] So too has at least one Independent Charity PAP.[210] As

204. *See* United States *ex rel.* Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 92 (3d Cir. 2018).

205. *See supra* text accompanying notes 193–196.

206. *See* Rockoff, *supra* note 25; Letter from John A. Murphy, III, Deputy Gen. Counsel for Health, Biotechnology Innovation Org., to Susan Edwards, Office of Inspector Gen., Dep't of Health & Human Servs. (Oct. 26, 2018) [hereinafter BIO Comment Letter], https://www.regulations.gov/contentStreamer?documentId=HHSIG-2018-0002-0283&attachmentNumber=1&contentType=pdf [https://perma .cc/62GU-BGEJ] ("[W]hen evaluating charitable support programs through the lens of small emerging biotechnology companies, the state of the law and guidances is murky.").

207. *See* Cameron T. Norris, *Reviving* Hanlester Network*: A Safe Harbor for Harmless Remunerations Under the Anti-Kickback Statute*, 67 VAND. L. REV. EN BANC 137, 154 (2014) ("[E]ven if the government does not go after borderline cases *in practice*, the AKS still allows them to *in theory*. The mere possibility of prosecution may be enough to deter health care providers from engaging in innovative and beneficial arrangements in the first place.").

208. *See supra* note 9 and accompanying text.

209. BIO Comment Letter, *supra* note 206, at 8.

210. *See* Press Release, APNews, Good Days Settles Inquiries (Oct. 25, 2019), https://www.apnews.com/PR%20Newswire/f5477ed6611f8014cb815d60d0f96266 [https://perma.cc/46LZ-T92M] ("'We will continue to comply with all regulatory requirements surrounding charitable copay assistance programs and we welcome further clarity and OIG

commentators have pointed out, it is not uncommon for the "pharmaceutical industry [to] protest[] that the paucity of case, statutory and regulatory guidance regarding the application of anti-fraud laws to them, and almost exclusive reliance on enforcement to convey the government's interpretation of and obtain compliance with these laws is unreasonable, inefficient and expensive."[211] However, in the context of the AKS implications of industry donations to Independent Charity PAPs, these criticisms seem apt given the limits of the OIG's guidance and the DOJ's reliance on settlements of potentially massive FCA liability to alter the behavior of industry donors.[212] If Independent Charity PAPs are indeed an important safety net for financially needy Medicare beneficiaries, then the OIG should take these calls seriously and promulgate an AKS safe harbor regulation to ensure that pharmaceutical manufacturers can lawfully contribute to Independent Charity PAPs.

According to former Inspector General Richard Kusserow: "[S]afe harbor regulations are a significant step toward alleviating concerns about the proper interpretation of the [AKS]. They give the health care community specific guideposts by which to tailor conduct, and thereby avoid prosecution for a kickback violation."[213] Congress specifically granted the OIG the authority to promulgate AKS safe harbor regulations in response to uncertainty about the reach of the AKS.[214] Furthermore, promulgating an AKS safe harbor regulation engages the public in the process of identifying which arrangements among federal health care program stakeholders are beneficial and worthy of protection from the reach of the AKS.[215]

A safe harbor may facilitate a balanced regulatory approach that can both protect against abusive uses of Independent Charity PAPs and preserve the safety net aid these entities provide to financially vulnerable patients.[216] In its guidance, the OIG has already identified criteria for

guidance to ensure we can continue to put patients in need first,' said Clorinda Walley, President of Good Days.").

211. Kathleen M. Boozang & Simone Handler-Hutchinson, *"Monitoring" Corporate Corruption: DOJ's Use of Deferred Prosecution Agreements in Health Care*, 35 AM. J.L. & MED. 89, 98 (2009).

212. *See supra* notes 92–96 and accompanying text.

213. Richard P. Kusserow, *The Medicare & Medicaid Anti-Kickback Statute and the Safe Harbor Regulations—What's Next?*, 2 HEALTH MATRIX 49, 62 (1992).

214. *See* 42 U.S.C. § 1320a-7b(b)(3)(E) (2012); *supra* notes 114–116 and accompanying text.

215. 42 U.S.C. § 1320a-7d(a); *see also* H.R. REP. NO. 104-496, at 84 (1996) (noting Congress's intent to encourage "public involvement in the process" of promulgating safe harbors).

216. Other agencies face similar challenges balancing competing interests in light of broad prohibitions against industry conduct. For instance, the FDA has intermittently employed binding and non-binding "safe harbor" guidance to address its concerns about the promotion of off-label drug use through industry-sponsored Continuing Medical Education (CME) programming. *See*

pharmaceutical manufacturer donations to Independent Charity PAPs that reduce the risks of fraud and abuse.[217] By codifying these factors as a safe harbor, the OIG would establish certainty for Independent Charity PAPs and their donors, but would not be condoning any conduct beyond what the agency has already concluded is appropriate.[218] Indeed, by clearly delineating the conditions under which pharmaceutical manufacturer donations to Independent Charity PAPs are permissible, a safe harbor would be responsive to those who have called upon the OIG to strengthen its regulation of such donations.[219] Even critics suggest that compliance with the criteria the OIG has previously suggested "could maximize the benefits and reduce the harms" of pharmaceutical manufacturer donations to Independent Charity PAPs.[220] A safe harbor would also provide a more stable regulatory structure than ad hoc guidance and would likely reduce the need for drastic measures to prevent interruptions in financially vulnerable Medicare beneficiaries' access to prescription drugs, such as the OIG's response to CVC's sudden suspension of financial assistance.[221] The provision of free drugs from a manufacturer arguably presents a stronger risk of steering than general financial assistance from an Independent Charity PAP because the patient must choose only that manufacturer's drugs and would not be able to use

generally Lars Noah, *Truth or Consequences?: Commercial Free Speech v. Public Health Promotion (at the FDA)*, 21 HEALTH MATRIX 31 (2011) (discussing the FDA's difficulty balancing constraints on the dissemination of information about the use of drugs and medical devices with First Amendment commercial free speech protections).

217. *See supra* Section II.C.

218. Moreover, a safe harbor protecting arrangements that defray Medicare beneficiaries' cost-sharing responsibilities would not be unprecedented. Statutory AKS safe harbors currently protect drug price discounts provided to Medicare beneficiaries in certain circumstances. *See* 42 U.S.C. § 1320a-7b(b)(3); *see also* Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,624 & n.4 (Nov. 22, 2005) (noting that a "safe harbor protects cost-sharing waivers offered to individuals who qualify for the [LIS]"). Under the Medicare Gap Discount Program, 42 U.S.C. § 1395w-114ag, "[m]anufacturers of brand-name drugs and originator biologics must provide a 50 percent discount during the coverage-gap phase of the [Medicare Part D] benefit as a condition for Part D to cover their drugs." MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 57, at 402.

219. Katherine Kraschel & Gregory Curfman, *Patient Assistance Programs and Anti-Kickback Laws*, 322 JAMA 405, 406 (2019).

220. Howard, *supra* note 11, at 99 ("Drug companies could maximize the benefits and reduce the harms associated with patient-assistance programs by targeting their assistance to low-income patients; providing assistance for all medical expenses, not just expenses for a specific drug; and limiting assistance to patients whose out-of-pocket costs have exceeded a threshold, similar to what is done when an out-of-pocket maximum is used in an insurance plan. Programs constructed along these lines would expand patient access without undermining the beneficial aspects of cost sharing."); *see also* Ubel & Bach, *supra* note 11, at 879 (suggesting short-term and long-term approaches to reduce "[t]he inflationary effects of copay assistance" and "address the underlying problem—the disassociation of drug prices from the benefits those drugs deliver").

221. *See supra* note 6 and accompanying text.

the in-kind assistance to defray ancillary treatment costs.

CONCLUSION

Fueled by drug company donations, Independent Charity PAPs have grown rapidly over the past two decades. These charitable entities offer a financial refuge for ailing Medicare beneficiaries struggling to afford their prescription drugs. However, federal prosecutors, *qui tam* relators, and regulators have increasingly scrutinized the relations between the pharmaceutical industry and Independent Charity PAPs. This scrutiny has exposed uncertainty about the applicability of the AKS to Independent Charity PAPs and their donors. To preserve the safety net assistance provided by Independent Charity PAPs and guard against the risk that misuse of these entities will lead to waste and abuse of federal health insurance program resources, it may be necessary for the OIG to promulgate an AKS regulatory safe harbor for Independent Charity PAPs and their donors.