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## Pharmaceutical Philanthropy or Resisting Regulations?: Why Pharmaceutical Donations Do Not Violate the Anti-Kickback Statute

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# Pharmaceutical Philanthropy or Resisting Regulations?

## WHY PHARMACEUTICAL DONATIONS DO NOT VIOLATE THE ANTI-KICKBACK STATUTE

### INTRODUCTION

With health care costs spiraling out of control in recent decades, the fear of being slammed with a bill that will cost an arm and a leg has made Americans literally risk losing that arm and leg. Instead of going to the doctor and receiving necessary treatment when sick or injured, a recent survey published by NORC and West Health reported that forty percent of Americans reported forgoing medical attention in 2018 alone due to financial concerns.<sup>1</sup> Due to the complex nature of health care, the many health care programs that the federal government has initiated remain insufficient at resolving this crisis.<sup>2</sup> These programs were designed to help groups, such as the elderly, the disabled, the indigent, veterans, and Native Americans.<sup>3</sup> Although these programs—such as Medicare and Medicaid—do provide access to health care for over one hundred million beneficiaries,<sup>4</sup> they do not guarantee affordable costs.<sup>5</sup> In fact, many respondents in the West

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<sup>1</sup> Press Release, NORC & West Health Inst., New Survey Finds Large Number of People Skipping Necessary Medical Care Because of Cost (Mar. 26, 2018), <http://www.norc.org/NewsEventsPublications/PressReleases/Pages/survey-finds-large-number-of-people-skipping-necessary-medical-care-because-cost.aspx> [<https://perma.cc/58FP-VY8D>].

<sup>2</sup> See, e.g., Bernie Sanders & James E. Clyburn, *American Healthcare Is in Crisis. We Must Fight for the Real Needs of the People*, GUARDIAN (June 30, 2017, 11:44 EDT), <https://www.theguardian.com/us-news/2017/jun/30/american-healthcare-bernie-sanders-james-clyburn> [<https://perma.cc/83W7-VPFF>]; COMM. ON ENHANCING FED. HEALTHCARE QUALITY PROGRAMS & INST. OF MED., LEADERSHIP BY EXAMPLE: COORDINATING GOVERNMENT ROLES IN IMPROVING HEALTH CARE QUALITY 28–29 (Janet M. Corrigan et al. eds., 2003) [hereinafter LEADERSHIP BY EXAMPLE] (noting that the federal government’s six major programs serving millions of Americans—“Medicare, Medicaid, the State Children’s Health Insurance Program (CHIP), the Department of Defense TRICARE and TRICARE for Life programs (DOD TRICARE), the Veteran’s Health Administration (VHA) program, and the Indian Health Service (IHS) program”—require reforms across the board to improve health care quality).

<sup>3</sup> See LEADERSHIP BY EXAMPLE, *supra* note 2, at 29.

<sup>4</sup> *Id.* at 28.

<sup>5</sup> See Hadley Heath Manning, *No Matter What You Call It, Government-Run Health Care Will Never Work*, HILL (Feb. 27, 2018, 1:30 PM), <https://thehill.com/opinion/>

Health survey reported receiving “a medical bill for something they thought was covered by their health insurance.”<sup>6</sup> To make matters worse, of the respondents that did make a trip to the doctor’s, one-in-three reported either a failure to purchase their prescription or use of a reduced dosage in order to save money.<sup>7</sup>

In an effort to combat this crisis, pharmaceutical companies have taken the initiative to absorb some of these costs.<sup>8</sup> Pharmaceutical manufacturers have designed financial channels, known as patient assistance programs (PAPs), to assist patients that need certain prescription drugs.<sup>9</sup> In 2006, the Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS) issued an advisory opinion stating that pharmaceutical companies would not categorically be subject to administrative sanctions for sponsoring patient assistance programs (PAPs).<sup>10</sup> Although this advisory opinion approved two specific PAPs which provided free prescription medications to uninsured patients and Medicare Part D enrollees,<sup>11</sup> HHS encouraged the pharmaceutical industry to heed the meaningful advice provided by OIG advisory opinions regarding the Anti-Kickback Statute.<sup>12</sup> Due to the OIG rescinding guidance regarding permissible PAPs, pharmaceutical funding for PAPs has been reduced.<sup>13</sup> The Department of Justice (DOJ) has started to crack down on the endeavors’ of PAPs.

In December 2017, drug maker United Therapeutics agreed to a \$210 million settlement with the DOJ to resolve claims that it violated the False Claims Act (FCA) by using an independent charity organization to funnel support to its Medicare patients

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healthcare/375810-no-matter-what-you-call-it-government-run-health-care-will-never-work [https://perma.cc/EH4K-DGZK].

<sup>6</sup> NORC & West Health Inst., *supra* note 1.

<sup>7</sup> *Id.*

<sup>8</sup> Marie A. Chisholm & Joseph T. DiPiro, *Pharmaceutical Manufacturer Assistance Programs*, 162 ARCHIVES INTERNAL MED. 780, 780–81 (2002).

<sup>9</sup> *Pharmaceutical Assistance Program*, MEDICARE.GOV, <https://www.medicare.gov/pharmaceutical-assistance-program/> [https://perma.cc/5M96-F7U4].

<sup>10</sup> Office of Inspector Gen., U.S. Dep’t of Health & Human Servs., Advisory Op. No. 06-03 (Apr. 18, 2006).

<sup>11</sup> Dara Corrigan et al., *HHS OIG Advisory Opinion Approves Two Patient Assistance Programs for Medicare Part D Enrollees*, ARNOLD & PORTER LLP (Apr. 2006), [https://files.arnoldporter.com/arnold&porteradvisory-hhsoigadvisoryopinionapprovestwopatientsassistanceprogramsformedicarepartdenrollees\(0406\).pdf](https://files.arnoldporter.com/arnold&porteradvisory-hhsoigadvisoryopinionapprovestwopatientsassistanceprogramsformedicarepartdenrollees(0406).pdf) [https://perma.cc/LX6N-3XDQ].

<sup>12</sup> Office of Inspector Gen., U.S. Dep’t of Health & Human Servs., Advisory Op. No. 02-1, <https://oig.hhs.gov/compliance/advisory-opinions/index.asp> [https://perma.cc/XHS3-JBUB].

<sup>13</sup> Michelle Huntsman, *Kicking Costs Back to Patients: How Regulatory Scrutiny of Patient Assistance Programs Will Affect Patients’ Wallets*, J. HEALTH CARE COMPLIANCE, July–Aug. 2018, at 27, 27.

taking a number of pulmonary arterial hypertension drugs.<sup>14</sup> Similarly, in May 2018, Jazz Pharmaceuticals PLC, the maker of the narcolepsy drug Xyrem, disclosed in its securities filing that it reached a \$57 million settlement agreement with the DOJ regarding a charities-donation investigation.<sup>15</sup> A few weeks later, drug manufacturer Pfizer, Inc. agreed to pay \$23.85 million to settle claims that it indirectly covered copays of its Medicare patients taking cancer medications, such as Sutent and Inlyta.<sup>16</sup>

As the health care industry rapidly evolves, so does the difficulty in interpreting and applying federal legislation, such as the Anti-Kickback Statute (AKS) and the FCA. The federal AKS penalizes any individual or entity for receiving remuneration for referring an individual in obtaining any item or service for which a federal health care program provides funds.<sup>17</sup> Although the AKS was originally enacted to combat unethical health care fraud, the OIG has increased scrutiny through its advisory opinions to encompass superficially harmless activities, such as the practice of pharmaceutical companies donating to independent PAPs.<sup>18</sup> The FCA creates civil liability for fraudulent submissions seeking reimbursements from the government.<sup>19</sup> The scope of this act has also extended to health care fraud, as it punishes those that submit fraudulent claims seeking reimbursement from Medicare or Medicaid.<sup>20</sup> Each of these pieces of legislation go hand-in-hand—as theorized in a *qui tam* suit brought against a specialty pharmacy.<sup>21</sup> The court in *Greenfield* drew a link between the FCA

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<sup>14</sup> Press Release, Office of Pub. Affairs, U.S. 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/7JF8-WVRN].

<sup>15</sup> Robert Langreth & Ben Elgin, *Jazz Pharmaceuticals Sets Aside \$57 Million to Settle DOJ Probe*, BLOOMBERG (May 8, 2018, 6:24 PM), <https://www.bloomberg.com/news/articles/2018-05-08/jazz-pharmaceuticals-sets-aside-57-million-to-settle-doj-probe> [https://perma.cc/W373-DQU5].

<sup>16</sup> Press Release, Office of Pub. Affairs, U.S. 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/EJK5-6EKD].

<sup>17</sup> 42 U.S.C. § 1320a-7b(b).

<sup>18</sup> See Richard P. Church et al., *Increased Scrutiny of Patient Assistance Programs: Enforcement Overview and Considerations*, K&L GATES (Mar. 20, 2018), <http://www.klgates.com/increased-scrutiny-of-patient-assistance-programs-enforcement-overview-and-considerations-03-20-2018/> [https://perma.cc/ZPM8-85GS].

<sup>19</sup> 31 U.S.C. § 3729.

<sup>20</sup> Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Justice Department Recovers Over \$2.8 Billion from False Claims Act Cases in Fiscal Year 2018 (Dec. 21, 2018), <https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018> [https://perma.cc/P87Z-QP4L].

<sup>21</sup> See *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018) (holding that temporal proximity between a kickback and a submission for claims reimbursement is insufficient to satisfy the elements of a False Claims Act violation).

and the AKS on the basis that “[b]ecause any kickback violation is not eligible for reimbursement, to certify otherwise violates the False Claims Act.”<sup>22</sup> The *Greenfield* court looked to legislative history of the statutes and reasoned that “Congress intended both statutes to reach a broad swath of ‘fraud and abuse’ in the federal healthcare system.”<sup>23</sup> The recent settlements illustrate efforts by the government to curb violations of the AKS and FCA by pharmaceutical donors and independent PAPs.

Congress has acknowledged the dangerously excessive costs of health care. By discouraging pharmaceutical donors from absorbing costs through PAPs, however, government prosecution of AKS violations raise an alarming public concern: lack of access to affordable health care. Currently, the DOJ and OIG investigate kickback violations by examining whether pharmaceutical donations to PAPs induce patients to purchase certain products, resulting in governmental subsidizations of such products.<sup>24</sup> Such inducement ties in with the remunerative aspects of PAPs which the OIG has addressed: (i) indirect remunerations such as donor contributions; and (ii) direct remunerations such as financial assistance.<sup>25</sup> Further, the OIG analyzes whether “a donation is made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor’s federally reimbursable items” and if direct financial assistance is made “to influence the patient to purchase . . . certain items.”<sup>26</sup> Due to the benefits that PAPs provide patients, a direct causal link test ought to be adopted both for the DOJ and the OIG in deciding whether or not to bring an enforcement action against a pharmaceutical company and also for the federal court system as courts interpret these statutes. By investigating why beneficiaries chose a specific PAP, a court can accurately identify whether or not the intent requirement is satisfied to find an AKS violation. The foundation of this argument rests on policy interests regarding the negative effects of restricting PAPs. This note will analyze the costs of the U.S. health care system in order to demonstrate the need for PAPs as a way to significantly reduce patient health care costs.

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<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 96.

<sup>24</sup> Brett Friedman et al., *Emerging Enforcement Trends for Patient Support Programs*, ROPES & GRAY LLP (May 16, 2018), <https://www.ropesgray.com/en/newsroom/alerts/2018/05/Emerging-Enforcement-Trends-For-Patient-Support-Programs> [<https://perma.cc/9PBP-79TW>].

<sup>25</sup> Office of Inspector Gen., Dep’t of Health & Human Servs., Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120, 31,121 (May 30, 2014).

<sup>26</sup> *Id.*

Part I of this note will provide background on the rising costs of health care in the United States to support the importance of providing leeway when assessing whether or not pharmaceutical companies have violated the AKS. Part II will examine the current state of federal health care legislation. Part III will address the mechanisms of PAPs and their interactions with pharmaceutical donors. Lastly, Part IV will propose a potential solution. When determining whether or not the AKS has been violated, courts must apply a direct causal link test: but-for the pharmaceutical company's donation, the patient would not have selected the specific provider.

## I. THE RISING COSTS OF HEALTH CARE

The United States spent more than \$3.3 trillion, or nearly a fifth of its gross domestic product (GDP), on health expenditures in 2016.<sup>27</sup> By comparison, the United States spent just five percent of its GDP on health care in 1960.<sup>28</sup> The United States spends an exorbitant amount of money on health care that is disproportional to the size of its wealth, compared to other wealthy nations, such as Canada, France, and the United Kingdom.<sup>29</sup> Other affluent nations only spend about half as much per person on health care in comparison.<sup>30</sup> While the United States spent approximately \$10,244 per person in 2017, the comparable country average was at \$5,280.<sup>31</sup> Part I discusses the many factors that have contributed to the rise in health care costs such as market consolidation, drug costs, and the effect of the rising uninsured rate.

### A. Market Consolidation

Prices—rather than the quantity of care—have driven the increase in U.S. spending.<sup>32</sup> One factor contributing to this

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<sup>27</sup> See NORC & West Health Inst., *supra* note 1.

<sup>28</sup> Kimberly Amadeo, *The Rising Cost of Health Care by Year and Its Causes: See for Yourself If Obamacare Increased Health Care Costs*, BALANCE (June 25, 2010), <https://www.thebalance.com/causes-of-rising-healthcare-costs-4064878> [<https://perma.cc/27VS-QFNT>].

<sup>29</sup> Bradley Sawyer & Cynthia Cox, *How Does Health Spending in the U.S. Compare to Other Countries?*, PETERSON-KAISER HEALTH SYS. TRACKER (Dec. 7, 2018), <https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start> [<https://perma.cc/EE9M-FLYK>].

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> See Joseph Walker, *Why Americans Spend So Much on Health Care—In 12 Charts*, WALL STREET J. (July 31, 2018), <https://www.wsj.com/articles/why-americans-spend-so-much-on-health-care-in-12-charts-1533047243> [<https://perma.cc/Z9MF-KGSR>].

increase in price is hospital consolidation,<sup>33</sup> which increases hospitals' market power.<sup>34</sup> Although a solution would be to scrutinize large hospital systems for potentially violating antitrust laws, health care professionals are concerned this would lead to hospital closures,<sup>35</sup> only aggravating the current health care crisis—necessitating a far less restrictive solution. Hospitals that monopolize in any given geographic area tend to charge more for procedures as opposed to areas with “four or more competing hospitals.”<sup>36</sup> Although “[h]ighly concentrated markets . . . are associated with higher health care prices . . . , [they] are not typically associated with higher quality of care.”<sup>37</sup> The legal system should reframe focus on reducing its scrutiny on pharmaceutical donations because concentration levels between providers and insurers vary across the United States due to the large role given to states in regulating health care provider and insurer markets.<sup>38</sup> Although insurers have higher bargaining power to reduce prices in highly concentrated provider-insurer markets, rarely do consumers benefit.<sup>39</sup> Insurers apply this power by utilizing pharmacy benefit managers (PBMs), which are companies that negotiate directly with pharmaceutical companies on behalf of insurance companies.<sup>40</sup> Just as negotiating power is shifted away from pharmaceutical companies, so should the scrutiny concerning their donations to PAPs.

## B. Drug Prices

The increase in prescription drug prices is a second factor of the upsurge in U.S. health care spending.<sup>41</sup> In 2014, total

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<sup>33</sup> *Id.*

<sup>34</sup> Brent D. Fulton et al., *Market Concentration and Variation of Health Care Providers and Health Insurers in the United States*, COMMONWEALTH FUND (July 30, 2018), [https://www.commonwealthfund.org/blog/2018/variation-healthcare-provider-and-health-insurer-market-concentration?mod=article\\_inline](https://www.commonwealthfund.org/blog/2018/variation-healthcare-provider-and-health-insurer-market-concentration?mod=article_inline) [<https://perma.cc/DX4R-SLZR>].

<sup>35</sup> Luanne Rife, *FTC Seeks to Determine if Hospital Monopolies Help or Harm Patients*, ROANOKE TIMES (July 1, 2019), <https://www.centerforhealthjournalism.org/fellowships/projects/ftc-seeks-determine-if-hospital-monopolies-help-or-harm-patients> [<https://perma.cc/99SD-FKKB>].

<sup>36</sup> Walker, *supra* note 32.

<sup>37</sup> Fulton et al., *supra* note 34.

<sup>38</sup> *See id.*

<sup>39</sup> *Id.*

<sup>40</sup> Joel T. Dodge, *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), <https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending> [<https://perma.cc/AV34-QQG5>].

<sup>41</sup> *See* OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING AND EVALUATION, U.S. DEP'T. OF HEALTH & HUMAN SERVS., REPORT TO CONGRESS: PRESCRIPTION DRUGS: INNOVATION, SPENDING, AND PATIENT ACCESS 4 (2016).

spending on prescription drugs was approximately \$424 billion.<sup>42</sup> Combined with the rise in drug prices, the funding required for the research and development of these drugs has also risen.<sup>43</sup> The “cost of bringing a new drug to market is very high,” while the cost of replicating existing products is low.<sup>44</sup> Research and development is driven by the rewards of pharmaceutical innovation such as market exclusivity and patent protection, which is made possible through stringent federal regulations.<sup>45</sup> By patenting new drugs, pharmaceutical companies are protected against competition, giving these companies the power to substantially dictate pricing.<sup>46</sup> Generally, pharmaceutical companies hold the exclusive patent rights for fourteen years.<sup>47</sup> When the patent expires, other companies are permitted to produce generic versions of the drug, which can be up to ninety-five percent cheaper than the original.<sup>48</sup>

Opponents of these intellectual property rights contend that pharmaceutical companies exploit exclusivity regulations through tactics such as “evergreening” and “hard switching.”<sup>49</sup> Evergreening—when a company patents a slightly different version of an existing drug—is a renewal process used to keep generic companies out of the market for a longer period of time.<sup>50</sup> This method extends patents for modifications in dosage, molecular structure, delivery mechanism, packaging, and much more.<sup>51</sup> Companies are permitted to market the newly patented alternative

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<sup>42</sup> *Id.*

<sup>43</sup> See Matthew Herper, *The Cost of Developing Drugs Is Insane. That Paper That Says Otherwise Is Insanely Bad*, FORBES (Oct. 16, 2017, 10:58 AM), <https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/#79e51dee2d45> [<https://perma.cc/FG86-8GWY>].

<sup>44</sup> Richard G. Frank & Paul B. Ginsburg, *Pharmaceutical Industry Profits and Research and Development*, HEALTH AFF. BLOG (Nov. 13, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171113.880918/full/> [<https://perma.cc/QGW2-JUUV>].

<sup>45</sup> See *id.*; see also *Frequently Asked Questions on Patents and Exclusivity*, FDA.GOV, <https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity> [<https://perma.cc/P7QT-D8H8>] (explaining the distinction between exclusivity and patents).

<sup>46</sup> Hazel Moir & Deborah Gleeson, *Explainer: Evergreening and How Big Pharma Keeps Drug Prices High*, CONVERSATION (Nov. 5, 2014, 2:27 PM EST), <http://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623> [<https://perma.cc/EN63-XDDU>].

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> Dennis Thompson, *What's Behind the Sharp Rise in Prescription Drug Prices?*, CBS NEWS (Aug. 24, 2016, 11:17 AM), <https://www.cbsnews.com/news/whats-behind-the-sharp-rise-in-prescription-drug-prices/> [<https://perma.cc/MQJ5-8HQ3>].

<sup>50</sup> Moir & Gleeson, *supra* note 46.

<sup>51</sup> See generally Arun Kumar & Arun Nanda, *Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries*, PHARMACEUTICAL REG. AFF.: OPEN ACCESS (Apr. 18, 2017), <https://www.omiconline.org/open-access/evergreening-in-pharmaceuticals-strategies-consequences-and-provisions-for-prevention-in-usa-eu-india-and-other-countries-2167-7689-1000185.pdf> [<https://perma.cc/BE32-73GK>] (surveying the many methods pharmaceutical companies employ to accomplish evergreening).



under a different name (known as “brand migration”), as evidenced by AstraZeneca marketing Nexium as the more effective version of Prilosec—a profitable treatment for heartburn with an expiring patent.<sup>52</sup> Hard switching occurs when “manufacturers stop selling an older drug [that is] about to go generic and replace it with a new high-price market-exclusive product.”<sup>53</sup> By removing a previous version of a brand drug, physicians and patients are significantly limited in their choice of prescription.<sup>54</sup>

While most consumers could refuse to pay for these drugs, Medicare beneficiaries cannot do so.<sup>55</sup> This is because federal law prevents the Center for Medicare & Medicaid Services (CMS) from negotiating with drug manufacturers.<sup>56</sup> Essentially, refusing to pay manufacturers’ prices is not an option. PBMs are believed to be better able to negotiate drug prices than the government.<sup>57</sup> PBMs are effective negotiators due to the fact that they use volume-buying to negotiate discounts.<sup>58</sup> The Medicare Modernization Act of 2003, which included a restriction on direct government involvement in Part D price negotiations, resulted in PBMs playing an active role in Part D plan negotiations.<sup>59</sup>

### C. *Rates of Uninsured*

Another factor contributing to the rise in health care costs is the number of uninsured individuals.<sup>60</sup> According to a Gallup report, over thirteen percent of U.S. adults were uninsured in 2018—the highest level since the implementation of the Affordable Care Act and the repeal of its individual

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<sup>52</sup> *Id.*

<sup>53</sup> Thompson, *supra* note 49.

<sup>54</sup> Chelsea E. Ott, Comment, *The Evolution of Pharmaceutical Regulatory Gaming Practices*, 47 SETON HALL L. REV. 849, 862 (2017).

<sup>55</sup> Thompson, *supra* note 49.

<sup>56</sup> 42 U.S.C. § 1395w-111(i)(1)–(2). *But see* Medicare Prescription Drug Price Negotiation Act of 2017, S. 41, 115th Cong. (2017) (seeking to amend Title XVIII of the Social Security Act to require CMS to negotiate with pharmaceutical companies regarding prices for drugs covered under the Medicare prescription drug benefit).

<sup>57</sup> John Wasik, *Why Medicare Can’t Get the Lowest Prices*, FORBES (Aug. 10, 2018, 8:26AM), <https://www.forbes.com/sites/johnwasik/2018/08/10/why-medicare-cant-get-the-lowest-drug-prices/#3e3b5bae302b> [<https://perma.cc/HB4K-QAP6>].

<sup>58</sup> *See* Cole Werble, *Pharmacy Benefit Managers*, HEALTH AFF. (Sept. 14, 2017), <https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full> [<https://perma.cc/4CHZ-HT8F>].

<sup>59</sup> *Id.*

<sup>60</sup> *See* David Mills, *Why You Should Care if Your Neighbor Doesn’t Have Health Insurance*, HEALTHLINE (May 14, 2018), <https://www.healthline.com/health-news/why-you-should-care-if-your-neighbor-doesnt-have-health-insurance#1> [<https://perma.cc/DQK9-6BS3>].

mandate.<sup>61</sup> The individual mandate, effected through a large overhaul of the U.S. tax code, required most Americans to purchase health insurance or else pay a fine.<sup>62</sup> But the number of uninsured individuals increases if there is no penalty for failure to have health insurance.<sup>63</sup> By weakening the law, the cost of health insurance premiums subsequently rises when there are fewer insured individuals.<sup>64</sup>

Reliance on PAPs does not have the potential to further exacerbate the underinsurance rate because PAP beneficiaries are those who are currently underinsured. In the event the number of PAP applicants does rise, PAPs would likely respond by tightening the eligibility criteria, similar to how other social safety nets operate when a culture of dependency is looming.<sup>65</sup>

With this dangerous rise in health care costs, efforts to improve both affordability and access to health care services are essential. Rather than targeting the intent of pharmaceutical donors when investigating AKS and FCA violations, the courts should apply a direct causal link test—ultimately encompassing the patients' reasons for selecting a PAP. If the intent requirements of the statute are not satisfied,<sup>66</sup> the result would be low-income individuals being able to afford the prescription drugs they need.

## II. CURRENT FEDERAL HEALTH CARE LEGISLATION

While Congress enacted current health care legislation, the executive branch, especially HHS, is in the best position to apply “all of the evidence, data, and reasoning necessary for the formulation of sound health policies”<sup>67</sup> in order to protect public well-being. HHS spearheads initiatives to improve public health

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<sup>61</sup> Dan Witters, *U.S. Uninsured Rates Rises to Four-Year High*, GALLUP (Jan. 23, 2019), <https://news.gallup.com/poll/246134/uninsured-rate-rises-four-year-high.aspx> [<https://perma.cc/JP6L-V4YG>].

<sup>62</sup> Yasmeen Abutaleb, *U.S. Healthcare Spending to Climb 5.3 Percent in 2018*; Agency, REUTERS (Feb. 14, 2018, 4:07 PM), <https://www.reuters.com/article/us-usa-health-care-spending/u-s-healthcare-spending-to-climb-5-3-percent-in-2018-agency-idUSKCN1FY2ZD> [<https://perma.cc/YM2R-6DG5>].

<sup>63</sup> See Sy Mukherjee, *The GOP Tax Bill Repeals Obamacare's Individual Mandate. Here's What That Means for You*, FORTUNE (Dec. 20, 2017), <http://fortune.com/2017/12/20/tax-bill-individual-mandate-obamacare/> [<https://perma.cc/46NN-NR98>].

<sup>64</sup> Abutaleb, *supra* note 62.

<sup>65</sup> Rema Hanna, *New Research Busts the Myth of Welfare Dependency*, WORLD ECON. F. (Aug. 12, 2019), <https://www.weforum.org/agenda/2019/08/golden-truth-behind-welfare-dependency> [<https://perma.cc/Y2Z5-KRHL>].

<sup>66</sup> See *infra* II.A–B.

<sup>67</sup> Lawrence Gostin, *The Formulation of Health Policy by the Three Branches of Government*, in SOCIETY'S CHOICES: SOCIAL AND ETHICAL DECISION MAKING IN BIOMEDICINE 335, 351 (Ruth Ellen Bulger et al. eds., 1995), <https://www.ncbi.nlm.nih.gov/books/NBK231979/> [<https://perma.cc/BW8T-3HJH>].

and furthers medical research.<sup>68</sup> Although HHS developed programs such as Medicaid and Medicare to benefit American citizens, rising health care fraud has resulted in detrimental effects to these individuals. The government sought to combat this fraud through legislation such as the AKS and the FCA.<sup>69</sup> However, as Congress broadened the reach of these laws, entities such as PAPs have come under increasing scrutiny<sup>70</sup> which has led to detrimental impacts on the public health crisis.

## A. *The Anti-Kickback Statute*

### 1. History and Development

The AKS is “an anti-corruption statute designed to protect federal health care program beneficiaries from the influence of money on referral decisions.”<sup>71</sup> The federal AKS penalizes any individual or entity that:

knowingly and willfully solicits or receives any remuneration . . . directly or indirectly, . . . in return for referring an individual to a person for the furnishing . . . of any item or service for which payment may be made in whole or in part under a Federal health care program . . . .<sup>72</sup>

The AKS reaches a broad range of business relationships, specifically in the “pharmaceutical and medical device sectors.”<sup>73</sup> This criminal statute “prohibits transactions intended to induce or reward referrals for items or services reimbursed by the federal health care programs” (i.e., drugs, supplies, or health care services for Medicare or Medicaid patients).<sup>74</sup> Remuneration encompasses “anything of value,” including “free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.”<sup>75</sup> Violating the AKS results in fines, jail terms, and exclusion from participation in federal health care programs.<sup>76</sup> Ultimately, through the AKS, Congress aimed to prevent overutilization of health care services,

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<sup>68</sup> *See id.*

<sup>69</sup> Thomas S. Crane et al., *What Is the Anti-Kickback Statute*, A.B.A. (2014), [https://www.americanbar.org/groups/young\\_lawyers/publications/tyl/topics/health-law/what-is-anti-kickback-statute/](https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/health-law/what-is-anti-kickback-statute/) [<https://perma.cc/HD56-RVXL>].

<sup>70</sup> *See infra* Part III.

<sup>71</sup> Crane et al., *supra* note 69.

<sup>72</sup> 42 U.S.C. § 1320a-7b(b).

<sup>73</sup> Crane et al., *supra* note 69.

<sup>74</sup> *Id.*

<sup>75</sup> *A Roadmap for New Physicians: Fraud & Abuse Laws*, OFF. INSPECTOR GEN., <https://oig.hhs.gov/compliance/physician-education/01laws.asp> [<https://perma.cc/VG2G-F38A>] [hereinafter *A Roadmap for New Physicians*].

<sup>76</sup> *Id.*

corruption of medical decision-making, increased program costs, patient steering, unfair competition, and poor-quality services.<sup>77</sup> The reasoning behind this legislation is that providers, who refer other health care professionals, can easily be targeted by kickback schemes.<sup>78</sup>

When Congress initially passed the AKS in 1972, the act had no scienter requirement, lacked exclusionary guidelines, and did not categorize the violation as a felony.<sup>79</sup> The act was intended to curb unethical referral activities that “led to the inappropriate use of scarce federal funds”<sup>80</sup> dedicated to the recently created Medicare and Medicaid programs.<sup>81</sup> However, the act’s limited punitive power reduced its viability as an enforcement tool.<sup>82</sup> In 1977, Congress broadened the act not only to include “bribes” or “kickbacks,” but also “to prohibit the payment of ‘remuneration’ . . . for referral.”<sup>83</sup> Congress also “upgraded the . . . violation from a misdemeanor to a felony.”<sup>84</sup> This expanded the possible range of conduct, enabling the AKS to combat fraud more effectively.<sup>85</sup>

According to committee reports on the Medicare and Medicaid Antifraud and Abuse Amendments, there were three purposes for amending the AKS.<sup>86</sup> First, Congress wanted to upgrade the penalty to a felony because the previous legislation failed to demonstrate effective deterrence.<sup>87</sup> The misdemeanor penalty was also inconsistent with federal criminal sanctions that punished similar behavior with felony penalties.<sup>88</sup> Second, the amendments were intended to “clarify ambiguous language.”<sup>89</sup> The word “remuneration” would be defined to include direct or indirect “kickbacks, bribes, or rebates.”<sup>90</sup> Third, the amendments sought to define certain business practices as outside the statute’s scope (e.g.,

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<sup>77</sup> See *A Roadmap for New Physicians*, *supra* note 75; Crane et al., *supra* note 69.

<sup>78</sup> *A Roadmap for New Physicians*, *supra* note 75.

<sup>79</sup> Robert Salcido, *Mixing Oil and Water: The Government’s Mistaken Use of the Medicare Anti-Kickback Statute in False Claims Act Prosecutions*, 6 ANNALS HEALTH L. 105, 109 (1997).

<sup>80</sup> *Id.* at 110.

<sup>81</sup> Marc Stephen Raspanti & Douglas E. Roberts, *A Practitioner’s Primer on History and Use of the Federal Anti-Kickback Statute*, PIETRAGALLO (Mar. 28, 2017), <http://www.pietragallo.com/keep-informed.php?action=view&id=402#XBu5WS-ZO8U> [<https://perma.cc/W3P8-AJLY>].

<sup>82</sup> *Id.*

<sup>83</sup> Salcido, *supra* note 79, at 111.

<sup>84</sup> *Id.*

<sup>85</sup> See Raspanti & Roberts, *supra* note 81.

<sup>86</sup> Salcido, *supra* note 79, at 111.

<sup>87</sup> *Id.* at 111–12.

<sup>88</sup> *Id.* at 112.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.* (quoting H.R. REP. NO. 95-393, pt. 2, at 53 (1977), as reprinted in 1977 U.S.C.C.A.N. 3039, 3056).

price discounts, so long as these reductions are “properly disclosed and reflected in the . . . reimbursement . . . claimed”).<sup>91</sup> In the 1980 amendment, Congress added the “knowingly and willfully” mens rea element,<sup>92</sup> resulting in interpretative differences which are the focus of this note.<sup>93</sup>

## 2. Current Interpretations of the Statute

Currently, the government is not required to show harm to the patient nor financial loss to the program to prove an AKS violation.<sup>94</sup> But the parties’ intent is the key element of their liability.<sup>95</sup> Circuit courts are divided on what constitutes the “knowing and willful” behavior necessary to violate the AKS.<sup>96</sup> In fact, the Ninth Circuit in *Hanlester Network v. Shalala* held that an AKS violation requires a “knowing and willful” mens rea that the prohibited financial arrangement violates the Anti-Kickback Statute.<sup>97</sup> The Eighth Circuit, however, has ruled that the “mens rea standard should only require proof that [the defendant] knew that [their] conduct was wrongful,” rather than proof that the defendant “knew it violated ‘a known legal duty.’”<sup>98</sup> Other courts, such as the Third Circuit, have adopted a broader view: if “one purpose” of the remuneration was to induce or reward referrals, it constitutes a violation of the AKS.<sup>99</sup> However, this broader view essentially results in the DOJ gaining unlimited discretion in alleging AKS violations against otherwise legitimate business arrangements.<sup>100</sup> Critics find it hard to believe that Congress intended such broad interpretation.<sup>101</sup>

As a result of these conflicting interpretations, Congress has directed the OIG to develop thirty regulatory “Safe Harbors,” each describing business arrangements that do not violate the AKS.<sup>102</sup> The OIG believes the inclusion of numerous standards in each safe harbor guarantees protection against the

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<sup>91</sup> *Id.* (quoting 1977 U.S.C.C.A.N. at 3056).

<sup>92</sup> *Id.*

<sup>93</sup> See *infra* Section II.A.2.

<sup>94</sup> *A Roadmap for New Physicians*, *supra* note 75.

<sup>95</sup> *Id.*

<sup>96</sup> Donn H. Herring, *Fundamentals of the Medicare Anti-Kickback Statute*, 2016 AHLA Seminar Papers 6 (Nov. 13, 2016).

<sup>97</sup> *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

<sup>98</sup> *United States v. Jain*, 93 F.3d 436, 441 (8th Cir. 1996) (emphasis omitted).

<sup>99</sup> *United States v. Greber*, 760 F.2d 68, 69, 72 (3d Cir. 1985) (holding that remuneration violated the Anti-Kickback Statute if “one purpose . . . was to induce future referrals”).

<sup>100</sup> See Herring, *supra* note 96.

<sup>101</sup> See *id.*

<sup>102</sup> *Id.*

AKS for certain business arrangements.<sup>103</sup> Failure for a business practice to fit into a safe harbor does not equate to an automatic violation of the AKS, rather it welcomes further scrutiny by the DOJ in its investigation.<sup>104</sup> Moreover, AKS violations can result in civil penalties up to three times each kickback and fines of \$15,000 per violation as well as criminal penalties.<sup>105</sup> Although Congress might have intended the AKS to prevent increased costs resulting from increased utilization of health care services, the statute itself hinders overall cost reduction attempts made by pharmaceutical companies.<sup>106</sup>

## B. *The False Claims Act*

### 1. What is the False Claims Act?

The AKS also opens the door for violations of the FCA.<sup>107</sup> The FCA protects the government against overcharging by pharmaceutical companies as well as falling victim to fraudulent sales of either goods or services.<sup>108</sup> The FCA can be differentiated between criminal and civil liabilities, as the former is brought by local, state, or federal prosecutors, whereas the latter is brought to court by the victim of the defrauding.<sup>109</sup> Additionally, criminal liability requires specific intent of the wrongdoing while civil liability foregoes such requirement.<sup>110</sup> Under the FCA, individuals or entities that submit false or fraudulent claims to Medicare or Medicaid seeking reimbursement are subject to civil liabilities.<sup>111</sup> To prove that a Medicare or Medicaid claim is false, the government must show that the procedure or provision of equipment either: (1) did not occur,<sup>112</sup> (2) did not occur as stated,<sup>113</sup>

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<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *See infra* Part III.

<sup>107</sup> 31 U.S.C. § 3729(a)(1).

<sup>108</sup> *A Roadmap for New Physicians, supra* note 75.

<sup>109</sup> *Criminal Fraud VS Civil Fraud: What's the Difference*, BOCHETTO & LENTZ PC (Mar. 23, 2015), <https://www.bochettoandlentz.com/criminal-fraud-vs-civil-fraud-whats-difference/> [<https://perma.cc/KQ5G-4QHD>].

<sup>110</sup> Norman E. Greenspan, *Best Practices: Civil Versus Criminal Liability for False Claims* (Nov. 9, 2016), <https://starfieldsmith.com/2016/11/best-practices-civil-versus-criminal-liability-for-false-claims/> [<https://perma.cc/FWF4-KX94>].

<sup>111</sup> 31 U.S.C. § 3729(a)

<sup>112</sup> *United States v. Awad*, 551 F.3d 930, 936 (9th Cir. 2009) (finding an “inference of willfulness . . . obvious” where the treatments billed to Medicare had never been performed).

<sup>113</sup> *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 498 (6th Cir. 2007) (finding inflated cost reports in Medicare and Medicaid claims to be, *inter alia*, willful conduct).

or (3) was not medically necessary.<sup>114</sup> Although the FCA “require[s] no proof of specific intent to defraud,” “the terms ‘knowing’ and ‘knowingly’” specify “a person, with respect to information” who “(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.”<sup>115</sup> Recovery under the FCA can result in penalties of up to \$11,000 per claim, as well as treble damages and the possibility of individual liability and criminal sanctions.<sup>116</sup>

## 2. Current Interpretations of the Act

Similar to the AKS, the FCA has been subject to interpretative differences regarding its intent requirement—yet another reason why courts ought to tighten the intent requirement. The Senate Judiciary Committee advised that, although individuals have an obligation to ensure accuracy when conducting business with the government, minor mistakes or inaccurate claims should not be punished.<sup>117</sup> Congress has further stated that the reckless disregard intent requirement is essentially comparable to gross negligence,<sup>118</sup> and that reckless disregard “does not require any proof of an intentional, deliberate, or willful act.”<sup>119</sup> Consistent with the legislation, courts have found for the government and have held health care professionals liable for violating the FCA, even if the defendants did not act with the specific intent to defraud the government.<sup>120</sup>

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<sup>114</sup> United States *ex rel.* Riley v. St. Luke’s Episcopal Hosp., 355 F.3d 370, 376–77 (5th Cir. 2004) (finding that allegations of unnecessary hospital admissions and upgrading of patient organ transplant status were sufficient to survive a motion to dismiss).

<sup>115</sup> 31 U.S.C. § 3729(b)(1).

<sup>116</sup> John W. Nisbett, *The Three-Headed Monster of Healthcare Fraud Enforcement: The False Claims Act, Stark Law, and the Anti-Kickback Statute*, A.B.A. (Aug. 1, 2015), [https://www.americanbar.org/groups/young\\_lawyers/publications/tyl/topics/health-law/three-headed-monster-healthcare-fraud-enforcement-false-claims-act-stark-law-anti-kickback-statute/](https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/health-law/three-headed-monster-healthcare-fraud-enforcement-false-claims-act-stark-law-anti-kickback-statute/) [<https://perma.cc/Q8NM-PMUP>].

<sup>117</sup> Salcido, *supra* note at 79, at 120 (citing S. REP. NO. 99-345, as reprinted in 1986 U.S.C.C.A.N. 5266, 5261–72).

<sup>118</sup> See 132 CONG. REC. 20,429, 20,535–36 (1986) (statement of Sen. Grassley).

<sup>119</sup> *Id.*

<sup>120</sup> See United States v. Krizek, 111 F.3d 934, 941–42 (D.C. Cir. 1997) (holding that the defendant violated the FCA by acting in reckless disregard when he knowingly submitted improper claims); see also United States v. Lorenzo, 768 F. Supp. 1127, 1132 (E.D. Pa. 1991) (holding the defendant liable under the FCA for acting in reckless disregard of the truth of falsity of the information when he submitted Medicare claims for oral cancer examinations, knowing they were improperly coded).

C. *Overlap of the Anti-Kickback Statute and False Claims Act*

Courts are split on whether a FCA action predicated on an Anti-Kickback Statute violation may be tried.<sup>121</sup> This tactic would result in plaintiffs possibly collecting damages in multiples.<sup>122</sup> The Third Circuit in *United States ex rel. Greenfield v. Medco Health Solutions, Inc.* held that “there must be some connection between a kickback and a subsequent reimbursement claim.”<sup>123</sup> In *Greenfield*, the former vice president of Accredo Health Group, Inc., a specialty pharmacy for patients with hemophilia, alleged its reimbursement claims violated the FCA because the company “made donations to charities, two of which allegedly recommended Accredo as an approved provider for hemophilia patients.”<sup>124</sup> The plaintiff argued that because the pharmacy violated the AKS by paying kickbacks to the charities designed as donations, these Medicare claims submitted for reimbursement were falsely certified—constituting a FCA violation.<sup>125</sup> Largely due to the fact the relator brought this action using circumstantial evidence, the court concluded that in order to prevail under this theory, the relator “must provide ‘evidence of the actual submission of a false claim’” that was made in violation of the AKS.<sup>126</sup> The court also noted that “Congress intended both statutes to reach a broad swath of ‘fraud and abuse’ in the federal healthcare system.”<sup>127</sup>

Similarly, a federal district court in Tennessee analyzed whether one may actually bring a FCA violation simultaneous to an AKS violation in *United States ex rel. Pogue v. American Healthcorp, Inc.*<sup>128</sup> In *Pogue*, the plaintiff alleged that because the defendants were involved in a scheme where physicians would refer their Medicare and Medicaid patients to a health care facility for treatment, in violation of the AKS, claim submissions for reimbursement violated the FCA, as these claims were fraudulent.<sup>129</sup> The court concluded that the FCA was not only intended to police fraudulent acts that defraud the government on their face, but also to apply to fraudulent acts that cause the

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<sup>121</sup> Salcido, *supra* note at 79, at 107.

<sup>122</sup> See *supra* Section II.B.

<sup>123</sup> *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018).

<sup>124</sup> *Id.* at 91

<sup>125</sup> *Id.* at 92.

<sup>126</sup> *Id.* at 97–98.

<sup>127</sup> *Id.* at 96 (quoting H.R. REP. NO. 95-393, at 47 (1977)).

<sup>128</sup> See *United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1508 (M.D. Tenn. 1996).

<sup>129</sup> *Id.*



government to reimburse “claimants it did not intend to benefit.”<sup>130</sup> A FCA action not only covers false claims, but also claims where a defendant is engaged in a fraudulent arrangement resulting in reimbursement from the government.<sup>131</sup> The court found there was a valid cause of action under the FCA because the “Defendants concealed their illegal activities from the government in an effort to defraud the government into paying Medicare claims it would not have otherwise paid.”<sup>132</sup>

The U.S. District Court for the Southern District of Texas in *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.* adopted a different approach.<sup>133</sup> In *Columbia/HCA*, plaintiff brought an action against defendants for violating the FCA, alleging that defendants’ “investment arrangements . . . provided financial inducements . . . for patient referrals.”<sup>134</sup> The defendants contended that even if the AKS was violated, there was no violation of the FCA because the cost reports (i.e., actual claims) themselves were not false, meaning they were medically necessary.<sup>135</sup> The court found for the defendants, concluding that the claim itself must be false or fraudulent in order to find liability under the FCA.<sup>136</sup> While the district court’s holding was partially vacated, the Fifth Circuit did, however, hold that claims of fraud cannot be based on “speculation and conclusory allegations.”<sup>137</sup>

The government contends that courts should permit such combined actions because, without combining the two, it would “dilute the Anti-Kickback Statute’s ‘knowing *and* willful’ standard into the False Claims Act’s ‘knowing’ standard.”<sup>138</sup> This is attractive for the government because it would essentially make it easier to find liability and to collect triple in damages, as permitted by the act. Nonetheless, an overly broad interpretation of the AKS will detrimentally affect the catalysts of change, such as PAPs, that benefit the health care industry.<sup>139</sup> Due to the differing views and lack of a definitive resolution, courts should clearly identify the reasoning behind patients’ PAP selection as a means of satisfying or failing to satisfy the legislative scienter requirements.

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<sup>130</sup> *Id.* at 1513.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, CHC Holdings, 938 F. Supp. 399, 406–07 (S.D. Tex. 1996) (holding the claim itself must be fraudulent), *aff’d in part and vacated in part*, 125 F.3d 899 (5th Cir. 1997).

<sup>134</sup> *Id.* at 401.

<sup>135</sup> *Id.* at 406.

<sup>136</sup> *Id.* at 406–07.

<sup>137</sup> *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, CHC Holdings, 125 F.3d 899, 903 (5th Cir. 1997).

<sup>138</sup> Salcido, *supra* note 79, at 108.

<sup>139</sup> *See id.*

While the government sources its discretionary power from the dual use of the statutes to combat health care fraud, it inadvertently curbs the beneficial practices employed by pharmaceutical companies—such as the use of PAPs—to reduce patient costs. It is thus imperative to not only analyze the policy ramifications of this enforcement strategy but also consider the legal test that courts apply to these violations. Since the government is using the FCA to bypass the intent requirements of the AKS, courts must apply a stricter legal test to determine whether companies violated the AKS.

### III. PATIENT ASSISTANCE PROGRAMS

The future of PAPs are under threat due to the government's prosecution of such programs under both the AKS and the FCA; however, the current interpretation of these two statutes must be reconsidered in light of the fact that these programs significantly improve patient access to affordable health care. By scrutinizing donations received by PAPs, the DOJ and OIG severely limit patient access to critical funds to receive prescription drugs and the government's prosecution further disincentivizes pharmaceutical companies from innovating new solutions for patients in need.

#### A. *What Are Patient Assistance Programs?*

Patient assistance programs, also known as pharmaceutical/prescription assistance programs, are offered by pharmaceutical companies as a method of financial assistance for consumers that need certain prescription drugs.<sup>140</sup> PAPs help patients by subsidizing out-of-pocket costs.<sup>141</sup> Independent charity organizations administer PAPs.<sup>142</sup> Other nonprofit groups and state government programs also sometimes offer assistance to cover the costs of these prescription drugs.<sup>143</sup>

Patients seeking assistance can apply directly through the pharmaceutical company.<sup>144</sup> Some examples of notable PAPs

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<sup>140</sup> NAT'L COUNCIL ON PATIENT INFO. & EDUC., UNDERSTANDING PRESCRIPTION ASSISTANCE PROGRAMS 1 (PAPs), <https://www.bemedwise.org/wp-content/uploads/2019/12/paps.pdf> [<https://perma.cc/VT7K-XJDF>].

<sup>141</sup> So-Yeon Kang et al., *Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs*, 322(5) NEW ENG. J. MED. 422–29 (Aug. 6, 2019).

<sup>142</sup> See *supra* note 18.

<sup>143</sup> *Patient Assistance Programs for Prescription Drugs*, WEBMD, <https://www.webmd.com/healthy-aging/patient-assistance-programs-for-prescription-drugs#1> [<https://perma.cc/592C-E9Y2>].

<sup>144</sup> *Id.*

include: the Bristol-Myers Squibb Patient Assistance Foundation,<sup>145</sup> Pfizer RxPathways,<sup>146</sup> Merck Patient Assistance Program,<sup>147</sup> and the GSK Patient Assistance Program.<sup>148</sup> PAPs typically collect both patient financial information, with the requirements being determined by the pharmaceutical company, and prescription information from the respective physicians.<sup>149</sup> The pharmaceutical company reviews the application and decides whether or not the patient is eligible for assistance.<sup>150</sup> Examples of eligibility requirements include: lack of insurance coverage for the necessary prescription drug, current residence in either the United States or one of the U.S. territories, current outpatient treatment by a U.S. licensed prescriber, and a yearly income at or below three hundred percent of the Federal Poverty Level.<sup>151</sup> Once approved, the patient or the patient's physician will receive a limited supply of the prescription at either no cost or a reduced cost.<sup>152</sup> PAPs have also covered co-payment obligations.<sup>153</sup> By doing so, PAPs provide financial relief for patients who need fundamental prescription drugs.

Some PAPs even include support systems that provide advice to patients about various medications.<sup>154</sup> For example, Pfizer Rx Pathways, a PAP associated directly with the manufacturer Pfizer, not only offers financial assistance, but also treatment-specific patient support hubs.<sup>155</sup> Specifically, hemophiliac patients prescribed BeneFix or Xyntha have access to "Pfizer Hemophilia Connect"—which has essentially created a community for patients to connect together.<sup>156</sup> This community provides educational information, counseling and support, scholarship assistance, and much more.<sup>157</sup>

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<sup>145</sup> *Why BMSPAF*, BRISTOL-MYERS SQUIBB, <http://www.bmspaf.org/#home> [<https://perma.cc/8BHE-T9ZQ>].

<sup>146</sup> *Pfizer RxPathways*, PFIZER, <https://www.pfizer.com/purpose/patient-assistance-programs> [<https://perma.cc/XMJ6-4NRK>].

<sup>147</sup> *The Merck Patient Assistance Program Helps Those in Need*, MERCK HELPS, <https://www.merckhelps.com/> [<https://perma.cc/V48P-MRXV>].

<sup>148</sup> *GSK For You*, GLAXOSMITHKLINE, <https://www.gskforyou.com/uninsured-patient-assistance/> [<https://perma.cc/LTF2-3NLS>].

<sup>149</sup> *Patient Assistance Programs for Prescription Drugs*, *supra* note 143.

<sup>150</sup> *Id.*

<sup>151</sup> *Why BMSPAF*, *supra* note 145.

<sup>152</sup> *Patient Assistance Programs for Prescription Drugs*, *supra* note 143.

<sup>153</sup> Huntsman, *supra* note 13, at 27.

<sup>154</sup> *See, e.g., Learn About Programs*, PFIZER RXPATHWAYS, <https://www.pfizer.com/rxpathways.com/learn-about-programs> [<https://perma.cc/R8H9-3JFV>].

<sup>155</sup> *See id.*

<sup>156</sup> *See Pfizer Hemophilia Connect*, BENEFIX.COM, <https://www.benefix.com/financial-support> [<https://perma.cc/M5CG-MHWW>]; *Resources and Support*, XYNTA.COM, <https://www.xyntha.com/resources#hemophilia-connect> [<https://perma.cc/R8LB-VMBJ>].

<sup>157</sup> *See Pfizer Hemophilia Connect*, *supra* note 156.

In April 2018, the Partnership for Prescription Assistance (PPA) reported that it connected ten million individuals to various PAPs.<sup>158</sup> The PPA is an entity that links patients to PAPs through a call center and website.<sup>159</sup> At the time of PPA's launch in 2005, the U.S. Census Bureau reported that over forty-six million individuals were uninsured.<sup>160</sup> Similarly, one study performed at Nassau University Medical Center found that a cancer medication PAP not only provided patients with treatment they would have not otherwise been able to afford, but also increased patient compliance with chemotherapy protocols.<sup>161</sup> The total cost savings in 2012 from this program was over \$1.7 million.<sup>162</sup>

*B. Patient Assistance Programs Violating the Anti-Kickback Statute*

In light of recent developments, however, pharmaceutical companies have feared that their PAPs could violate the federal AKS since the introduction of Medicare Part D in 2006.<sup>163</sup> Medicare Part D is a voluntary prescription drug benefit for Medicare beneficiaries.<sup>164</sup> Enrollees can select to either supplement their existing coverage, or can enroll in a more inclusive plan.<sup>165</sup> Medicare Part D was designed to protect beneficiaries against “cost-related underuse of medications.”<sup>166</sup>

Although CMS permits PAPs to provide assistance to low-income individuals, such as Medicare Part D enrollees, CMS is determined to ensure separateness between Part D benefits

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<sup>158</sup> Hannah Mooney, *PPA Celebrates 13 Years of Helping Patients Access Their Medicines*, PHARMACEUTICAL RES. & MANUFACTURERS AM. (Apr. 5, 2018), <https://catalyst.phrma.org/ppa-celebrates-13-years-of-helping-patients-access-their-medicines> [<https://perma.cc/RW28-4KLP>].

<sup>159</sup> *Partnership for Prescription Assistance*, AM. ACAD. FAM. PHYSICIANS, <https://www.aafp.org/about/initiatives/prescription-assistance.html> [<https://perma.cc/B7CE-3HYI>].

<sup>160</sup> *Id.*

<sup>161</sup> Limin Gao et al., *Utilization of Pharmaceutical Patient and Prescription Assistance Programs via a Pharmacy Department Patient Assistance Program for Indigent Cancer Patients*, 51 HOSP. PHARMACY 572, 572 (July 5, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4981105/> [<https://perma.cc/5L9Z-7VQ2>].

<sup>162</sup> *Id.*

<sup>163</sup> Rachel S. Brown et al., *Medicare Coverage and Major Medicare-Related Coverage Options for Elders and Persons with Disabilities*, in ESTATE PLANNING FOR THE AGING OR INCAPACITATED CLIENT IN MASSACHUSETTS, at ch. 28, § 28.13.1 (4th ed. Supp. 2018).

<sup>164</sup> *An Overview of the Medicare Part D Prescription Drug Benefit*, KAISER FAM. FOUND. (Nov. 13, 2019), <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/> [<https://perma.cc/5APB-SNRZ>].

<sup>165</sup> *Id.*

<sup>166</sup> Yuting Zhang et al., *The Effect of Medicare Part D on Drug and Medical Spending*, 361 NEW ENG. J. MED. 52–61 (July 2, 2009), <https://www.nejm.org/doi/full/10.1056/NEJMsa0807998> [<https://perma.cc/TA4F-FBD8>].

and PAP assistance.<sup>167</sup> It can be inferred that this is so the government will not have to reimburse Medicare Part D claims submitted for prescription drugs that were provided through PAP assistance. In 2005, the OIG issued a Special Advisory Bulletin stating that PAPs might be unlawful if pharmaceutical companies arranged to pay for prescriptions during the coverage gap known as the “donut hole”<sup>168</sup> only if the beneficiary agreed to use the manufacturers’ drugs.<sup>169</sup>

The “donut hole” is the coverage gap that surrounds Medicare Part D.<sup>170</sup> It is “a temporary limit on what most Medicare Part D . . . plans pay for prescription drug costs.”<sup>171</sup> During this gap, individuals end up paying higher costs for their prescription drugs.<sup>172</sup> Reaching this coverage gap occurs when the patient and the plan spend a combined \$3,820 (as of 2019) after reaching the deductible requirement and paying the plan’s cost share for covered medications.<sup>173</sup> During the “donut hole,” patients are likely to pay “[twenty-five percent] of the plan’s cost for brand-name drugs and generic drugs.”<sup>174</sup> After the patient reaches \$5,100 in out-of-pocket spending on drug costs, the patient moves past the coverage gap and into the catastrophic coverage phase returning to reduced co-insurance and co-payment amounts for covered prescriptions.<sup>175</sup>

The government’s biggest concern regarding independent PAPs is whether these services promote the pharmaceutical companies’ medications.<sup>176</sup> Prosecutors are not only investigating donations, but also the unlimited availability offered by health care professionals when patients contact them with questions.<sup>177</sup> Government investigators want to know if the AKS and the FCA

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<sup>167</sup> See *Pharmaceutical Manufacturer Patient Assistance Program Information*, CENTERS FOR MEDICARE & MEDICAID SERVICES (July 23, 2018), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html> [<https://perma.cc/F3PA-S5V9>].

<sup>168</sup> *The Medicare Part D Coverage Gap (“Donut Hole”) Made Simple*, MEDICARE (Apr. 28, 2019), <https://medicare.com/medicare-part-d/coverage-gap-donut-hole-made-simple/> [<https://perma.cc/J5W2-N6WG>].

<sup>169</sup> Office of Inspector Gen., Dep’t of Health & Human Servs., Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005).

<sup>170</sup> *The Medicare Part D Coverage Gap (“Donut Hole”) Made Simple*, *supra* note 168.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> Ed Tobias, *Could Government Probe Threaten Pharma Patient Assistance Programs?*, MULTIPLE SCLEROSIS NEWS TODAY (Oct. 5, 2018), <https://multiplesclerosisnewstoday.com/2018/10/05/ms-medications-services-could-us-probe-threaten-pharma-patient-assistance-programs/> [<https://perma.cc/5L3F-H48J>].

<sup>177</sup> *Id.*

are being violated when PAPs promote certain products that are reimbursed by federal government health programs.<sup>178</sup>

It is important to note that this practice of pharmaceutical companies engaging in PAPs was not always scrutinized.<sup>179</sup> In response to an advisory opinion request, the OIG advised that donors can fund an independent PAP on the condition that these donations comply with HHS.<sup>180</sup> The OIG's 2005 special advisory bulletin set out guidelines to help companies avoid violating the AKS when contributing to independent PAPs.<sup>181</sup> Contributions would not violate the AKS so long as the independent PAP retains control, and: (1) drug company donors do not "exert[] any direct or indirect influence or control over the . . . program;" (2) the assistance is awarded "in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary[;]" (3) the independent PAP provides assistance without catering to the interests of the pharmaceutical donor or deference to "the beneficiary's choice of product, provider, practitioner, supplier or Part D drug plan;" (4) the independent PAP "provide[s] assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner;" and (5) the pharmaceutical donor does "not solicit or receive data from" the independent PAP that would "facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products."<sup>182</sup>

In 2014, the OIG supplemented the 2005 special advisory bulletin, further probing independent PAPs.<sup>183</sup> This guidance advised that the disease funds should not appear to be narrowly defined in a manner that favors any of the fund's donors.<sup>184</sup> By narrowly limiting independent PAPs to a specific disease, financial assistance is limited to only expensive drugs, essentially steering patients to only drugs that are available through the financial assistance program: the pharmaceutical donor's own products.<sup>185</sup> In 2015, the DOJ began investigating the activities of

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<sup>178</sup> *See id.*

<sup>179</sup> *See, e.g.*, Office of Inspector Gen., Dep't of Health & Human Servs., Advisory Op. 97-01 (June 11, 1997).

<sup>180</sup> *Id.* at 6–7.

<sup>181</sup> Office of Inspector Gen., Dep't of Health & Human Servs., Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005).

<sup>182</sup> *Id.* at 70,626.

<sup>183</sup> Office of Inspector Gen., Dep't of Health & Human Servs., Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120, 31,121–122 (May 30, 2014).

<sup>184</sup> *Id.* at 31,121.

<sup>185</sup> *Id.* at 31,122.

pharmaceutical donors and independent PAPs in conjunction with the concern over sharply rising drug prices.<sup>186</sup>

Closer to the writing of this note, in January 2020, the OIG issued a favorable advisory opinion in which it concluded a pharmaceutical manufacturer could provide certain patients with financial assistance for travel, lodging, and other expenses.<sup>187</sup> The opinion stated that although the assistance could possibly violate the AKS, the OIG will not impose sanctions on the cell therapy drug manufacturer.<sup>188</sup> This is significant in that the OIG permitted this arrangement because “only certain providers could offer the necessary care” and because this “was not used a marketing tool.”<sup>189</sup> This beckons an inquiry into whether other PAPs can currently meet this criteria within their programs.

On one hand, PAPs help patients who would otherwise not be able to afford life-saving medication.<sup>190</sup> On the other hand, the government argues that these services create individual patient dependency on specific drugs over alternatives.<sup>191</sup> The continued use of these drugs will drive health care costs by “pushing higher-priced drugs on patients.”<sup>192</sup> Manufacturers might continue to increase prices if patient demand becomes less susceptible to the prices of brand-name drugs.<sup>193</sup> In fact, this raises a valid question: “[d]o high prices makes [PAPs] necessary, or do [PAPs] lead to higher drug prices?”<sup>194</sup>

By receiving a deep discount on their medication, low-income patients are attracted to drug-specific PAPs.<sup>195</sup> This leads to an increase in demand, which ultimately can be used to increase price and thus profits. While pharmaceutical companies benefit from this, patients, who desperately need these medications, are nonetheless able to procure these drugs at an affordable price.

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<sup>186</sup> Brett Friedman et al., *Emerging Enforcement Trends for Patient Support Programs*, LAW360 (May 15, 2018, 12:43 PM), <https://www.law360.com/articles/1042623/emerging-enforcement-trends-for-patient-support-programs> [<https://perma.cc/SR89-L54Z>].

<sup>187</sup> Office of Inspector Gen., Dep’t of Health & Human Servs., Advisory Op. 20-02 (Jan. 15, 2020).

<sup>188</sup> *Id.*

<sup>189</sup> Jane Haviland & Karen S. Lovitch, *OIG Advisory Opinion Permits a Pharmaceutical Manufacturer to Provide Financial Assistance to Needy Patients Receiving Risky Cell Therapy*, JDSUPRA (Feb. 3, 2020), <https://www.jdsupra.com/legalnews/oig-advisory-opinion-permits-a-59493/> [<https://perma.cc/5JTN-Q893>].

<sup>190</sup> Richard J. Sagall, *Pharmaceutical Companies Helping Patients Get Their Medicines*, NEEDY MEDS (Mar. 4, 2018), <https://www.needymeds.org/article> [<https://perma.cc/GS3Q-W3FA>].

<sup>191</sup> Tobias, *supra* note 176.

<sup>192</sup> *Id.*

<sup>193</sup> David H. Howard, *Drug Companies’ Patient Assistance Programs—Helping Patients or Profits?*, 371 NEW ENG. J. MED. 97, 98 (2014).

<sup>194</sup> *Id.*

<sup>195</sup> Tobias, *supra* note 176.

From a purely practical, health-oriented perspective, PAPs provide a tremendous amount of relief to Americans that cannot otherwise afford necessary prescription drugs. They are a safety net for both those without health insurance and for those that have inadequate coverage.<sup>196</sup> One-third of Americans and two-thirds of the elderly population report having difficulty paying for prescription medications,<sup>197</sup> with more than twenty-five percent of patients being unable to fill a prescription.<sup>198</sup> PAPs were designed to address this public health concern.<sup>199</sup> It is estimated that, between 2005 and 2009, the Pharmaceutical Research and Manufacturers of America (PhRMA) group have helped 5.5 million Americans through its PPA program.<sup>200</sup> The beneficial effects can be seen by programs like Biogen's PAP for multiple sclerosis, which has capped co-payments at less than one percent of the drug's total cost.<sup>201</sup> Another pharmaceutical company, Dendreon, covers a significant portion of its patients' out-of-pocket costs for its customers using its \$93,000 prostate therapy treatment.<sup>202</sup> While patients may duck these costs, the remaining expenses are absorbed both by pharmaceutical manufacturers and the health system.<sup>203</sup>

The OIG is aware of the need for PAPs and is cognizant of their benefits, especially for patients who require costly prescriptions to treat chronic diseases.<sup>204</sup> But the government maintains that pharmaceutical companies are "potentially violat[ing] laws by providing free services to doctors and patients,"<sup>205</sup> partly because of the "two remunerative aspects of PAPs."<sup>206</sup> One of these remunerative aspects includes pharmaceutical donor contributions to PAPs, which the government characterizes as indirect remuneration.<sup>207</sup> Under this theory, a donation made to a PAP is analyzed to see if its purpose was to dictate purchase of the pharmaceutical donor's drugs.<sup>208</sup> The second aspect posits that an

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<sup>196</sup> Niteesh K. Choudhry et al., *Drug Company-Sponsored Patient Assistance Programs: A Viable Safety Net?*, 28 HEALTH AFF. 827, 827 (2009).

<sup>197</sup> *Id.*

<sup>198</sup> *Id.*

<sup>199</sup> Sagall, *supra* note 190.

<sup>200</sup> Choudhry, *supra* note 196, at 828.

<sup>201</sup> Howard, *supra* note 193, at 97.

<sup>202</sup> *Id.*

<sup>203</sup> Ramsey Baghdadi, *Patient Financial Support*, HEALTH AFF. (Sept. 14, 2017), <https://www.healthaffairs.org/doi/10.1377/hpb20171409.000176/full> [<https://perma.cc/R7XU-ZJ9W>].

<sup>204</sup> Huntsman, *supra* note 13, at 28.

<sup>205</sup> Peter Loftus, *U.S. Probes Drugmakers Over Free Services*, WALL STREET J., (Sept. 21, 2018), [https://www.wsj.com/articles/drugmakers-free-services-spur-government-scrutiny-1537531201?mod=searchresults&page=1&pos=1&mod=djemHL\\_t](https://www.wsj.com/articles/drugmakers-free-services-spur-government-scrutiny-1537531201?mod=searchresults&page=1&pos=1&mod=djemHL_t) [<https://perma.cc/PC5L-C8YE>].

<sup>206</sup> Huntsman, *supra* note 13, at 28.

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*



AKS violation occurs where a PAP directly assists a patient in order to induce them to buy a specific drug.<sup>209</sup>

### C. *Government Scrutiny into PAPs*

Among the most recent pharmaceutical companies scrutinized by the government for allegedly inducing sales through PAPs are Amgen Inc., Bayer AG, Eli Lilly & Co., Sanofi SA, and Gilead Sciences Inc.<sup>210</sup> These investigations are drawing attention to the services offered by drug companies similar to the notoriety surrounding the once-common practice of enticing high-prescribing physicians with special treatment.<sup>211</sup> Although pharmaceutical companies argue that their assistance programs benefit patients, prosecutors and critics contend that these services encourage continued use of brand-name products over generic alternatives.<sup>212</sup>

In one instance, the government has argued that Sanofi violated the AKS by offering patients disease education about diabetes.<sup>213</sup> The U.S. Attorney's Office for the Southern District of New York requested documents and information regarding the pharmaceutical company's "certified diabetes educator program."<sup>214</sup> Sanofi's program consisted of health care professionals answering patients' questions about diabetes and showing them how to use its diabetes treatments.<sup>215</sup>

Moreover, AbbVie Inc. is presently engaged in a lawsuit against California's insurance commissioner, who has alleged that physicians were induced into prescribing Humira, the world's highest-selling drug, because doctors saved time and money by having AbbVie send registered nurses to visit and educate patients on how to use the drug.<sup>216</sup> At the time of writing, the action was remanded to the Superior Court of California for the County of Alameda.<sup>217</sup> Proponents of these lawsuits argue that although pharmaceutical services, such as educating patients and defraying co-payment costs help patients, these services "undermine[] medical decision making."<sup>218</sup> Opponents of PAPs have argued that these programs are also associated with hidden costs created by shifting the cost from individual patients to

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<sup>209</sup> *Id.*

<sup>210</sup> Loftus, *supra* note 205.

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> *Id.*

<sup>214</sup> *Id.*

<sup>215</sup> *Id.*

<sup>216</sup> *Id.*

<sup>217</sup> California v. Abbvie Inc., 390 F. Supp. 3d 1176, 1178–79 (N.D. Cal. 2019).

<sup>218</sup> Loftus, *supra* note 205.

insurers and taxpayers.<sup>219</sup> In contrast, targeting low-income patients or providing assistance for all medical costs (not just the specific drug) would not be an ideal solution due to issues of under-inclusiveness and over-inclusiveness. This would not only narrow the category of patients that drug companies could provide assistance to, but also substantially raise costs for pharmaceutical companies to take on the burden of paying for all incurred medical costs, including the specific prescription drug.

Among these settlements, one PAP organization challenged the government by alleging that HHS violated its free speech rights.<sup>220</sup> In January 2018, Patient Services, Inc. (PSI), brought a lawsuit against HHS, its Acting Secretary, and the OIG, seeking an order to allow PSI to exercise its constitutionally protected right to free speech in order to continue assisting the nation's most vulnerable patient population through its PAP.<sup>221</sup> The plaintiff claims that the advisory opinion<sup>222</sup> restricts PSI's ability to communicate critical information regarding disease-specific drugs to the PAP's beneficiaries.<sup>223</sup> Since the filing, the OIG has responded through a motion for leave to take discovery, requesting supporting evidence that the advisory opinion did actually cost PSI millions of dollars in donations.<sup>224</sup> The advisory opinion precluded PSI from asking donors and potential donors for information "about a wide range of issues, including diseases, drugs and patient populations."<sup>225</sup> Although this case was dismissed with prejudice January 2020,<sup>226</sup> the crux of this complaint fails to address a solution regarding the possible AKS violation.<sup>227</sup> Even if PSI is successful on the merits of the First Amendment claim and the OIG is enjoined from prohibiting certain communications between the PAP and its beneficiaries, there still could be consequences if PSI does not comply with the AKS. This is where courts should apply a direct causal link analysis to limit intrusion into legitimate beneficial PAP

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<sup>219</sup> Howard, *supra* note 193, at 99.

<sup>220</sup> Jeff Overley, *Pharma Charity Likely Waived Free Speech Right, OIG Says*, LAW360 (July 19, 2018), <https://www.law360.com/articles/1065085> [<https://perma.cc/JMS8-UU5G>].

<sup>221</sup> See Complaint at 1–3, *Patient Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:18-cv-00016 (E.D. Va. July 18, 2018) [hereinafter Complaint].

<sup>222</sup> See generally Office of Inspector Gen., Dep't of Health & Human Servs., Notice of Modification of Advisory Op. 2-1 (Mar. 3, 2017) (issuing a notice of modification regarding patient assistance program guidance).

<sup>223</sup> Complaint, *supra* note 221, at 2–3.

<sup>224</sup> Memorandum in Support of Defendants' Motion for Leave to Take Discovery at 12, *Patient Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:18-cv-00016 (E.D. Va. July 18, 2018).

<sup>225</sup> Church et al., *supra* note 18.

<sup>226</sup> *Patient Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:18-cv-00016 (E.D. Va. Jan. 22, 2020).

<sup>227</sup> See generally Complaint, *supra* note 221.

practices. By investigating why beneficiaries chose a specific PAP, a court can accurately identify whether or not the mens rea is satisfied to find an AKS violation.

#### IV. A SOLUTION: THE DIRECT CAUSAL LINK TEST

It is imperative for courts to modify how they address the issue of PAPs potentially violating the AKS. Although Congress designed the AKS with the intention of protecting federal health care program beneficiaries from the financial influence of referral decisions,<sup>228</sup> courts must weigh the patients' interests that are served by curing the defective intent requirements. With patients drowning in health care costs, pharmaceutical donors often act as lifeguards.<sup>229</sup> They are not necessarily intervening in order to induce future sales; rather they are acting philanthropically, usually to carry out goals, such as "deliver[ing] innovative medicines that help patients prevail over serious diseases."<sup>230</sup> Courts, not Congress, are the ideal candidates to implement this solution as they are more readily able to determine, from the evidence and facts, whether or not a patient had the intention to participate in a specific PAP because of a manufacturer's donation.

##### A. *Two-Prong Analysis*

Courts should: (1) apply a direct causal link test, which would then (2) require shifting the intent inquiry from the health care professional to the patient. The direct causal link test would require courts to ask whether, but for the donation to the PAP, the patient would not have chosen to participate in that specific PAP. Under the first prong, the court would ascertain whether the beneficiary chose a specific PAP because they knew that the organization receives donations from a pharmaceutical manufacturer. The inquiry under the second prong would seek to determine whether the pharmaceutical donor knew the beneficiary chose a specific PAP because of knowledge of the organization receiving donations from a pharmaceutical manufacturer, and *then* knowingly and willfully acted on this information with the intent of inducing patients' dependency on the product, resulting in future sales. Narrowing down the

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<sup>228</sup> See *supra* Part II.

<sup>229</sup> See GLOB. ALL. FOR PATIENT ACCESS, THE ROLE OF DRUG DONATIONS IN EXPANDING ACCESS TO MEDICINES 2 (Aug. 2017), [http://gafpa.org/wp-content/uploads/GAFPA\\_Drug\\_Donations\\_August-2017.pdf](http://gafpa.org/wp-content/uploads/GAFPA_Drug_Donations_August-2017.pdf) [<https://perma.cc/9KN6-CCHF>].

<sup>230</sup> *Our Mission and Our Commitment*, BRISTOL-MYERS SQUIBB, <https://www.bms.com/lu/our-mission.html> [<https://perma.cc/R95T-MV56>].

specific actions and intentions of the beneficiary would ultimately guide the court in determining whether or not the intent requirement of the AKS is satisfied.

If the government fails to prove that, but for the pharmaceutical donation to an independent PAP, the patient would not have selected that charity organization to seek financial assistance, no violation exists. This solution was chosen because of its similarity to legal standards applied in products liability cases—an area of law with which the pharmaceutical industry is very well versed.<sup>231</sup> “Pharmaceutical liability relates to the liability of a pharmaceutical manufacturer when its pharmaceutical product is alleged to have injured a person”<sup>232</sup> Products can cause harm through manufacturing or design defects, failure to warn, and many other theories.<sup>233</sup> Products liability law exists to protect consumers, such as patients, from the harms created by the manufacturer. In products liability cases, plaintiffs have the burden to prove that “but for the product’s defect, the plaintiff would not have suffered the injury,” and that “the product defect is the ‘proximate cause’ of the injury.”<sup>234</sup> Just as it is wrong for a manufacturer to harm the patient, it is wrong for the government to harm the patient; and just as patients have to prove they were harmed by a defective drug, the government should bring out patient testimony to see if there was an actual harm (i.e. Did they contribute to inducing sales?). Although the government is trying to curb the potentially unethical behavior of pharmaceutical companies, such action ultimately affects patients’ access to life-changing medications. In light of that, patients should be afforded a fair opportunity to participate in the government investigations. If they learn that their access to specific drugs will be severed, patients have a reason to come testify as to their intentions for choosing a specific PAP. If the government has trouble finding willing participants, it should consider subpoenaing patients. Patients would likely participate as their failure to do so could lead to the termination of their PAP benefits if a court finds sufficient proof for AKS or FCA violations. Alternatively, PAPs could stipulate in their agreement with patients that compliance with court subpoenas are mandatory to receive continued assistance.

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<sup>231</sup> *Bitter Pill: Proving Causality in Pharmaceutical Cases Can Be Difficult*, REED SMITH CLIENT ALERTS (Dec. 3, 2001), <https://www.reedsmith.com/en/perspectives/2001/12/bitter-pill—proving-causality-in-pharmaceutical-c> [<https://perma.cc/77H9-VH7A>].

<sup>232</sup> *Id.*

<sup>233</sup> THEODORE V.H. MAYER ET AL., HUGHES HUBBARD & REED LLP, PRODUCTS LIABILITY IN THE UNITED STATES, ISSUES FOR DUTCH COMPANIES 2–3.

<sup>234</sup> *Id.* at 23.

## B. *Patient Participation*

In order to address this one-sided investigation, prosecutors should interview the beneficiaries participating in suspect PAPs. The government can first narrow down geographically to where it believes an increase in sales exists as a result of donor influence. For example, if prosecutors believe “X Pharmaceuticals” is generating more revenue in “State Z,” the investigation should begin by contacting the PAP beneficiaries in “State Z,” assuming there is evidence that the PAP received donations from “X Pharmaceuticals.” Investigators would need to interview these beneficiaries to identify why they selected a particular PAP. Similar to a class action suit, the government would need to collect a sample of beneficiaries that would be willing to testify as to why they selected a specific PAP, and then move forward with a trial, if prosecutors can obtain sufficient evidence to support a theory that revenue increased due to the pharmaceutical donations. Prosecutors must broaden the focus beyond just health care professionals to also include the individual decisions made by patients. By homing in on the direct actions of the patients, specifically why they chose to participate in a distinct PAP, there is an opportunity to revisit the intent requirement within the AKS.

## C. *Strengthening the Scierter Requirement*

The direct causal link test would additionally address problems with the scierter requirement. The AKS contains a distinct scierter requirement.<sup>235</sup> Specifically, it requires the violator to act in a “knowing[] *and* willful[]” manner.<sup>236</sup> Prosecutors have been circumventing this intent requirement by pursuing actions based on violations of the False Claims Act,<sup>237</sup> which has a looser knowledge requirement.<sup>238</sup> Applying the direct causal link test will prevent prosecutors from using the FCA as a vehicle to recover AKS violations. These lawsuits allege AKS violations triggered violations of the FCA.<sup>239</sup> Under this theory, the face of the submitted claim might not actually

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<sup>235</sup> See 42 U.S.C. § 1320a-7b(b).

<sup>236</sup> *Id.* (emphasis added).

<sup>237</sup> See *United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1508–09 (M.D. Tenn. 1996).

<sup>238</sup> Compare 42 U.S.C. § 1320a-7b(b) (requiring the violator to act in a “knowing[] and willful[]” manner), with 31 U.S.C. § 3729(a)(1)(A) (requiring the violator to know the submitted claim was false).

<sup>239</sup> Robert N. Rabecs, *Kickbacks as False Claims: The Use of the Civil False Claims Act to Prosecute Violations of the Federal Health Care Program’s Anti-Kickback Statute*, 2001 L. REV. M.S.U.-D.C.L. 1, 3.

be false; instead, they are alleged to be fraud based on accepting or paying of kickbacks.<sup>240</sup>

#### D. *Actual Causation*

Finally, this “but-for” test addresses actual causation.<sup>241</sup> Addressing actual causation provides clarity as to whether the AKS’s scienter requirement is satisfied. Clearly identifying the reason a patient chose a specific PAP will prevent courts from second-guessing pharmaceutical companies’ donative intent. Specifically, the burden increases for prosecutors to show that donors did, in fact, “knowingly and willfully” act to induce future sales.<sup>242</sup> Under the “but-for” test, “an act . . . was a cause of an injury if and only if, but for the act, the injury would not have occurred.”<sup>243</sup> Here, courts would determine whether the beneficiary chose a specific PAP because the beneficiary knew the PAP was receiving contributions from a pharmaceutical donor. Courts could look to see whether or not there is evidence to support the fact that a pharmaceutical donor knew a beneficiary selected a specific PAP because of the continuous stream of funds coming into that organization, or because they actually required those prescription drugs associated with that specific PAP. Essentially the questions boil down to: (1) why did the patient choose “PAP A” instead of “PAP B”; and (2) did the patient choose “PAP A” because “PAP A” received donations from “X Pharmaceuticals”?

To be sure, gathering information from every beneficiary is a monumental task—but it is a critical one. Although the government may argue that it is impractical, it should embrace this burden. By identifying the beneficiaries’ intent, the government would be able to demonstrate whether or not the knowledge requirement within the AKS’s scienter has been met. The benefit of identifying the reason why an individual chose a specific PAP goes directly towards determining whether or not a pharmaceutical company induced sales for self-gain. This benefit outweighs the burden because it more accurately pinpoints whether a PAP violated the AKS or whether there was another reason for an increase in sales.

Although it may look like the pharmaceutical company is being punished by the decisions made by either the court or the DOJ, ultimately it is really patients who are the ones affected by

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<sup>240</sup> *Id.*

<sup>241</sup> Richard W. Wright, *Causation in Tort Law*, 73 CALIF. L. REV. 1735, 1775 (1985).

<sup>242</sup> 42 U.S.C. § 1320a-7b(b).

<sup>243</sup> Wright, *supra* note 241, at 1775.

the final decision. If the government continues to scrutinize pharmaceutical companies for contributing to PAPs, eventually these companies will have no choice but to stop providing patient assistance. If that happens, these patients will not be able to obtain the prescription drugs they need to survive. For example, the state of California passed AB265 in 2017, which prohibits pharmaceutical companies from discounting individual out-of-pocket costs if a lower cost generic equivalent is available.<sup>244</sup> The effect of this law is the “propensity to raise the out of pocket cost of prescriptions.”<sup>245</sup> The government probing into these charity organizations can have far-reaching consequences to the patients, even if prosecutors are only trying to ensure compliance from pharmaceutical manufacturers.<sup>246</sup> While drug manufacturers will still be able to sell their products, those sales will not necessarily equate to low-income patients receiving affordable prescriptions. This circles back to the high costs associated with bringing new drugs into the market.<sup>247</sup> Although generic drugs are an option, this would not necessarily equate to the same quality as brand-name products, rendering patients optionless.

If a beneficiary chose “PAP A” instead of “PAP B” solely because the beneficiary knew “PAP A” received donations from “X Pharmaceuticals,” then courts can proceed to the second prong: Did the pharmaceutical donor know, or should it have known, that, *but for the donations*, the beneficiary would not have chosen to participate in that specific PAP? This second prong targets the heart of the AKS’s intent requirement. Factors that need to be met in order to satisfy this prong include: (1) the donor has knowledge that by making a donation to the PAP, it is influencing a beneficiary’s decision to participate in that PAP; (2) the donor has knowledge that the beneficiary is participating in that PAP specifically because of its contributions; and (3) the donor has knowledge that by the beneficiary’s participation in that PAP, it is inducing future sales through dependency. If all three factors are met, the second prong would be satisfied. If

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<sup>244</sup> Thomas Sullivan, *California Bans Prescription Discounts with Generic Equivalents*, POL’Y & MED. (May 4, 2018), <https://www.policymed.com/2017/10/california-passes-legislation-on-prescription-discounts.html> [<https://perma.cc/9F4Q-ZUGU>].

<sup>245</sup> *Id.*

<sup>246</sup> Caring Voice Coalition, one of the largest PAPs in the United States that has provided support to more than 100,000 individuals, ceased its financial aid program in January 2018 due to the government’s concerns regarding undue influence over the charity by pharmaceutical companies. Nate Raymond, *Drug Charity Halts Patient Aid After U.S. Health Agency Pulls Approval*, REUTERS (Jan. 5, 2018), <https://www.reuters.com/article/us-usa-healthcare-charity/drug-charity-halts-patient-aid-after-u-s-health-agency-pulls-approval-idUSKBN1EU1V6> [<https://perma.cc/P7SH-GCWH>].

<sup>247</sup> See *supra* Section I.B.

both prongs are satisfied, then, *and only then*, should courts find an AKS violation.

By determining the beneficiary's intent as to why they chose a certain PAP, it becomes easier to narrow down whether or not the pharmaceutical donor meets the scienter requirement. Accordingly, courts should first determine whether or not an AKS violation exists before moving forward to the FCA violation, in the context of government actions that allege violations of both statutes. Similar to *Columbia/HCA*, courts should only find a False Claims Act violation if the actual claim itself was false or fraudulent.<sup>248</sup>

## CONCLUSION

The direct causal link analysis provides a thorough means of determining whether or not a health care professional violated the AKS. Analyzing *why* the beneficiary chose a specific PAP, and whether the reason was related to a pharmaceutical donation, narrows the AKS's "knowing[] and willful[]" element.<sup>249</sup> Although the government could argue that the heightened burden will hinder investigations (and prosecutions), it is essential that prosecutors clear this hurdle in order to accurately show that pharmaceutical donors did in fact violate the AKS.

The court must take into consideration the policy argument for this proposal: that PAPs address the public health care crisis in our country. The amount of money the United States spends on health care is alarming when compared to how much other nations spend.<sup>250</sup> CMS estimates the United States will spend \$5.96 trillion on health care by 2027.<sup>251</sup> Prescription drug spending is projected to increase by an average of over six percent per year during the next decade.<sup>252</sup>

Since PAPs attempt to resolve this issue, it is vital for courts to weigh these facts against the risk that donors may violate the AKS. When prosecutors circumvent the intent requirements under the AKS and pursue action through the FCA,

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<sup>248</sup> See *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 938 F. Supp. 399 (S.D. Tex. 1996), *aff'd in part and vacated in part*, 125 F.3d 899 (5th Cir. 1997).

<sup>249</sup> 42 U.S.C. § 1320a-7b(b).

<sup>250</sup> See Sawyer & Cox, *supra* note 29.

<sup>251</sup> Yusra Murad, *CMS Estimates Annual U.S. Healthcare Spending to Hit \$5.96 Trillion by 2027*, MORNING CONSULT (Feb. 20, 2019), <https://morningconsult.com/2019/02/20/cms-estimates-annual-u-s-health-care-spending-to-hit-5-96-trillion-by-2027/> [<https://perma.cc/N6HZ-HCT3>].

<sup>252</sup> Harris Meyer, *Healthcare Spending Will Hit 19.4% of GDP in the Next Decade*, CMS Projects, MOD. HEALTHCARE (Feb. 20, 2019), <https://www.modernhealthcare.com/article/20190220/NEWS/190229989/healthcare-spending-will-hit-19-4-of-gdp-in-the-next-decade-cms-projects> [<https://perma.cc/GP8H-G23V>].



it is detrimental to the beneficiary who relied on that PAP for support and access to the necessary prescription drug. By narrowing the AKS using the direct causal link analysis, the government will have a harder time proving FCA violations, which are distinct from violations of the AKS. Moreover, this new test can be utilized so that courts can protect the beneficiaries Congress had in mind when the AKS was developed.

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