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Industry Payments to Physicians are Kickbacks. How Should Stakeholders Respond?

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Abstract

Payments from the pharmaceutical industry to US physicians are common. In determining which payments rise to the level of an illegal kickback under the Anti-Kickback Statute (AKS), the Department of Health and Human Services Office of Inspector General (HHS OIG) has stated in non-binding guidance that influencing or "swaying" physician prescribing is key. OIG has highlighted as a compliance standard the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Professions, which stipulates that permissible payments are those that do not interfere with prescribing. However, recent evidence has shown that most payments influence physician prescribing, driving higher prescription drug costs by increasing use of brand-name and low-value drugs. This evidence implies that many payments that are currently commonplace could be subject to prosecution under AKS. Given that these payments increase costs to patients and the healthcare system, there is a public interest in curtailing them. This article proposes a range of actions available to stakeholders—including industry, providers, regulators, and payers—to mitigate the cost-increasing effect of industry payments to physicians.

Keywords

industry payments; conflict of interest; anti-kickback statute; false claims act; pharmaceutical industry

I. Introduction

Financial relationships between the pharmaceutical industry and US physicians are common. Payments from industry to physicians and teaching hospitals, excluding funding for scientific research, totaled over $3.6 billion in 2019 ("The Facts About Open Payments Data: 2019 Totals" n.d.). Approximately half of US physicians accept personal payments

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from industry each year, most commonly in the form of free meals, speaking fees, consulting fees, and travel, (Marshall et al. 2020), and a substantially greater portion will do so during their careers (Inoue et al. 2019).

Concern that these payments constitute inappropriate commercial influence on physician practice is longstanding (Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice 2009; Wazana 2000). More recently, data available through the Open Payments reporting system (created by the Sunshine Act provision of the Affordable Care Act) has produced a substantial body of research into physician-industry financial relationships.

Receipt of industry payments is associated with prescribing changes that contribute to higher drug costs without improving patient outcomes. A consistent finding has been an increased proportion of brand-name prescriptions relative to generics (Brunt 2019; Morse, Hanna, and Mehra 2019; Qian et al. 2017; Rhee and Ross 2019; Yeh et al. 2016). Industry payments are also associated with the prescribing of low-value, expensive drugs (Hartung et al. 2018; Sharma et al. 2018). Every published, peer-reviewed study that has evaluated the association between payments and prescribing using a causal inference framework has found evidence that receipt of industry payments increases physicians' prescribing (A. Mitchell et al. 2021), supporting these concerns. Industry payments should therefore be of concern to stakeholders seeking to control costs and maximize health care value, such as federal and commercial payers.

In this analysis, we review the literature regarding physician-industry financial relationships, with an emphasis on prescription drug costs. We then assess the legality of these relationships, with respect to existing anti-fraud and abuse legislation (the federal antikickback statute (AKS) and the federal False Claims Act), case law, and recent empirical data. Finally, we present potential actions available to various stakeholders to mitigate the cost-inflating impact of physician-industry financial relationships.

II. Physician-industry financial relationships and prescription drug costs: empirical findings

Remuneration from pharmaceutical manufacturers to physicians is associated with increased prescribing. Through 2020, every published empirical study assessing the relationship between industry payments and physician prescribing found this association (A. Mitchell et al. 2021). This finding was consistent across all drug classes and physician specialties studied.

Several strands of evidence support that the association between payments and prescribing is causal. The high consistency of the association suggests causality, as does the observed "dose response" relationship between the amount of payment and the magnitude of the prescribing increase. One study described a close temporal association between physicians attending a vacation sponsored by a drug manufacturer and their subsequent rapid increase in prescriptions for that company's drug (Orlowski and Wateska 1992). Additionally, multiple studies have applied causal inference designs to evaluate the association with

payments and prescribing, and found evidence that payments cause prescribing increases. Two of these studies used event study methods, conducting robust within-physician time series (e.g., comparing each physician's prescribing post-payment to their own prescribing pre-payment) and observed increases in prescribing immediately following receipt of each payment (Carey, Lieber, and Miller 2020; Agha and Zeltzer 2019). Another study used a difference-in-differences model to estimate the change in future prescribing associated with receipt of industry payments, comparing physicians who historically had similar prescribing (Zezza and Bachhuber 2018). Within the inherent limitations of observational designs, these studies are minimally susceptible to confounding factors that may contribute to a non-causal association between payments and prescribing, strongly suggesting that money and gifts from industry directly influence physicians.

In addition to these empirical findings, a consideration of industry motivations to make physician payments suggest that they influence physician prescribing. These large public companies exist to return profit to shareholders, and maximizing profits means increasing drug sales. Companies closely track the prescribing practices of physicians to whom they market (Fugh-Berman and Ahari 2007). It is very unlikely that these companies would expend billions of dollars in would-be profits annually on physician payments if they had any doubt that they would more than recoup this expense by generating more prescriptions.

The influence of industry money directly impacts prescription drug spending. Physicians who receive industry payments engage in more expensive prescribing (Perlis and Perlis 2016). One mechanism contributing to higher costs is increased prescribing volume, particularly of low-value drugs. For example, repository corticotropin is an injectable endocrine therapy used to treat multiple sclerosis and several rheumatologic conditions. There is not good evidence to support its use, and alternative treatment options are readily available (Hartung et al. 2017). Nevertheless, repository corticotropin's manufacturer has increased its price more than 20-fold in recent years, relying almost exclusively on prescribing by physicians whom it pays (Hartung et al. 2018). The cost to the health care system is substantial; Medicare alone spent over $0.5 billion on repository corticotropin in 2015 (Hartung et al. 2017). Receipt of industry payments also increases prescribing of novel, oral anticoagulant drugs (Agha and Zeltzer 2019). Though these drugs are beneficial in some settings, industry payments appear to increase prescribing equally in high-value and lower-value settings (patients at high risk for bleeding complications). The influence of industry payments is estimated to add $1.4 billion in anticoagulant spending annually. Among the available treatments for chronic myeloid leukemia, receipt of industry payments shifts prescribing towards drugs that are more expensive than generic imatinib (A. P. Mitchell, Winn, and Dusetzina 2018), are no more effective, and have more serious toxicities (Cole et al. 2020). Industry spends heavily to promote drugs with serious safety signals; for example, in 2019 Pfizer spent over $5 million on personal payments to physicians to promote tofacitinib (Xeljanz), despite its boxed warnings for increased incidence of lymphoma and cardiovascular death. Taken together, these observations suggest that industry relationships are likely to increase spending on lower-value, less-innovative, and potentially dangerous drugs (Greenway and Ross 2017; Lexchin 2017).

Another well-established mechanism by which industry payments increase pharmaceutical costs is increasing prescription of branded drugs over generics. Physicians who receive payments write a higher percentage of branded prescriptions (Qian et al. 2017), resulting in higher mean, per-prescription costs (Wood et al. 2017; Brunt 2019). Similarly, a study examining opioid prescribing found that receipt of payments shifted prescribing towards more expensive drugs, increasing the mean per-patient per-day opioid spending (Zezza and Bachhuber 2018). Other drug classes or disease groups for which industry payments have been linked to increased branded prescribing over generics – or of more expensive drugs over less-costly alternatives – include: cholesterol-lowering drugs (Yeh et al. 2016; Inoue et al. 2021; DeJong et al. 2016), blood pressure medications (DeJong et al. 2016), anti-depressants (DeJong et al. 2016), gabapentinoids (Rhee and Ross 2019), inflammatory bowel disease (Khan et al. 2019), proton pump inhibitors (Morse, Fujiwara, and Mehra 2018), and anti-vascular endothelial growth factor inhibitors (Singh et al. 2018; Taylor et al. 2016). Perhaps most concerning is that industry payments can increase prescribing of "re-branded" medications, in which manufacturers create new brand names (and charge higher prices) for drugs already available as generics (Sharma et al. 2018). Taken together, this body of literature strongly suggests that industry payments increase pharmaceutical spending in ways that are unlikely to improve patient outcomes.

III. Physician-industry relationships and the law

The most relevant statute with respect to physician-industry relationships is the federal anti-kickback statute (AKS). The AKS prohibits paying or receiving – or offering or soliciting – any remuneration in return for purchasing, ordering, recommending, or referring a patient for, "any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program" (Anti-Kickback Statute n.d.). The law prohibits both *bribes* which come before purchases or referrals, and *kickbacks* which come after them. Remuneration is defined broadly, including payments made "directly or indirectly, overtly or covertly, in cash or in kind." AKS establishes criminal liability, punishable by fines of up to $100,000 and 10 years in prison per offense; because AKS prohibits both making and receiving payment, both parties may be prosecuted. Amendments to AKS passed as part of the Affordable Care Act clarified that actions deemed criminal by AKS would "[constitute] a false or fraudulent claim for purposes of" the Federal False Claims Act, with the potential for additional civil liability.

How to define appropriate payments vs. kickbacks and inducements is a central question given the findings linking payments to prescribing. The Pharmaceutical Research and Manufacturers of America (PhRMA), a drug industry trade group, took a proactive step in 2002, proposing a voluntary Code on Interactions with Healthcare Professionals ("PhRMA Code on Interactions with Healthcare Professionals, 2002" 2002). This "Code" outlined practices deemed appropriate, adherence to which would avoid the appearance of impropriety. The following year, the Department of Health and Human Services Office of Inspector General (HHS OIG) referenced the Code in its guidance to pharmaceutical manufacturers on compliance with the AKS. HHS OIG advised that compliance with the Code would "substantially reduce the risk of fraud and abuse and help to demonstrate a good faith effort to comply with the applicable federal health program requirements."

("Compliance Program Guidance for Pharmaceutical Manufacturers." 2003). In 2021, PhRMA issued its most recent update of the Code, which became effective on January 1, 2022. While the Code does not carry legal weight, the HHS OIG's endorsement caused it to be accepted by industry as a non-binding compliance standard. Moreover, three states – California, Connecticut, and Nevada – require drug manufacturers to comply with the PhRMA Code, thus making the Code a legal requirement.

The provisions of the Code are therefore important in evaluating the status of physician-industry financial relationships under AKS. The Code allows for "modest" meals at informational presentations and educational events and for payment to physicians for speaking and consulting if a "legitimate need for the services has been clearly identified," the venue and circumstances are conducive to the provision of that service, the number of paid physicians is "reasonably necessary" to meet the identified need, and the degree of compensation is "reasonable" and "fair market value." The Code stipulates manufacturers should ensure that such arrangements are "neither inducements nor rewards for prescribing." The Code also contains broad language on the "Independence and Decision Making" of healthcare professionals, stating that "nothing should be offered or provided" that would "interfere with the independence of a healthcare professional's prescribing practices" ("Code on Interactions with Health Care Professionals" 2021).

Several recent AKS cases highlight the boundaries of the Code, and the types of marketing practices that HHS OIG views to fall outside of these boundaries and in violation of the AKS. In 2020, Novartis settled an AKS lawsuit related to its "sham" speaker program ("Novartis Settlement Agreement" 2020). Several lines of evidence to support allegations that this program paid illegal kickbacks were presented with reference to the Code. Meals at speaking events were not "modest"; the suit provided examples of high-end restaurant venues and tabs exceeding $400 per attendee. Speakers were often fed and paid without any lecture having taken place, a violation of the Code's stipulation that payments are appropriate only when accompanying presentations that "provide scientific or educational value." Events were held at sporting events, golf courses, and wine tastings, and involved alcohol consumption to the point of intoxication, in violation of the "venue and manner conducive to informational communication" clause of the Code. The frequency of Novartis' events – and the commonality of repeat attendees to presentations on the same drug – was presented as further evidence that the intent of these events was not to convey scientific information but rather to provide a pretext to pay kickbacks to physicians.

A 2019 settlement involving Insys Therapeutics presented similar evidence that Insys' speaker program violated AKS ("Insys Therapeutics, Inc. Corporate Integrity Agreement and Conditional Exclusion Release." 2019). Speaking events "often did not involve any education or presentations about the drug" or "had no attendees at all," suggesting that "program events…served as a vehicle to pay a bribe to the speaker in the disguised form of an honoraria." The same speakers received multiple honoraria for speaking events in which no licensed prescribers were in attendance, further supporting the claim that honoraria were designed as bribes to influence the prescribing behavior of the speakers themselves.

Similar logic was applied in a case leading to a settlement by Teva Pharmaceuticals ("U.S. Ex Rel. Arnstein v. Teva Pharmaceuticals" 2019). Health care providers rotated through sequential Teva presentations, serving "as the speaker at one and audience member at the other," suggesting that conveyance of scientific information was not an intended outcome of these events. Both the Insys and Teva cases alleged that prescribing volume was a primary criterion for selecting speakers, violating the Code requirement that "decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation…" ("Code on Interactions with Health Care Professionals" 2021).

IV. Empirical findings on physician-industry relationships support broader enforcement of AKS

While some forms of industry payments to physicians have been prosecuted as illegal kickbacks, others have been generally permitted and remain highly prevalent. However, empirical findings now suggest that even these latter types of industry payments (eg. "modest" meals and "legitimate" speaking fees) still influence physician prescribing. This puts these payments in violation of the Code's language on physician independence, which may subject them to possible prosecution under AKS.

The Code's "independence and decision making" clause nominally prohibits any remuneration that would "interfere with" physician prescribing ("PhRMA Code on Interactions with Healthcare Professionals, 2002" 2002). HHS OIG used even broader language in its 2003 compliance program guidance: relationships that "have a potential to interfere with, or skew, clinical decision-making" would be at "greatest risk of prosecution" (emphasis added) ("Compliance Program Guidance for Pharmaceutical Manufacturers." 2003). In a 2020 Special Fraud Alert on speaker programs, the HHS OIG further clarified its definition of "skew." Citing several studies of the impact of industry payments on prescribing, it concluded that "[health care providers] who receive remuneration from a company are more likely to prescribe or order that company's products…[which] may skew their clinical decision making in favor of their own and the company's financial interests, rather than the patient's best interests" ("Special Fraud Alert: Speaker Programs" 2020). In other words, payments that cause even modest changes to physician practice may be considered illegal kickbacks.

The empirical evidence that industry payments influence – or "skew" – physicians' prescribing is now strong. This is true for not only egregious bribes such as the sham speaker programs that have already resulted in AKS lawsuits, but also other types of payments that are commonly regarded as acceptable. The majority of industry payments to physicians come in the form of free meals, consulting fees, or speaking fees (Tringale et al. 2017; Inoue et al. 2019); these are the payment types that have been the focus of prior studies and have been associated with increased prescribing. Studies have specifically evaluated meals (Carey, Lieber, and Miller 2020; DeJong et al. 2016) and consulting/speaking arrangements (A. P. Mitchell et al. 2019), and have found increased prescribing associated with both.

Advocates for maintaining the status quo of physician-industry financial relationships point out that payments have purposes other than influencing physicians prescribing (Nakayama 2010; Rosenbaum 2015). Payments purportedly have beneficial goals: speakers fees and free meals support education and informational presentations wherein physicians learn about new drugs, and consulting arrangements allow industry to identify areas of clinical need to prioritize future research and development. However, federal case law and HHS OIG guidance have clearly established that payments with an identified "legitimate" reason may still qualify as illegal kickbacks. A payment is a kickback if "any one purpose of the remuneration may be to induce or reward the referral or recommendation." Restated, "a lawful purpose will not legitimize a payment that also has an unlawful purpose" ("Compliance Program Guidance for Pharmaceutical Manufacturers." 2003). HHS OIG has concluded that based on the available evidence – and the fact that legitimate information may be conveyed to physicians without such payments – one goal of industry payments to health care providers (HCPs) must be to influence prescribing, putting them in violation of AKS:

> "Furthermore, studies have shown that HCPs who receive remuneration from a company are more likely to prescribe or order that company's products. This remuneration to HCPs may skew their clinical decision making…There are many other ways for HCPs to obtain information about drug and device products and disease states that do not involve remuneration to HCPs. The availability of this information through means that do not involve remuneration to HCPs further suggests that at least one purpose of remuneration associated with speaker programs is often to induce or reward referrals."
>
> ("Special Fraud Alert: Speaker Programs" 2020)

By the PhRMA Code's own language, any type of industry payment to physicians that has been demonstrated to influence their prescribing would violate the Code. More importantly, by HHS OIG's interpretation of the statute, any such payment would by prosecutable as an illegal kickback under AKS. Therefore, because many common types of payments – even those purported to have other positive consequences such as meals, speaking, and consulting – have been clearly linked to changes in physician prescribing, the OIG's discretion to prosecute illegal kickbacks under AKS could be applied far more broadly than it has been historically.

Importantly, there remain some (less common) forms of industry payment, such as physician research funding and grants, that appear much less likely to violate AKS. The empiric literature is unclear on whether these types of payments influence prescribing, nor is it evident that the intent of such payments is to influence prescribing.

V. Potential stakeholder actions to mitigate harm from physician-industry relationships

Various stakeholders across healthcare delivery and financing have an interest in the potential consequences of physician-industry relationships. Each stakeholder has a different set of available actions to address these relationships and mitigate potential harms, many

of which have been discussed previously (Brennan et al. 2006; M. A. Rodwin 2012). The recent increase in available evidence strongly suggesting that industry payments to physicians increase prescribing and healthcare costs – and may therefore constitute AKS violations – raises several additional, potential actions to mitigate these payments beyond those that have previously been identified. We discuss these potential actions in the context of an existing conceptual framework for COI mitigation based on the relative timing of the conflict and the mitigation effort (Table 1) (M. Rodwin 2019).

The stakeholders with the greatest immediate capacity to curtail financial COI are the involved parties: drug manufacturers and physicians. For both, there are philosophical and practical interests in reducing the potential harm from financial COI. To the extent that payments to physicians result in suboptimal prescribing practices, it is contrary to physicians' professional obligations to serve their patients' interests, and misaligned with the stated missions of drug manufacturers, which prioritize improving human health. Practically, both manufacturers and physicians may suffer downstream consequences if engagement in COI erodes public trust.

Physicians could apply various means of self-regulation to reduce the prevalence of COI and the potential for it to inappropriately influence prescribing. A concern commonly raised in defense of physician-industry COI is that industry money and gifts (often, free food) typically accompany information on new drug products, allowing busy clinicians to stay up to date more easily (Nakayama 2010). However, physician professional societies are well positioned to fill this informational need, obviating the need for information or gifts from industry. Many societies already have infrastructure in place for peer-education and rapid dissemination of new prescribing information, which could be further expanded to fully replace industry in this role. Such societies could also set stricter standards for what is considered a permissible relationship, especially among its members who serve on clinical practice guideline committees or have other leadership roles.

A potential advantage of physician self-regulation is precision in deciding which industry relationships to permit vs. curtail. Provider organizations could adopt stricter rules for the specific types of relationships that present the greatest risk for bias and the lowest potential for benefit (Brennan et al. 2006). For example, physicians might elect to end the acceptance of compensation that serves primarily industry marketing purposes, such as free meals and speaking fees, while permitting relationships that have greater potential for public benefit, such as early-stage collaborative research on pre-market products. However, the likelihood of successful physician self-regulation may be limited, because physician-industry relationships remain popular. The majority of physicians believe that accepting remuneration from industry does not adversely affect their practice (Fischer et al. 2009; Korenstein, Keyhani, and Ross 2010). Physicians feel that accepting industry remuneration is appropriate (Brett, Burr, and Moloo 2003; Korenstein, Keyhani, and Ross 2010), and some actively advocate in favor of this practice (Nakayama 2010). Consistent with this perspective, the amount of industry payment physicians accept annually has remained largely unchanged since reporting through Open Payments began in 2013 (Ornstein, Weber, and Jones 2019).

The drug industry is also positioned to reduce COI by directly reducing payments to physicians. In acknowledging that current evidence demonstrates that many types of payments, such as sponsored meals and speaking fees, are inconsistent with its stated principles on physician "Independence and Decision Making," PhRMA could update its Code to make it more stringent. By prohibiting such payments, industry self-regulation would similarly have the advantage of targetability, because industry has the most direct insight into which payments serve scientific vs. simply marketing purposes. PhRMA has taken similar actions in the past; the Code's 2009 and 2021 updates prohibited several types of physician payments that were previously permitted, including recreational events for physicians serving as consultants or speakers, and gifts such as pens and mugs. Industry self-regulation may be an unlikely solution, however. Though it would be aligned with PhRMA's stated principles on physician independence, reducing physician payments would be directly counter to drug manufacturers' financial interests (M. Rodwin 2015).

Another direct avenue to reducing physician-industry COI would be a direct ban on such activity. This would require new action by lawmakers. Such action could be justified as being in the public interest, insofar as the federal government and the US taxpayer have a stake in reducing the excess spending generated by industry payments, which contributes to the budgetary strain on the federal health care programs and exposes Medicare and Medicaid beneficiaries receiving treatment with unnecessarily expensive and potentially suboptimal drugs. Such legislation might broadly prohibit all forms of industry remuneration to physicians, or might focus on types of payments that have come under the greatest scrutiny for fraud (such as payment in speaker programs ("Special Fraud Alert: Speaker Programs" 2020)), or those that serve no beneficial purpose other than marketing (such as free meals). Such prohibitions have precedent in the states. Vermont, for example, prohibits drug manufacturers from providing meals to Vermont health care practitioners, except as part of fair market value compensation for a service ("GUIDE TO VERMONT'S PRESCRIBED PRODUCTS GIFT BAN" 2019). This approach has the advantage of being preventive, before any potential adverse consequences of physician-industry COI may occur. The primary disadvantage of a prospective ban may be political infeasibility, as it would likely be highly unpopular among the affected parties.

The interests of payers are aligned with the goal of reducing excessive pharmaceutical costs, and even if a prospective ban is infeasible then payers may have other options to mitigate the cost-increasing potential of physician-industry COI. Both commercial and public payers may be able to reduce the consequences of industry payments through closer supervision of physician-industry COI and differential treatment of providers who do vs. do not accept industry payments. Payers might easily apply publicly availability of industry payment data to identify physicians in their networks who have substantial financial ties with industry. Payers could use this information in combination with existing contract negotiation and utilization-management tools to exclude payment-accepting physicians from preferred networks, or apply prior authorization or step therapy requirements to non-generic, generic-eligible prescriptions written by physicians who receive payments from the manufacturer. Alternately, physicians who do not accept payments could have prior authorization requirements relaxed. These approaches would have the advantage of targeting only the COI with the greatest potential for harm: instances where the conflicted provider

is actively prescribing the drug[s] relevant to the conflict. Instances of conflict without evidence of influencing patient care could be permitted. A limitation of this approach would be the timing lag of Open Payments data. Data are released in full calendar years approximately 6 months after each year's end; therefore, a new conflict occurring in January would not become apparent in Open Payments data for well over a year. There would also be the potential for heterogeneous application of Open Payments data among commercial payers, such as varying criteria for what constitutes a concerning level of COI, causing confusion among physicians and complicating efforts to maintain COI within acceptable thresholds.

Federal regulators could reduce physician-industry COI through increased penalization of such activities. As outlined in section III, industry payments influence ("skew") physician prescribing, in violation of PhRMA Code language regarding physician independence, which per HHS OIG guidance may make them subject to prosecution as illegal kickbacks under AKS. If mitigating physician-industry COI were a priority, HHS OIG, working in collaboration with the Department of Justice, would appear to have substantial leeway to increase prosecution of many prevalent forms of COI within the bounds of its current interpretation of AKS.

In addition to AKS prosecution, the prescriptions linked to industry payments may be subject to additional civil penalties under the federal False Claims Act (FCA). The FCA prohibits a variety of activities which constitute the submission of a false or fraudulent claim for compensation from the federal government, such as overbilling Medicare or Medicaid for health care services rendered. This specifically includes any health care service resulting from an illegal kickback (Krause 2013). Restated, AKS penalizes the kickback (industry payment), and FCA penalizes the resulting claims for fraudulently-rendered health care services. Courts have held that once an illegal kickback has been established, to further establish that false claims resulted, it is sufficient to demonstrate only that the kickback recipient subsequently prescribed the promoted product; it is not necessary to demonstrate that the prescription occurred *because of* the kickback ("U.S. Ex Rel. Arnstein v. Teva Pharmaceuticals" 2019; "U.S. Ex Rel. Greenfield v. Medco Health Solutions, Inc.; Accredo Health Group, INC.; Hemophilia Health Services, Inc." 2018). This standard would be straightforward to establish given the public availability of Medicare prescription drug claims. As an additional penalty for certain forms of fraud and abuse, including payment or receipt of kickbacks or submission of false claims, HHS also has authority to exclude offending pharmaceutical manufacturers and health care providers from federal health care programs.

A primary advantage of this penalization approach – through AKS, FCA, and potentially the federal health program exclusion – is its availability. These penalties can be sought under existing interpretations of these laws, and without the need for further action or assent from other stakeholders. The magnitude of these penalties (consider the substantial portion of health industry revenue derived through the federal health care programs) would substantially increase the likelihood that they successfully discourage physician-industry COI (M. Rodwin 2015). If the federal government communicated an intent to broaden its enforcement and application of these penalties, this alone would likely be sufficient to

effect a large reduction in physician-industry payment activity. A potential risk of increased penalization is that some physicians, out of an abundance of caution to avoid these hefty penalties, might also cease industry relationships that had low risk of harm and potential benefit.

VI. Conclusions

The empirical evidence regarding industry payments and prescribing has grown quickly in recent years. There is now strong evidence to suggest that payments influence prescribing. By the interpretation of AKS previously put in place by HHS OIG, this implies that additional forms of industry payments to physicians may be subject to prosecution under AKS beyond those that have been historically. Such sanctions would present a new and potentially highly effective method to reduce industry payments and mitigate the degree to which they may increase prescription drug spending. Stakeholders may consider AKS enforcement alongside a spectrum of existing options to better regulate physician-industry conflict of interest.

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Table 1:

Potential stakeholder actions to mitigate effects of physician-industry conflict of interest. DHHS, Department of Health and Human Services.

Strategic approach	**PREVENTION**	**REGULATION**	**SANCTIONS/RESTITUTION**
Timing of intervention	Stop conflicts from ever arising **before** they occur	Supervise conflicts **during** their occurrence	Penalize actors **after** an inappropriate conflict occurs
Examples of specific actions, and the applicable stakeholder	**Industry**: Self-regulation to curtail types of payments empirically demonstrated to conflict with PhRMA Code's "independence and decision-making" language **Physicians**: Self-regulation to curtail the most harmful kinds of payments **Lawmakers**: New legislation to prospectively prohibit industry payments	**Payers**: Exclude payment-accepting physicians from preferred networks **Payers**: Apply additional prior authorization and step therapy requirements to non-generic prescriptions by payment-accepting physicians	**DHHS, Office of Inspector General / Department of Justice**: Prosecute a broader range of industry payments to physicians as illegal kickbacks and/or false claims **DHHS, Office of Inspector General**: Exclude payment-accepting physicians from reimbursement through the Federal Health Care Programs

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