Safe Harbors (and Other Strategies) for Life Sciences and Healthcare Companies in the International Anti-Corruption Storm

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INTRODUCTION

For life sciences and healthcare companies accustomed to operating within the bounds of U.S. fraud and abuse laws, certain gaps between domestic and international anti-corruption laws can cause compliance challenges This article focuses on two such gaps.

First, unlike the Anti-Kickback Statute (AKS), the Foreign Corrupt Practices Act (FCPA) lacks safe harbors that expressly permit a range of routine interactions between pharmaceutical, medical device, and healthcare companies, on the one hand, and individual healthcare professionals (HCPs) and institutions, on the other Attorneys from the FCPA Units of the U.S Department of Justice (DOJ) and U.S Securities and Exchange Commission (SEC) generally do not approach these issues from a U.S healthcare compliance perspective; they are often skeptical of certain arrangements with HCPs that are common in the United States and can be structured to comply with the law based on well-known statutory exceptions or regulatory guidance In recent enforcement actions, both DOJ and the SEC have targeted conduct that, had the defendant companies more carefully structured their business arrangements with HCPs, might have satisfied the standards of an AKS safe harbor, and thus presented far less significant corruption risks.

Second, whereas the Prescription Drug Marketing Act (PDMA) generally authorizes pharmaceutical companies to provide free prescription drug samples to HCPs and other healthcare institutions for promotional purposes here in the United States, the FCPA itself offers less certainty as to the circumstances under which free samples and other demonstration products are appropriate. Because life sciences companies routinely provide free prescription drug samples or demonstration devices to providers to familiarize them with the products' therapeutic benefits and/or to help patients begin a course of treatment, the FCPA's ambiguities can result in confusion and regulatory exposure for these companies.

After addressing recent FCPA enforcement actions that highlight these gaps, this article turns to compliance measures and considerations for life sciences and healthcare companies operating overseas DOJ and FCPA enforcement actions against such companies often echo the fraud and abuse concerns that animated the limitations in AKS safe harbors and the PDMA and signal that certain good practices associated with domestic healthcare compliance programs can mitigate international anti-corruption risks as well.

Indeed, DOJ and the SEC should recognize risk-mitigating factors outlined in the AKS safe harbors and the PDMA in evaluating FCPA enforcement actions. By providing clearer guidance on the FCPA's bounds, or at least weighing these factors more explicitly and heavily in exercising enforcement discretion, DOJ and the SEC would narrow the gaps between domestic and international anti-

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corruption enforcement, clarify their expectations for overseas pharmaceutical and device sales and marketing activities, and confirm that certain beneficial sales and marketing practices do not run afoul of the FCPA.

RELEVANT LAWS

The AKS and Relevant Safe Harbors

The AKS prohibits life sciences and healthcare companies from "knowingly and willfully" offering or paying "remuneration," directly or indirectly, to induce patient referrals, reward a referral source, or generate business involving any item or service "for which payment may be made in whole or in part under a [U.S.] Federal health care program." Under the statute, "remuneration" "includ[es] any kickback, bribe, or rebate in cash or in kind."[2]

Because of this definition's broad reach, Congress has enacted 10 exceptions to the statute's prohibitions and also directed the Secretary of the Department of Health and Human Services (HHS) to promulgate safe harbors that exempt certain categories of "payment practice[s]" from the definition of "remuneration."[3] Currently, there are more than 34 such regulatory safe harbors.[4]

The HHS Office of Inspector General (OIG), which has authority to impose administrative sanctions (including exclusion) for violations of the AKS, has noted that companies "may voluntarily seek to comply with [the safe harbors] so that they have the assurance that their business practices would not be subject to any anti-kickback enforcement action.[5] "[C]ommon business arrangements" protected by the AKS safe harbors include (1) personal services and management contracts; (2) investment interests; and (3) discount and rebate agreements This article discusses each of these safe harbors in additional detail below.

The PDMA

As OIG has observed, "[t]he provision of drug samples is a widespread industry practice that can benefit patients, but can also be an area of potential risk[.]"[6] In the United States, this practice is governed by the PDMA, as amended both by the Prescription Drug Amendments of 1992 and the FDA Modernization Act of 1997 The PDMA delineates how pharmaceutical companies may permissibly distribute prescription drug samples Under the PDMA, drug manufacturers may provide prescription drug samples to licensed prescribers if the prescribers request such samples, so long as the recipient does not sell them or bill a payor for them and certain recordkeeping requirements and other conditions are satisfied Entities that fail to adhere to these requirements can face both civil and criminal liability.[7]

Generally speaking, domestic enforcement actions relating to drug sampling have targeted companies that provided samples to HCPs "who, in turn, sold them to the patient or billed federal health care programs" for them [8] For example, in the TAP Pharmaceutical Products, Inc. enforcement action, the company pleaded guilty to conspiring to violate the PDMA based on allegations that the company caused physicians to submit claims to Medicare for reimbursement for thousands of free samples of a prostate cancer drug.[9]

The PDMA does not, however, protect device or diagnostic companies or durable medical equipment manufacturers that provide free-of-charge products Nor does the AKS include a particular statutory exception or safe harbor for the provision of free devices or medical equipment for demonstration or evaluation purposes Accordingly, DOJ and OIG have challenged the provision of a range of devices and diagnostic materials as impermissible remuneration[10] Nonetheless, device and durable medical equipment manufacturers commonly (and appropriately) provide demonstration and evaluation equipment to providers under the ambit of controls intended to mitigate the risk that the equipment will be considered an improper inducement.

The FCPA

The FCPA's anti-bribery provisions prohibit corruptly giving, promising, or offering anything of value to a foreign official with the intent to influence that official to secure an improper advantage (and thereby to obtain or retain business)[11] From a jurisdictional standpoint, these provisions apply to "U.S. persons and businesses (domestic concerns), U.S. and foreign public companies listed on stock exchanges in the United States or that are required to file periodic reports with the SEC (issuers), and certain foreign persons and businesses

acting while in the territory of the United States (territorial jurisdiction)."[12] The statute's accounting provisions require "issuers" (generally entities with shares traded on U.S. stock exchanges or with periodic reporting obligations to the SEC) to make and keep accurate books and records and implement an adequate system of internal accounting controls; Congress enacted these provisions to deter off-the-books expenditures [13] Whereas the AKS has several statutory exceptions, the FCPA has just one exception (that applies to a narrow category of payments that facilitate "routine government action") and two affirmative defenses.

The first affirmative defense applies to activities that are expressly permissible under the local law of the host country [14] The second defense sanctions "reasonable and bona fide expenditure[s]" (e.g., "travel and lodging expenses") so long as they are directly related to the "promotion, demonstration, or explanation of products or services," or to the "execution or performance of a contract with a foreign government or agency thereof."[15] Accordingly, by statute, life sciences and healthcare companies may support travel by foreign officials (including HCPs) to meetings tied to product promotions, demonstrations, or explanations; but they must be sure not to make the expenditures "corruptly in return for an official act or omission."[16] One 30-year-old FCPA Opinion Release suggests that DOJ had concluded that product samples intended to demonstrate a product's attributes and quality fall within this affirmative defense (where the samples were not provided to officials for their individual use and where the government entity employing the recipients was aware of the free samples)[17] More recently, DOJ indicated that it would not bring an enforcement action against a medical device entity that planned to provide free-of-charge medical devices (and associated accessories and services) to recipients associated with a government healthcare system for product testing and evaluation purposes (in light of several risk-mitigation measures that the entity pledged to undertake).[18]

FCPA Enforcement Actions Relating to Personal Services Relationships with HCPs

Despite the absence of FCPA safe harbors with granular requirements like those promulgated by HHS pursuant to the AKS, recent DOJ and SEC enforcement actions have included factual allegations echoing those requirements Although these actions allege additional evidence of bribery, it is noteworthy that they highlight lapses otherwise addressed by the safe harbors in the domestic context Applying those safe harbor concepts in the FCPA compliance and controls context should help life sciences and healthcare companies further mitigate their foreign bribery risks arising from the various types of personal services relationships with HCPs that such companies may properly pursue.

Consulting Relationships and Speakers' Bureaus

Domestic Safe Harbor and Related Arrangements

Under the personal services and management contracts AKS safe harbor, life sciences, and healthcare companies routinely engage HCPs to provide bona fide services as consultants on marketing strategies and product technologies, medical directors, and educators (e.g., speakers) This safe harbor insulates arrangements in which a company provides fair market value compensation to HCPs or healthcare entities for providing bona fide services, so long as the agreement:

- is set out in a writing signed by the parties,
- covers (and specifies) all of the services for the agreement's term,
- lasts no more than a year,
- provides for a compensation methodology that is "set in advance," and compensation that is "consistent with fair market value," and "not determined in a manner that takes into account the volume or value of any referrals," and
- includes services that "do not exceed those which are reasonably necessary to accomplish commercially reasonable business purposes."[19]

Life sciences and healthcare companies routinely structure relationships with HCPs who serve as advisors, consultants, preceptors, proctors, and speakers under this safe harbor [20] Similarly, in light of state corporate practice of medicine laws, healthcare entities such as hospice, nursing, longterm care,

and hospital systems and institutions generally structure relationships with their medical directors under this safe harbor Historically, diagnostic companies (e.g., entities that conduct blood or urine testing) also have compensated HCPs for the time they spend processing and handling samples[21] In 2014, OIG issued a Special Fraud Alert challenging these practices to the extent they (among other high-risk characteristics) tie compensation to the value or volume of referrals or compensate the physician for services reimbursed by a third-party payor (e.g., Medicare).[22]

Implications for FCPA Matters

As explained above, ensuring that transactions are structured appropriately to meet AKS safe harbor requirements may help companies mitigate corruption risks and better address DOJ and SEC concerns regarding transactions with HCPs DOJ and the SEC have targeted these types of relationships in recent FCPA enforcement actions and, in so doing, have revealed both the importance of taking risk mitigation steps mirroring those in the safe harbors and, more broadly, the potential gaps between domestic and international anti-corruption laws.

DOJ has periodically targeted life sciences or healthcare companies that made payments to consultants in connection with government tenders for drug or device products In many of those actions, DOJ has highlighted the company's failure to document its relationship with the consultant as additional evidence that payments to the consultant were, in fact, intended to be channeled to government officials For instance, DOJ entered into a March 2019 non-prosecution agreement (NPA) with Fresenius Medical Care AG & Co KGaA, under which the German provider of medical products and services agreed to pay $231 million and admitted that it "engaged in various schemes to pay bribes to publicly-employed health and/or government officials" in several countries[23] The conduct described in the NPA included a consulting relationship with a public HCP in Spain (the Head of Nephrology at a state-owned hospital) According to the admitted statement of facts, Fresenius paid the HCP more than $80,000 without a written consulting agreement, and the HCP's hospital thereafter awarded a tender to Fresenius in 2011.

Similarly, in certain recent enforcement actions, the SEC has viewed consulting and speakers' fees as presumptively problematic if the company that paid them lacked supporting paperwork For example, in the SEC's parallel FCPA resolution with Fresenius, the agency alleged that a "wholly consolidated distributor" of Fresenius paid a Saudi official associated with an organization that "reviewed and approved dialysis products for use in tenders" under "consulting contracts" even though "there was no evidence that services were performed."[24] The SEC also alleged that Fresenius "made over $957,000 in payments to a Bosnian healthcare executive to assist FMC's establishment of clinics in Brcko and Hercegovina, without any evidence of services performed."[25]

The SEC's focus on a lack of supporting documentation in the Fresenius action as an indicator of corruption tracked similar assertions in many prior SEC enforcement actions, including:

- In a 2020 enforcement action against Alexion Pharmaceuticals Ltd , the SEC asserted, in relevant part, that the company's subsidiary hired and paid a consultant who passed on a portion of the payments to government officials in an effort to obtain more patient approvals for the subsidiary's drug The SEC alleged that the subsidiary made those payments without requiring the consultant to provide sufficient documentation of expenses or of the services provided by the consultant in exchange for the payments According to the SEC, the consultant "provided little or no explanation for many expenses, and failed to provide independent documentation for most of the purported expenses."[26]

- In a 2017 enforcement action against Biomet, Inc., the SEC alleged, in relevant part, that Biomet, through its Mexican subsidiary and third-party customs brokers, unlawfully paid Mexican customs officials "to facilitate the importation of Biomet's unregistered and unlabelled dental products into Mexico."[27] Biomet's Mexican subsidiary allegedly hired a customs broker without entering into a written contract or fee schedule with the customs broker and made payments to the customs broker and its sub-agents According to the SEC, the payments that Biomet made to the sub-agents were "unusually large and lacked supporting documentation, containing only one-line invoic-

es[.]"[28] The customs broker's invoices had no supporting fee schedule and included vague line items The company also allegedly improperly recorded the "unsupported and/or improper charges[.]"[29]

- Similarly, in a 2016 resolution with AstraZeneca PLC, the SEC alleged that the company's subsidiary in China "paid speaker fees to HCPs despite [maintaining] service contracts that were incomplete, containing no meeting date, venue, subject or fees associated with the particular speaker event."[30]

Other echoes of the AKS personal services safe harbor recur in recent FCPA enforcement actions For example, according to the SEC, the financial relationships between Fresenius employees and HCPs also hinged in part on the volume or value of products purchased The SEC asserted that Fresenius employees "entered into a sham marketing agreement with" the chief nephrologist at two Moroccan state-owned military hospitals Under that agreement, Fresenius obligated itself to pay the HCP a 10 percent commission on a contract with one hospital.[31] Separately, Fresenius purportedly "entered into sham consultant agreements with three government hospital executives" in Gabon; those agreements allegedly resulted in "kickback[s]" based on "each dialysis kit sold" to the public hospital (payments that were "falsely recorded as 'export commissions'"). [32] The SEC alleged that Fresenius also paid an Angolan official a 20 percent commission on all dialysis kits sold to Angolan military hospitals.[33]

Investment Interests

Domestic Safe Harbor and Related Arrangements

Healthcare entities also have historically availed themselves of the investment interests safe harbor to partner with HCPs on new businesses and joint ventures.

In addition to protecting certain investments by HCPs in large (i.e., $50 million-plus in assets) publicly traded healthcare companies[34] and investments in entities providing healthcare in "underserved area[s],"[35] this safe harbor demarcates appropriate investments (and returns) on limited partnership and joint venture stakes Among other requirements:

- the terms of the investment opportunity cannot vary in favor of HCP investors who have the ability to refer business to the entity,
- the terms cannot obligate the investor to refer business,
- the entity (or another investor) cannot loan funds to an investor that has the ability to refer business "if the investor uses any part of such loan to obtain the investment interest,"
- investment returns must be "directly proportional to the amount of the [investor's] capital investment (including the fair market value of any pre-operational services rendered)[,]" and
- no more than 40 percent of the entity's gross revenue from furnishing healthcare items or services in the past year can come from referrals or business generated by investors.[36]

Innovative and entrepreneurial HCPs often invest in entities that provide ancillary products or services to their core medical practices Historically, for instance, certain nephrologists have entered into joint ventures with companies that provide end-stage renal disease treatments.[37] Similarly, surgeons who develop device technologies have routinely formed companies to market those devices, and some surgeons have taken stakes in (or secured royalties from) entities that sell or distribute medical devices to inpatient facilities or ambulatory surgical centers where those same HCPs perform surgeries (using the devices they sell or distribute).[38]

Because of the potential referral streams at issue, U.S. regulators are quite skeptical of HCP investments of this nature Notably, OIG has published two Special Fraud Alerts (among other guidance documents) identifying AKS risk factors associated with physician-owned distributorships, and an OIG rule that went into effect in January 2021 reiterates OIG's concerns about physician-owned distributorships.[39] Although OIG views these arrangements as "inherently suspect under the [AKS]," some physicians have sought to structure investment interests of this nature so that they fall within the investment interests safe harbor.

Implications for FCPA Matters

As OIG has observed with respect to domestic arrangements, such as new businesses and joint ventures between healthcare entities and HCPs, they can raise significant corruption concerns if structured inappropriately overseas Joint-venture relationships with HCPs figured prominently in Fresenius's resolution with DOJ In its NPA, Fresenius acknowledged that it offered shares in Fresenius's local subsidiary (a joint venture) to an Angolan Armed Forces Medical Services Division official and a prominent Angolan HCP According to the NPA's agreed-upon statement of facts, Fresenius offered these foreign officials 15 percent stakes in the joint venture in an effort to secure business The SEC further alleged that Fresenius transferred the stakes to the Angolan officials "without their having paid anything in exchange and without any due diligence conducted on the transaction."[40]

Similarly, Fresenius admitted that it established joint ventures with public HCPs in Turkey, investment stakes which resulted in significant profits for at least one HCP (when Fresenius bought back his shares) According to the SEC, "[b]etween 2005 and 2014, [Fresenius's Turkish subsidiary] entered into four separate joint ventures with publicly employed doctors in exchange for those doctors directing business from their public employer to [Fresenius] clinics," while the HCPs "did not provide any capital in exchange for their shares."[41] For example, the SEC alleged that Fresenius conferred an investment stake on a "professor with ties to the Turkish Minister of Health, for referring patients from the university's clinics."[42] The SEC asserted that the professor did not contribute capital to the joint venture, but ultimately "was paid $323,000 for his 40% stake despite having an outstanding $1,553,000 receivable."[43]

Discounts

Domestic Safe Harbor and Related Arrangements

Domestically, the discount and rebate safe harbor to the AKS encourages life sciences and healthcare companies to implement policies and procedures relating to discounts and rebates

By statute, prohibited "remuneration" does not include "a discount or other reduction in price if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider" that received the discount or price reduction.[44] The discount safe harbor promulgated by the Secretary of HHS adds a series of additional strictures (purportedly to clarify the statutory exception) The safe harbor, for example, expressly protects "arms-length" price reductions unless, for example, they are in cash or cash equivalents (except for certain rebates by check), they are provided to one payor but not to federal payors, or they are provided on one good or service "to induce the purchase of a different good or service" (except in circumstances where the different goods or services are reimbursed under the same federal healthcare program methodology and the reductions are disclosed to the program).[45] Further, the safe harbor details the disclosure obligations on sellers, buyers, and discount offerors (all intended to ensure that discounts/rebates inure to the benefit of federal healthcare programs as appropriate).

Discounts and rebates are fundamental features of the U.S pharmaceutical supply chain Generally speaking, manufacturers enter into a range of discount and/or rebate arrangements with wholesalers, pharmacies (including specialty pharmacies), and pharmacy benefits managers.[46] Device and diagnostic companies also enter into discount and/or rebate arrangements with HCPs or payors that directly purchase devices, reagents, or testing kits Indeed, payors such as Medicare "expect[] providers to take advantage of available discounts," including "cash, trade and quantity [purchase] discounts."[47]

Implications for FCPA Matters

Absent policies and procedures relating to discounts and rebates that apply internationally, companies can run into significant corruption-related risks DOJ and the SEC routinely have pursued companies for providing purportedly inflated discounts to third-party distributors that enabled the distributors to make improper payments to public HCPs For example, in a 2018 enforcement action, the SEC alleged that managers of a multinational pharmaceutical company's Kazakh subsidiary schemed with distributors to "corruptly influence the award of tenders at public institutions" via funds generated from "20-30 percent discount[s] to the distributors."[48] According to the SEC, the company "had no standardized commercial policy for distributor discounts and did not review the discounts provided by local management."[49] The

SEC asserted that the Kazakh subsidiary and its distributors would secure public tenders and then, after doing so, agree on a "sale price between [the company] and the distributor [that] included a pre-determined discount or credit note from the sale price between the distributor and the public institution."[50] That discount allowed the distributor to "designate a portion as the fund which [it] used to bribe Kazakh officials."[51] Thus — at least according to the SEC — the company failed to either compensate its distributor based on the fair market value of its services (as the personal services safe harbor would require) or transparently disclose the discount to the ultimate payor (as the discount safe harbor would require).

Similar fact patterns appear in a slew of SEC FCPA enforcement actions, such as:

- In 2019, the SEC alleged that Fresenius converted a relationship with a West African sales agent into a distributor relationship and then provided that distributor "a significant margin on sales to the Ministry of Health" of Gabon and several public hospitals "to fund the payments to HCPs."[52] Fresenius also positioned an Angolan distributor to make sales to a large customer and structured the arrangement to "create[] a significant margin, approximately 60% of sales, that was provided to the government officials on over $433,000 in sales."[53]

- In 2017, the SEC alleged that Orthofix's Brazil subsidiary "provided a high discount ranging in certain instances of up to 70% to the distributors, who then used part of the profit generated by that discount to make improper payments to certain doctors."[54] According to the SEC, the distributors "openly discussed the improper payments in person with certain" employees of the subsidiary in an effort to secure "higher discounts from the company to facilitate the payments."[55]

- In 2014, the SEC targeted Bio-Rad for securing sales to public institutions in Vietnam by bribing public HCPs Bio-Rad's Singaporean subsidiary purportedly sold "products to a Vietnamese distributor at a deep discount, which the distributor would then resell to government customers at full price, and pass through a portion of it as bribes."[56]

Product Samples / Free Goods

Domestic Legal Protections and Related Activities

Under the PDMA, pharmaceutical companies may distribute prescription drug samples to HCPs to promote their products, so long as the recipient is a licensed practitioner who has requested the samples in writing and the distributing company has a system to track the samples (and ensure that they are free from contamination or adulteration).[57] Further, pharmaceutical companies must implement measures to ensure that recipient HCPs do not sell the samples or bill payors for them.[58] Unlike other transfers of value to domestic HCPs, pharmaceutical companies are not required to report drug samples pursuant to the Physician Payment Sunshine Act.[59]

Implications for FCPA Matters

Absent the PDMA's protections, product sampling overseas can draw unwelcome scrutiny under the FCPA, which does not delineate specifically how to manage samples compliantly This is so even when the circumstances do not evince any effort by the receiving HCP to benefit personally from the samples.

In 2018, for instance, the SEC alleged that Sanofi violated the FCPA's accounting provisions based on, in part, a subsidiary entity's purported provision of product samples to an HCP in Jordan.[60] According to the SEC, an HCP affiliated with a "large public hospital in Jordan" requested samples of an expensive cancer drug as a "[f]avor."[61] The SEC asserted that "no justification was provided" for the sampling and claimed that the HCP who requested the samples was a key opinion leader and a tender committee member at the hospital.[62]

The SEC's allegations in that resolution parallel similar assertions in the agency's earlier action against Wyeth for conduct in Indonesia According to the SEC, Wyeth Indonesia provided free-of-charge "nutritional products to employees of Indonesian government-owned hospitals, including doctors employed by the Indonesian government."[63] The company purportedly instructed its in-country distributors "to generate invoices and to deliver the products, but to then charge back the value of the goods" to the company.[64] By providing the products for free, Wyeth Indonesia allegedly induced HCPs to recommend the company's nutritional products, make those

products available to new mothers, and secure data for marketing purposes.

Compliance Takeaways

AKS safe harbors and the PDMA requirements are intended to promote transparency in HCP relationships and mitigate undue influence on HCPs' medical decision-making As the OIG Compliance Program Guidance explains, "[i]n light of the obvious risks inherent in [relationships with HCPs and other persons and entities in a position to make or influence referrals], whenever possible prudent manufacturers and their agents should structure relationships with physicians to fit in an available safe harbor[.]"[65]

Structuring overseas arrangements with HCPs, third-party business partners, and customers to fall within the prescriptive requirements of AKS safe harbors is no panacea to potential FCPA exposure The SEC, in particular, may question even well-documented, bona fide personal services agreements with public HCPs operating overseas, investment arrangements, and/or discounts provided to distributors But just as entities in the United States routinely mitigate risk by structuring relationships to satisfy some of a safe harbor or multiple safe harbors' requirements, companies with international operations can use safe harbor elements to enhance their existing anticorruption compliance programs For example, subject to their particularized risk profile and tolerance, healthcare companies should consider the following compliance priorities:

Documenting HCP Relationships

As the DOJ and SEC FCPA enforcement actions described above underscore, carefully documenting financial relationships with HCPs can lessen the risk not only of an FCPA violation but also the risk of a full-blown investigation by U.S. regulators. By analogizing to the personal services safe harbor's elements and implementing associated compliance controls overseas, companies can ensure that they have written contracts for services provided by HCPs (e.g., consulting or speaking services), that those contracts transparently and accurately describe the work to be performed (and the capabilities of the HCP to provide those services), that the company retains evidence of the work performed by the HCP for the compensation provided, that the engagement is reasonably related to a company commercial objective (other than product usage by that particular HCP), and that the HCP understands that the company is not seeking to improperly influence prescribing or product use decisions.

Focusing on Fair Market Value

By tying a variety of different financial relationships directly to fair market value, companies can mitigate the risk that skeptical regulators will second-guess the relationship Coverage under the personal services safe harbor expressly hinges, in part, on compensation that is set at fair market value and independent of the value or volume of referrals Similar principles underlie the investment interests safe harbor: the terms of an HCP's investment opportunity should reflect the fair market value of services contributed (independent of referrals) and be commensurate with the capital invested by the HCP As the Fresenius NPA makes clear, arrangements that fall short of the standards of the investment interest safe harbor can trigger significant scrutiny under the FCPA For example, deals with terms favorable to public-institution HCPs who have the ability to refer business will invariably raise suspicions particularly if those terms result in investment returns disproportionate to the HCP's investment And loaning such HCPs the funds to invest can spark even more skepticism.

In auditing or monitoring consulting agreements, speakers' fees, royalties paid to HCPs, and joint ventures with HCPs, companies should focus on the extent to which commercial, medical affairs, and/or other company functions have sought to calibrate compensation that the company pays to an HCP to the market value of the corresponding services or investments by the HCP

The same holds true for discount arrangements and other pricing terms that the company has struck with third-party business partners If the margins afforded an agent or distributor vary from fair market value for the agent or distributor's services, then they will be particularly susceptible to scrutiny by U.S. regulators.

Avoiding Improper Return-on-Investment Analyses

The AKS safe harbors and associated OIG guidance stress the importance of separating the value or volume of potential referrals from the terms of a company's financial relationship with HCPs In structuring financial relationships with overseas HCP customers who also happen to provide services or investment capital, companies should be especially careful not to tie the relationship's value to the volume or value of referrals from that particular HCP customer U.S. regulators have, in recent domestic and international anti-kickback and anti-corruption enforcement actions, leveraged companies' analyses of the return on their investment in a particular HCP relationship to show a willful intent to induce (under the AKS and FCA) and corrupt intent (under the FCPA).

Controlling Product Samples

Free pharmaceutical or device products can be valuable to HCPs and their patients Domestically, the PDMA makes clear that prescription drug samples can be provided appropriately (so long as the HCP does not sell or bill for the samples) Internationally, the FCPA's affirmative defense for bona fide and reasonable expenditures associated with product demonstration may provide companies some coverage But companies should be especially careful to document their rationales for providing samples, inform the government entity that employs the HCP who receives the samples of the samples, and, of course, adhere to local product sampling laws and regulations [66] By controlling the flow of samples, recording the justification for providing them, and clarifying that they are being provided to a government entity (or informing the government entity that they are being provided to the entity's HCPs), companies can mitigate the risk that samples distributed for salutary purposes (e.g., HCP education and/or patient assistance) are deemed suspicious by U.S. regulators.

Safe Harbors and Enforcement of the FCPA

As described above, the FCPA currently only includes one exception and two affirmative defenses and these provisions do not cover the full scope of conduct protected by the AKS safe harbors Because Congress and HHS rightly recognized the value of the common arrangements protected by the AKS exceptions and safe harbors, DOJ and the SEC can, and should, incorporate the core principles underlying the safe harbors into their enforcement approach to the FCPA and their associated policy statements.

To provide clarity on their approach to activities like those covered by the AKS safe harbors and PDMA, DOJ and the SEC could supplement the FCPA Resource Guide that they jointly publish, which provides "detailed information about the statutory requirements of the [FCPA] while also providing insight into DOJ and SEC enforcement practices."[67] In particular, DOJ and the SEC could use hypotheticals in the FCPA Resource Guide to emphasize that beneficial practices by life sciences and healthcare companies, like those protected by the AKS safe harbors and PDMA, are unlikely to result in any FCPA enforcement action A hypothetical applying the FCPA's exception for reasonable and bona fide product promotion to pharmaceutical sampling and demonstration devices, for example, would provide welcome comfort to life sciences companies operating overseas.

DOJ also could update its FCPA Corporate Enforcement Policy to delineate specific requirements that a company should follow when considering engaging in a relationship with an HCP — and incentivize compliant arrangements by providing some comfort regarding the likelihood of enforcement.[68] Alternatively, the Fraud Section could also issue a memorandum, similar to those previously issued, laying out revisions to its FCPA enforcement strategy and discretion, and specific requirements and guidance to companies regarding how best to comply with DOJ's expectations.[69]

The SEC has offered less enforcement guidance related to the FCPA than DOJ Nevertheless, when evaluating whether a company has violated the FCPA's internal controls provisions, the SEC could consider implementing a presumption similar to that discussed above: if a company takes all necessary steps required under guidelines that mirrored the AKS safe harbors or the PDMA requirements, then the SEC would presume that the company's internal controls are sufficient with respect to that proposed arrangement.

CONCLUSION

Key gaps between domestic fraud and abuse laws and the FCPA can give rise to a mismatch between life sciences and

healthcare companies' commercial operations and compliance programs, on the one hand, and DOJ and the SEC's expectations with respect to international anti-corruption compliance, on the other The exacting standards set by the AKS safe harbors and the PDMA offer no protection for interactions with foreign HCPs But principles underlying the safe harbors and the PDMA — and companies' associated compliance controls — can help drug, device, and healthcare companies mitigate international anti-corruption risks By leveraging these domestic controls to enhance international compliance programs, drug, device, and healthcare companies can meaningfully mitigate core corruption risks.

Endnotes

1 42 U.S.C. § 1320a-7b(b). A "claim that includes items or services resulting from" a violation of the AKS is a false claim for purposes of the False Claims Act (FCA). 42 U.S.C. § 1320a-7b(g). The FCA provides for recovery of civil penalties and treble damages from any person who knowingly submits or causes the submission of false or fraudulent claims to the United States for money or property. 31 U.S.C. §§ 3729-3733.

2 42 U.S.C. § 1320a-7b(b)(1).

3 U.S.C. § 1320a-7b(b)(3)(E). The U.S. Food and Drug Administration (FDA) is an operating division HHS.

4 42 C.F.R. § 1001.952. In light of the overlap between many of the AKS exceptions and the regulatory safe harbors, this article will use the term "safe harbor" to encompass both.

5 Dep't of Health & Human Servs., Office of Inspector Gen., Proposed Rule, RIN 0936AA10, 84 Fed. Reg. 55694, 55698 (Oct. 17, 2019).

6 Dep't of Health & Human Servs., Office of Inspector Gen., OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23739 (May 5, 2003) [hereinafter "OIG Compliance Program Guidance"].

7 *See* 21 U.S.C. § 333(b).

8 OIG Compliance Program Guidance, 68 Fed. Reg. at 23739.

9 Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges (Oct. 3, 2001), https://www.justice.gov/archive/opa/pr/2001/October/513civ.htm.

10 *See,* e.g., Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Medical Equipment Company Will Pay $646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America (Mar. 1, 2016), https://www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals (alleging, in part, that a medical equipment company provided free or heavily discounted equipment to HCPs in the United States and Central and South America, thereby violating the AKS and FCA (as to the domestic conduct) and the FCPA); Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Resmed Corp. to Pay the United States $37.5 Million for Allegedly Causing False Claims Related to the Sale of Equipment for Sleep Apnea and Other Sleep-Related Disorders (Jan. 15, 2020), https://www.justice.gov/opa/pr/resmed-corp-pay-united-states-375-million-allegedly-causing-false-claims-related-sale (asserting that a medical equipment manufacturer's provision of free and below-cost devices and machines to doctors violated the AKS and FCA); Brief for the United States of America as Amicus Curiae Supporting Appellee, Ameritox, Ltd. v. Millennium Labs, Inc., No. 14¬14281 (11th Cir. 2015) (asserting that a urine testing company's provision of free point-of-care testing cups to HCPs violated the AKS and Stark Law).

11 15 U.S.C. §§ 78dd-1(a), 78dd-2(a), 78dd-3(a). The statute defines "foreign official" as "any officer or employee of a foreign government or any department, agency, or instrumentality thereof," as well as "any person acting in an official capacity for or on behalf of" such a governmental entity. 15 U.S.C. § 78dd-1(f)(1); 15 U.S.C. §§ 78dd-2(h)(2)(A), 78dd-3(f)(2)(A). The FCPA's definition of public officials also includes employees of "public international organization[s]" such as the United Nations. Id.

12 U.S. Dep't of Justice & Sec. & Exch. Comm'n, A Resource Guide to the Foreign Corrupt Practices Act PA Resource Guide), 1, 9-11 (2d Ed. July 2020), https://www.justice.gov/criminal-ud/file/1292051/download.

13 15 U.S.C. § 78m(b)(2)(A), (B); see also FCPA Resource Guide, 38

14 15 U.S.C. §§ 78dd-1(c)(1), 78dd-2(c)(1), 78dd-3(c)(1).

15 15 U.S.C. §§ 78dd-1(c)(2), 78dd-2(c)(2), 78dd-3(c)(2).

16 H.R. Rep. No. 100-576, at 922 (1988) (Conf. Rep.).

17 *See* Dep't of Just. FCPA Ad. Op. 81-02 (Dec. 11, 1981) (concluding that DOJ would not pursue an enforcement action against a beef packing company that intended to provide "samples of its packaged beef products to officials of the Soviet Ministry of Foreign Trade" "for their inspection, testing and sampling, and to make these officials aware of the quality of the company's products").

18 *See* Dep't of Just. FCPA Ad. Op. 09-01 (Aug. 3, 2009) (concluding that DOJ would not pursue an enforcement action because "the proposed provision of 100 medical devices and related items and services fall outside the scope of the FCPA in that the donated products will be provided to the foreign government, as opposed to individual government officials").

19 In November 2020, OIG issued a final rule loosening some of the restrictions in the personal services safe harbor. Under the rule, which took effect in January 2021, the safe harbor now insulates certain outcomes-based payments intended to incentivize improved patient or population health outcomes (and thereby reduce healthcare costs). To that end, the revised safe harbor required the compensation methodology (rather than the compensation itself) to be fixed in advance. Dep't of Health & Human Servs., Office of Inspector Gen., Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbor Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77684 (issued Dec. 2, 2020; effective Jan. 19, 2021) (codified at 42 C.F.R. parts 1001 and 1003).

20 Although companies have long relied on the personal services safe harbor to conduct speaker program events, U.S. regulators have expressed significant skepticism about these events — and are increasingly pursuing enforcement actions against drug and device companies for alleged AKS-premised FCA violations associated with speaker events. Further, in November 2020, OIG issued a Special Fraud Alert regarding speaker programs that highlighted the fraud and abuse risks of such programs and provided a list of "suspect characteristics" that could potentially indicate that a program violated the AKS. Such suspect characteristics include, but are not limited to, the following: sponsoring programs where little to no substantive information is presented; providing alcohol or a meal "exceeding modest value" to program attendees; holding programs at locations, such as restaurants or entertainment or sports venues, that are "not conducive to the exchange of educational information;" and paying HCP speakers more than fair market value or compensation that takes into account the speakers' volume or value of past or future business. Dep't of Health & Human Servs., Office of Inspector Gen., Special Fraud Alert: Speaker Programs (Nov. 16, 2020), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf.

21 *See*, e.g., Carreyrou, J. & McGinty, T., A Fast-Growing Medical Lab Tests Anti-Kickback Law, The Wall St. J. (Sept. 8, 2014), https://www.wsj.com/articles/a-fast-growing-medical-lab-tests-anti-kickback-law-1410143403

22 Dep't of Health & Human Servs., Office of Inspector Gen., Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG SFA Laboratory Payments 06252014.pdf

23 Non Prosecution Agreement, Fresenius Medical Care AG & Co. KGaA A-2 (Mar. 29, 2019) [hereinafter "Fresenius NPA"].

24 Corrected Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order, Fresenius Medical Care AG & Go. KGaA 3-4 (Mar. 29, 2019) [hereinafter "Fresenius SEC Order"].

25 Fresenius SEC Order, at 13

26 Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Remedial Sanctions and a Cease-and-Desist Order, Alexion Pharmaceuticals, Inc. 4 (July 2, 2020).

27 Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order, Biomet, Inc. 2 (Jan. 7, 2017).

28 *Id.* at 7
29 *Id.*
30 Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order, AstraZeneca PLC 3 (Aug. 30, 2016).
31 Fresenius SEC Order, at 5.
32 *Id.* at 6.
33 *Id.* at 7.
34 42 C.F.R. § 1001.952(a)(1).
35 42 C.F.R. § 1001.952(a)(3).
36 42 C.F.R. § 1001.952(a)(2).
37 *See*, e.g., Fresenius, Annual Report (Form 20-F) at 7 (Feb. 20, 2020) ("A number of the dialysis clinics and health care centers that we operate are owned, or managed, by joint ventures in which one or more hospitals, physicians or physician practice groups hold an interest. Physician owners, who are usually nephrologists, or dialysis clinics may also provide medical director services and physician owners may refer patients to those centers or other centers we own and operate or to other physicians who refer patients to those centers or other centers we own and operate. Because our relationships with physicians are governed by the federal and state anti-kickback statutes, we have structured our joint venture arrangements to comply with many of the criteria for safe harbor protection under the U.S. Federal Anti-Kickback Statute; however, our investments in these joint venture arrangements do not satisfy all elements of such safe harbor.").
38 Dep't of Health & Human Servs., Office of Inspector Gen., Special Fraud Alert: Physician-Owned Entities (Mar. 26, 2013), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD Special Fraud Alert.pdf; see also Dep't of Health & Human Servs., Office of Inspector Gen., Publication of Special Fraud Alerts: Joint Venture Arrangements (August 1989), reprinted at 59 Fed. Reg. 65372, 65374 (Dec. 19, 1994), https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html; U.S. Senate, Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern (2016), https://www.advamed.org/sites/default/files/resource/2016 sfc pods report.pdf.
39 39Dep't of Health & Human Servs., Office of Inspector Gen., Special Fraud Alert: Physician-Owned Entities (Mar. 26, 2013), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf; see also Dep't of Health & Human Servs., Office of Inspector Gen., Publication of Special Fraud Alerts: Joint Venture Arrangements (August 1989), reprinted at 59 Fed. Reg. 65372, 65374 (Dec. 19, 1994), https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html; U.S. Senate, Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern (2016), https://www.advamed.org/sites/default/files/resource/2016_sfc_pods_report.pdf; see also Dep't of Health & Human Servs., Office of Inspector Gen., Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbor Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77713 (issued Dec. 2, 2020; effective Jan. 19, 2021) (codified at 42 C.F.R. 1001, 1003).
40 Fresenius SEC Order, at 8.
41 *Id.* at 9.
42 *Id.* at 10.
43 *Id.*
44 42 U.S.C. § 1320a-7b(b)(3)(A).
45 42 C.F.R. § 1001.952(h).
46 See, e.g., Pharmaceutical Research and Manufacturers of America, Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines (November 2017).
47 Ctrs. for Medicare & Medicaid Servs., Provider Reimbursement Manual ch. 8 § 802.1.
48 Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Remedial Sanctions and a Cease-and-Desist Order, Sanofi 4 (Sept. 4, 2018) [hereinafter "Sanofi SEC Order"], at 3.
49 *Id.* at 4.
50 *Id.* at 3.
51 *Id.*
52 Fresenius SEC Order, at 6.
53 *Id.* at 8.
54 Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Remedial Sanc-

tions and a Cease-and-Desist Order, Orthofix Int'l N.V. 5 (Jan. 18, 2017).

55 *Id.*

56 Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Remedial Sanctions and a Cease-and-Desist Order, Bio-Rad Laboratories, Inc. 7 (Nov. 3, 2014).

57 U.S.C. § 353(d)(3).

58 21 U.S.C. § 353(c)(1)–(2); 21 C.F.R. § 203.3(i)–(j); see also OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,739 (May 5, 2003), at 37–38, https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf (describing controls that pharmaceutical companies should implement to prevent recipients from selling or billing for samples).

59 42 U.S.C. § 1320a-7h(e)(10)(B)(ii).

60 Sanofi SEC Order

61 *Id.*

62 *Id.*

63 Complaint at 5, *U.S. Sec. and Exch. Comm'n v. Wyeth LLC*, No. 1:12-cv-01304 (D.D.C. 2012).

64 *Id.*

65 OIG Compliance Program Guidance, 68 Fed. Reg. at 23737

66 *See* Dep't of Just. FCPA Ad. Op. 81-02 (Dec. 11, 1981).

67 U.S. Dep't of Justice & Sec. & Exch. Comm'n, A Resource Guide to the Foreign Corrupt Practices Act, (2d Ed. July 2020), https://www.justice.gov/criminal-fraud/file/1292051/download.

68 U.S. Dep't of Justice, U.S. Atty's Manual, The FCPA Corporate Enforcement Policy, § 9-47.120, https://www.justice.gov/criminal-fraud/file/838416/download.

69 *See*, e.g., Weissmann, A., Chief, Fraud Section, DOJ, The Fraud Section's Foreign Corrupt Practices Act Enforcement Plan and Guidance 2-3, 7-8 (Apr. 5, 2016), https://www.justice.gov/archives/opa/blog-entry/file/838386/download.