EVALUATING U.S. FRAUD AND ABUSE COMPLIANCE CONTROLS, INCLUDING CORPORATE INTEGRITY AGREEMENT PROVISIONS, FOR A GLOBAL ANTI-CORRUPTION COMPLIANCE PROGRAM

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Introduction

The March 2016 U.S. Department of Justice ("DOJ") settlement with Olympus Corp. of the Americas[1] underscores the overlapping risks for companies under the Anti-Kickback Statute ("AKS"),[2] the False Claims Act ("FCA"),[3] and the Foreign Corrupt Practices Act ("FCPA").[4] Because physicians and other healthcare practitioners are government employees in many countries (and therefore may be considered foreign officials for purposes of the FCPA),[5] FCPA enforcement against drug and device companies and healthcare providers operating abroad often resembles AKS enforcement at home.[6] As Principal Deputy Assistant Attorney General David Bitkower stated in the DOJ press release announcing the Olympus settlement, "The FCPA resolution announced today demonstrates the department's commitment to ensuring the integrity of the health-care equipment market, *regardless whether the illegal bribes occur in the U.S. or abroad.*"[7]

Like Olympus, many drug and device makers and healthcare providers (e.g., clinical networks and physician systems) (collectively, "healthcare companies") that operate both in the United States and abroad have entered into Corporate Integrity Agreements ("CIAs") with the Department of Health and Human Services' Office of Inspector General ("OIG") that impose staggering compliance-related costs in connection with settlements of fraud allegations and cases committed by domestic operations. For companies that are operating under a CIA, winding down their time under a CIA, or simply looking to CIAs imposed on other companies for guidance, the controls imposed by the OIG in various cases may serve as useful guideposts for enhancing a global anti-corruption compliance program. But healthcare companies with overseas operations — and potential FCPA exposure — need not export *every* CIA-imposed compliance control to their foreign subsidiaries or operating entities in order to implement an effective global anti-corruption compliance program.

To the contrary, the DOJ and the U.S. Securities and Exchange Commission ("SEC") — and foreign regulators — have admonished that companies should adopt *risk-based* FCPA compliance programs with certain core elements. Because CIA-imposed obligations often go much further than the core compliance elements recommended by the DOJ and the SEC — and also may not match a company's risk profile overseas — a full-scale export of a company's CIA-imposed obligations is unlikely to be necessary or practical.

For healthcare companies with expanding overseas operations, it is critical to identify the right combination of risk-based controls to mitigate corruption risks abroad without burdening their business with unnecessary restrictions. With an eye toward reconciling CIA-based requirements with U.S. regulators' expectations regarding global anti-corruption compliance programs, this article reviews U.S. fraud and abuse compliance practices — including a few controls imposed by CIAs — that may assist companies in tailoring their foreign anti-corruption compliance programs to better detect, prevent, and remediate corruption issues abroad. Further, this article discusses certain CIA-imposed controls that may be unworkable, unwise, or even unlawful overseas.

A Comparison of the Elements of the AKS and the FCPA[8]

The AKS prohibits, among other things, 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 payable by federal healthcare programs.[9] Because the AKS is tied to items or services "for which payment may be made in whole or in part under a Federal health care program,"[10] the AKS does not generally apply to companies' overseas payment practices.

The FCPA's anti-bribery provisions, by contrast, focus on payments or offers to "any foreign official," "any foreign political party or official thereof," "any candidate for foreign political office," or any other person, while knowing that the payment will be offered, given, or promised to an individual included within one of these three categories.[11] Whereas jurisdiction under the AKS is tied to federal healthcare program business,

continued on page 26

continued from page 25

the FCPA's anti-bribery provisions extend to issuers, domestic concerns, and anyone who takes an act in furtherance of corrupt payment within U.S. territory.[12]

Despite these differences, the AKS and FCPA have elements that overlap significantly. The table below describes the commonalities between the two anti-corruption statutes:

"Best" Practices and Overlapping AKS and FCPA Compliance Controls

Given the overlap between the conduct proscribed by the AKS and the anti-bribery provisions of the FCPA, a company's domestic U.S. healthcare fraud and abuse compliance program is a natural starting point for U.S. healthcare companies that are expanding their overseas operations or enhancing their global anti-corruption compliance controls. In both the AKS and FCPA context, U.S. regulators have recognized several core compliance elements that an effective compliance program must incorporate to address several key risk areas.

AKS Elements[13]	FCPA Elements[14]
Knowingly and Willfully. The government must establish that that the defendant "acted with an evil-meaning mind, that is to say, that he acted with knowledge that his conduct was unlawful."[15] Section 6402(f)(2) of the Patient Protection and Affordable Care Act of 2010 specifies, however, that a person "need not have actual knowledge of [the AKS] or specific intent to" violate the AKS.[16]	**Corruptly (and, for Individuals, Willfully).** Like the AKS, the FCPA requires a heightened mens rea showing. To establish that a defendant acted "corruptly," the government must show "a bad or wrongful purpose and an intent to influence a foreign official to misuse his official position."[17] To hold an individual criminally liable, the government also must show that the defendant acted willfully.[18]
Offer or Pay (or Solicit or Receive). The AKS applies both to those who offer or pay remuneration for referrals *and* to those who solicit or receive such remuneration.[19]	**Offer, Pay, Promise to Pay, or Authorize Payment Of.** The FCPA, unlike the AKS (and the U.K. Bribery Act),[20] does not apply to so-called "passive corruption," a term of art used to describe the act of receiving a bribe.[21]
Remuneration. By statute, "remuneration" "includ[es] any kickback, bribe, or rebate…in cash or in kind."[22] According to the OIG, the term remuneration encompasses a broad swath of payments, including "[e]ntertainment, recreation, travel, meals,…[g]ifts, gratuities, and other business courtesies," as well as compensation for consulting, speaking, clinical research, market research, medical directorships, and other services.[23] In accordance with Congress's directive in the AKS,[24] however, the Secretary of HHS has promulgated more than two dozen safe harbors that exempt certain categories of "payment practice[s]" from the definition of "remuneration."[25] There is no safe harbor for de minimis payments.	**Anything of Value.** The FCPA does not define the phrase "anything of value," and the statute's legislative history offers no insight. Nevertheless, the phrase is generally understood to include cash, gifts, meals, travel, entertainment, charitable contributions, and political donations.[26] Although there is no exception for things of de minimis value, the DOJ and the SEC have acknowledged that such things are "unlikely to improperly influence an official."[27]
Directly or Indirectly. The AKS applies not only to schemes involving direct remuneration, but also to situations in which a defendant channels payments through an agent or other third party.[28]	**Directly or Indirectly.** The FCPA prohibits offering, giving, or authorizing the gift of anything of value to "any person, while knowing that all or a portion of such…thing of value will be offered, given, or promised directly or indirectly to any foreign official."[29]

To Induce (or in Return for) Referrals. The AKS implicates payments or offers made to induce — or in return for — referring an individual for the furnishing or arranging of any item or service for which payment may be made under a federal healthcare program. Further, the AKS applies to offers or payments of remuneration "in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal healthcare program."[30] Several courts have indicated that the statute applies where just one purpose of the remuneration was to secure federal healthcare program business.[31] But certain courts have indicated that the government must show that the remuneration was offered in exchange for the referrals (i.e., as a quid pro quo).[32] This is consistent with the AKS provision that proscribes solicitation or receipt of remuneration "in return for" referrals.[33]	**To Obtain or Retain Business.** Although the FCPA does not define this element, the legislative history indicates that obtaining or retaining business means more than just securing contracts.[34] In a seminal opinion on the FCPA's business purpose element, the Fifth Circuit held that the government must show that the "bribery was intended to produce an effect…that would assist [the defendant] in obtaining or retaining business."[35] According to the DOJ and the SEC, this may include "[w]inning a contract, [i]nfluencing the procurement process, [c]ircumventing the rules for importation of products, [g]aining access to non-public tender information, [e]vading taxes or penalties, [i]nfluencing the adjudication of lawsuits or enforcement actions, [o]btaining exceptions to regulations, and [a]voiding contract termination."[36] Notably, the statute proscribes offers and payments to assist in obtaining or retaining business with "any person" (not just business with a government entity).[37]
Exceptions and Safe Harbors. The AKS includes ten statutory exceptions, and, as noted above, the Secretary of HHS has promulgated regulatory safe harbors that carve out particular remunerative relationships from the statute's reach.[38]	**Exception and Affirmative Defenses.** The FCPA, by contrast, has just one statutory exception — for facilitating payments made to expedite or secure routine governmental action — and two affirmative defenses.[39]

As explained below, certain compliance controls keyed to domestic U.S. fraud and abuse risks may be practicable and appropriate to mitigate foreign anti-corruption risks. Similarly, CIA-imposed controls may provide companies with a helpful framework for evaluating and enhancing a global anti-corruption program. Many CIA-imposed controls, however, overreach the DOJ's and the SEC's expectations for global anti-corruption compliance measures. The challenge for any company that is operating, or has operated, under a CIA (or is looking to CIAs imposed on other companies for guidance) is determining which CIA-imposed controls may be effectively implemented abroad to mitigate FCPA exposure, while ensuring that any such controls are commensurate with the company's risks.[40]

Core Compliance Functions

In various AKS- and FCPA-related guidance documents, the DOJ, the SEC, and the OIG have advised that a company's anti-corruption compliance program, whether domestic or global in nature, should include several critical pillars:

- Compliance leadership and oversight;
- Policies and procedures;
- Communications and training;
- Internal reporting and investigation;
- Evaluation of third parties (e.g., agents, consultants, distributors, joint venture partners, and merger or acquisition targets) and related payments;
- Auditing, monitoring, and risk assessment; and
- Discipline and remediation.[41]

These core elements of a compliance program also appear in the standard terms that the DOJ requires companies to accept when they resolve an FCPA enforcement action. Indeed, the DOJ routinely demands, as a condition of settlement, that companies implement the following pillars of a compliance program:

- High-level commitment to compliance;
- Policies and procedures addressing specified risk areas and financial and accounting controls;
- Periodic risk assessments;
- Senior-level responsibility for the compliance program;
- Training and guidance;
- Internal reporting and investigation;
- Enforcement and discipline;
- Due diligence and compliance requirements relating to third-party relationships;
- Policies and procedures for mergers and acquisitions; and
- Monitoring and testing.[42]

continued on page 28

continued from page 27

These high-level elements (derived from DOJ, SEC, and OIG guidance and the terms of FCPA resolutions) are the core pillars of an FCPA- or AKS-focused compliance program.[43] However, U.S. regulators generally recognize that companies must tailor their compliance programs to their "specific needs, risks, and challenges," focusing on, among other factors, the territories in which they operate, the size and scope of their operations, and their business models.[44] Because they recognize that compliance programs should be tailored to a company's specific risks, U.S. regulators (with the notable exception of the OIG) rarely prescribe *specific* compliance controls that companies can implement to operationalize the high-level elements of an effective compliance program. Thus, to flesh out the fundamental elements of a global anti-corruption compliance program with practicable, pragmatic internal controls, U.S. healthcare companies generally must look elsewhere for guidance.[45]

Risk-Based Compliance Controls

As detailed below, there are several critical areas of risk that healthcare companies must address to comply with the AKS and the FCPA. Some CIA-imposed controls may aid companies in addressing these risks, but many lack the risk-based, tailored approach that the DOJ and the SEC expect with respect to FCPA-focused compliance programs. Further, some CIA-mandated controls may be impractical or even illegal overseas.

Sales and Marketing

Interaction with healthcare professionals presents substantial risk for healthcare companies, as evidenced by numerous AKS and FCA enforcement actions targeting conduct related to the provision of gifts and hospitality, rebates and discounts, and free or discounted products. Given the connection between many healthcare professionals and state-owned or state-controlled entities abroad, the same type of behavior can create exposure under the FCPA's anti-bribery provisions.

For example, in March 2016, Olympus resolved criminal and civil claims under the AKS, the FCA, and state false claims statutes for more than $623 million; the enforcement action included allegations that Olympus personnel provided kickbacks to doctors and hospitals in the form of foreign travel, expensive meals, recreation and leisure activities, as well as access to free use of hundreds of thousands of dollars' worth of endoscopes and other medical equipment.[46] Notably, the company's Miami-based subsidiary separately agreed to pay $22.8 million to settle alleged criminal FCPA violations for behavior in Latin America that, according to Principal Deputy Assistant Attorney General David Bitkower, "mirrored Olympus's conduct in the United States."[47]

As part of its resolution, Olympus — like many other healthcare companies targeted for alleged AKS violations — entered into a CIA with the OIG.[48] Among other controls relating to Olympus's sales and marketing activities, the CIA required Olympus to:

- Secure annual compliance certifications (with specified language) from certain business personnel;
- Conduct training for sales representatives (among others);
- Implement policies governing:

  —the "review and approval of travel and related expenses" for healthcare professionals;

  —the "identification and tracking of medical and surgical equipment and products" provided for "demonstration or evaluation," "medical education," "replacement" of products requiring repair, and "trade shows and conference displays";

  —the information distributed by sales representatives and through social media; and

  —compensation for sales representatives and their managers (to eliminate "financial incentives [that] inappropriately motivate such individuals");
- Establish a "Field Force Monitoring Program…to evaluate and monitor its sales personnel's interactions" with healthcare professionals by, among other measures, requiring compliance personnel to conduct annually at least 25 "full day ride-alongs with sales representatives" and prepare written reports regarding those observations; and
- Implement a plan to periodically review sales records (e.g., sales representatives' "emails and other records," travel and expense reports, communications from managers, and call notes) from all regions where government-reimbursed products are sold).[49]

Although each CIA's provisions generally are tailored to address the particular conduct at issue in the underlying enforcement action, other companies' CIAs include similar controls (and, in some instances, controls even more prescriptive than those in the Olympus agreement).[50]

Depending on a healthcare company's particular risks overseas, some of these controls may be prudent and practicable. Indeed, some are consistent with recommendations in the DOJ and SEC FCPA Resource Guide. For example, the DOJ and the SEC counseled that companies should have means to "ensure that relevant policies and procedures have been communicated

throughout the organization, including through periodic training and certification for all directors, officers, [and] relevant employees."[51] Further, the DOJ and the SEC advised that companies should adopt a risk-based set of policies and procedures, after assessing factors such as "the nature and extent of transactions with foreign governments, including payments to foreign officials; use of third parties; gifts, travel, and entertainment expenses; charitable and political donations; and facilitating and expediting payments."[52]

But companies looking to the Olympus CIA for guidance as to specific compliance controls will find that some cannot be implemented overseas without encountering legal and practical obstacles. For example, the periodic, targeted review of e-mail correspondence, call notes, expense reports, and/or other records from personnel in the United States may be appropriate to address domestic fraud and abuse risks. But undertaking these measures anywhere overseas — let alone in *every region* — may be disproportionate to companies' varying risks in different countries (not to mention prohibitively expensive).[53] Similarly, companies may well question the wisdom of devoting significant resources to having compliance personnel conduct observational "ride-alongs" with foreign sales personnel.[54]

More fundamentally, efforts to implement in-person observations and record reviews may violate international data privacy laws and/or other worker protections.[55] For example, countries that, like Germany, have strong works council provisions may circumscribe companies' ability to collect and review e-mail and other electronic documents.[56] Similarly, to the extent a compliance department is headquartered in the United States, data privacy laws may limit the ability of compliance personnel to review e-mail communications and other records from overseas.[57] In light of these concerns, companies seeking to enhance their international compliance programs might consider a more responsive yet still active approach in which they concentrate oversight efforts in particularly risky geographic regions and other areas flagged through reports to the companies' legal or compliance departments.

Third-Party Agents, Consultants, Distributors, and Joint-Venture Partners

Both the AKS and the FCPA's anti-bribery provisions encompass direct and indirect corrupt payments. Accordingly, financial relationships with third-party agents, consultants, distributors, and joint-venture partners present another key risk area for healthcare companies both in the U.S. and abroad. These relationships primarily raise two types of risk: (1) a third party may channel payments to a foreign official or U.S. healthcare professional in an effort to drive sales on behalf of the company, and (2) if a third-party agent or consultant is himself or herself a foreign official or a person with the power to prescribe or recommend services or products covered by federal healthcare programs, then payments to the third party may be suspect.

In addition to appropriate vetting of third parties to confirm that they are exclusion-free, companies seeking to comply with domestic fraud and abuse laws should assess the legitimacy of third-party payments in connection with advisory boards, consulting initiatives, and speakers' programs. Failing to structure any such relationship so that it falls within the AKS's personal service safe harbor may have serious consequences.[58] In 2015, for example, Japanese pharmaceutical company Daiichi Sankyo paid $39 million to settle off-label promotion claims and allegations that it provided kickbacks in the form of speaker fees and expensive dinners to physicians participating in its Physician Organization and Discussion programs, or "PODs" — even when physicians spoke only to staff in their own offices.[59] Other blockbuster FCA and AKS settlements also have addressed allegedly improper speaker and other consultant-related activities. The U.S. government's $3 billion settlement in 2012 with GlaxoSmithKline ("GSK") included allegations that GSK paid millions of dollars to healthcare professionals to speak at or attend sponsored dinner programs and similar promotional activities.[60]

The risks arising out of joint venture and similar agreements in the AKS context primarily revolve around the purported use of joint ventures to improperly induce referrals. In 2014, for example, the DOJ alleged that between 2005 and 2014 DaVita Healthcare Partners Inc. identified physicians and physician groups that were likely to refer patients to DaVita's dialysis practices.[61] According to the DOJ, DaVita then offered specific physicians an opportunity to take part in a joint venture in a dialysis unit, while allegedly manipulating financial models to decrease the physicians' buy-in cost and increase their rate of return to disproportionate levels.[62]

In the FCPA context, U.S. regulators focus not only on excessive compensation for third-party consultants who are themselves foreign officials[63] but also on payments to third parties who serve as conduits for improper payments to other state-owned or state-controlled entities down the line.[64] In 2015, Mead Johnson Nutrition Company, for example, agreed to pay $12 million to the SEC to settle allegations that its Chinese subsidiary made improper payments to healthcare professionals at government-owned hospitals through "distributor allowance" funds in exchange for product recommendations to patients.[65] The SEC alleged that, even though these funds contractually belonged to the third-party distributors who marketed, sold, and distributed the company's products in China, employees of the Chinese subsidiary retained some control over the manner in which those funds were spent.[66]

continued on page 30

continued from page 29

Although U.S. regulators have not apparently brought an enforcement action in which a joint venture or investment agreement executed by a healthcare company led to liability under the FCPA, U.S. authorities have brought enforcement actions against companies that failed to exercise sufficient control over joint venture partners that engaged in improper conduct.[67]

Overlapping domestic and foreign risks counsel in favor of efforts to implement third-party due diligence, training, contracting, monitoring, and, as appropriate, auditing controls. U.S. regulators, including the DOJ, the SEC, and the OIG, have demanded as much.[68] Notably, CIAs like those involving Daiichi Sankyo and GSK include an array of controls relating to payments to third parties. In addition to provisions mandating general policies and procedures regarding consultant and fee-for-service arrangements with healthcare professionals and institutions, these CIAs require companies to:

- Conduct speaker and consultant training;
- Execute written contractual agreements with third parties describing the scope of work to be performed, fees to be paid, and any relevant compliance-related obligations;
- Pay fair market value for these services according to a centrally managed, pre-set rate structure;
- Maintain centralized systems tracking all speaker and consultant engagements that include participant eligibility and qualifications and "controls designed to ensure that…[the] programs are used for legitimate and lawful purposes";
- Develop annual engagement plans articulating a budget and relevant business rationale for the sought-after services and to conduct prospective "needs assessments" outlining the number and qualifications of consultants to be engaged and the type of work to be performed; and
- Implement consultant and speaker "monitoring programs" under which the company must review documentation supporting contractual arrangements and related consultant work and/or conduct independent reviews of certain speaker programs — including live audits of the speaking engagements, materials presented, and even sales representative activities during the program.[69]

Similarly, DaVita's CIA illustrates some steps that companies may wish to consider taking to ensure that joint venture partnerships do not result in improper remunerative relationships. For example, the CIA requires DaVita to:

- Train all of its joint venture partners on DaVita's corporate compliance program and the elements of its CIA;[70] and
- Develop "Selection Criteria" for any joint venture agreement, which criteria "must relate to a Health Care Provider's eligibility and ability to perform the functions required in connection with each such type of [agreement], and shall not include a Health Care Provider's ability to refer patients to DaVita."[71]

Some of these CIA-imposed controls are commensurate with those that the DOJ and the SEC expect in the context of FCPA enforcement. For example, the DOJ and the SEC emphasize the importance of conducting appropriate due diligence to understand the "qualifications and associations" of potential third-party partners, articulating the business rationale supporting said third-party involvement, and reflecting the same in written contracts and other documentation.[72] Given the FCPA's expansive knowledge standards, implementing standardized due diligence controls (and documenting due diligence) at the front end can bolster later arguments that a company did not blind itself to improper third-party behavior.[73]

However, other controls from Daiichi Sankyo and GSK CIAs are not well suited to a risk-based global anti-corruption compliance program. For instance, a centrally managed, pre-set rate structure for third-party agents and consultants is likely to be impracticable for a company that operates in many different territories worldwide. Similarly, CIA-imposed in-person observations and/or reviews of speaker and consultant activities can be resource-intensive — and may raise concerns regarding the worker protections discussed above.

Instead of in-person observations or reviews, companies may consider more discerning, risk-based controls to "undertake some form of ongoing monitoring of third-party relationships" in accordance with the DOJ's and the SEC's recommendation.[74] For example, companies may require certifications, in which third parties confirm their commitment and adherence to applicable compliance programs and lawful business practices.[75] Companies also should consider exercising contractual audit rights to evaluate the activities of high-risk third parties.[76] Companies may explore measures to monitor particularly high-risk subsidiaries, affiliates, product lines, markets, and/or categories of third-party engagements. Educating personnel on common corruption "red flags" also is commensurate with a more targeted approach to FCPA compliance.[77]

However, as the DaVita CIA recognizes, a company may not be able to secure the contractual right to require joint venture partners to

undergo training,[78] and requiring *all* joint venture partners to undergo compliance training may not be commensurate with a particular company's risks. Depending on a company's level of control over a joint venture, the FCPA may only require the company to take reasonable, good faith steps to impose compliance controls.[79]

Research and Development

A company's research and development initiatives often involve a variety of participants, including contract research organizations ("CROs"), individual clinical investigators, and U.S. and foreign regulators. Healthcare companies should implement compliance controls related to their clinical research funding.[80]

Recent AKS enforcement actions have addressed alleged kickbacks disguised as research and development efforts. The Olympus settlement discussed above, for instance, involved allegations that the company improperly awarded millions of dollars through a "Grant Committee" composed primarily of sales and marketing personnel.[81] According to the DOJ, the Committee considered sales and customer relations when making the awards and delayed the provision of a grant until after the recipient agreed to purchase Olympus equipment.[82]

Because healthcare professionals participating in research and development initiatives abroad may be linked to state-owned or state-controlled entities, these types of arrangements can also create liability under the FCPA. Pharmaceutical company Novartis AG, for instance, agreed in March 2016 to pay $25 million to settle SEC charges regarding allegedly improper payments via its China-based subsidiary to healthcare professionals for patient data studies.[83] The SEC alleged that senior sales and marketing personnel participated in the design and execution of the patient studies, which purportedly were used to reward healthcare professionals for prescribing the company's drugs.[84]

To address this area of risk, CIAs like Olympus's contain provisions keyed to clinical research and medical grants, including requirements that the company:

- Establish policies governing:

  —"sponsorship or funding of grants"[85] and "sponsorship of post-marketing clinical trials, post-marketing [investigator-initiated studies], and all other post-marketing studies of Government Reimbursed Products… including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research…[and] uses made of publications relating to Research";

  —the process through which research is "initiated, designed, reviewed, and approved by the medical and research and development organizations of [the company,]" including insulation from commercial or sales and marketing personnel;

  —the requirement that "all Research and any resulting publications address legitimate scientific questions or needs, and are intended to foster increased understanding of scientific, clinical, or medical issues";[86] and

  —related disclosure requirements;[87]

- Execute written contractual agreements describing the scope of work to be performed, payment at fair market value, and other compliance-related responsibilities;[88]

- Confirm, in advance of retention, that the proposed participants are "appropriately qualified to perform" the services and that "there is a legitimate business or scientific need" for the service;[89]

- Process requests through a centralized management system separate from sales and marketing using "standardized, objective criteria… [such as] the qualifications of the requestor or the quality of the program funded";[90] and

- Periodically review and/or audit supporting documentation for research and other initiatives.[91]

These CIA-imposed controls overlap significantly with the third-party due diligence, contracting, and documentation procedures that, as discussed above, are key features of an effective FCPA compliance program. Indeed, the DOJ and the SEC expect that companies will ensure that they understand the qualifications and reputation of potential third-party partners and articulate the business need for engaging third parties.[92] This guidance applies equally to a company's research and development initiatives. Prudent healthcare companies also should seek to segregate clinical research functions from sales and marketing personnel and outline objective criteria guiding review of grant or research requests.[93] In keeping with the DOJ and the SEC's suggestion that companies consider the applicable "payment terms,"[94] healthcare companies operating overseas should ensure that they implement risk-based controls that avoid ties between research funding and the recipient's utilization of the funder's products or services.[95]

For practical reasons, however, companies may not be able to implement centralized management systems to evaluate all research funding requests across the globe. For example, a centralized review and approval committee may lack the breadth and depth of expertise to assess the qualifications of clinical investigators and scientific researchers from multiple countries. As to monitoring and auditing controls, the DOJ and the SEC have recognized that companies should focus their monitoring and auditing efforts on higher-risk operations and locations.[96] While periodic reviews and audits are a good practice, companies should balance the risks associated with their research and

continued on page 32

continued from page 31

development activities against the costs related to monitoring and auditing activities.

Conclusion

Although not all domestic compliance measures are appropriate for export — including some imposed under CIAs — many elements of an effective domestic fraud and abuse compliance program can be effectively implemented abroad to help companies avoid violations of the FCPA and other global anti-corruption laws. Global opportunities in the drug, device, and healthcare industries continue to grow, and U.S. regulators continue to target corruption abroad. As such, healthcare companies would be wise to implement compliance controls carefully calibrated to their overseas operational risks, including, as appropriate, controls borrowed from their domestic fraud and abuse compliance programs.

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Endnotes

1 On March 1, 2016, the DOJ announced that it had entered into an agreement with Olympus arising out of allegations that the company and its Latin American subsidiary (Olympus Latin America, or "OLA") had made improper payments both to U.S. physicians and to physicians and hospitals abroad to induce business. Although the bulk of the overall settlement related to payments made in the United States, the DOJ noted that "OLA's illegal tactics in Central and South America mirrored Olympus's conduct in the United States." *See* Press Release, 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).

2 42 U.S.C. § 1320a-7b.

3 31 U.S.C. §§ 3729–3733.

4 15 U.S.C. § 78dd-1, *et seq*.

5 *See, e.g.*, Press Release, U.S. Dep't of Justice, AGA Medical Corporation Agrees to Pay $2 Million Penalty and Enter Deferred Prosecution Agreement for FCPA Violations (June 3, 2008) (discussing FCPA action brought by the DOJ for improper payments to physicians at state-owned hospitals in China). *Cf. United States v. Esquenazi*, 752 F.3d 912, 921–26 (11th Cir. 2014) (setting forth factors for determining what constitutes a government "instrumentality," employees of which qualify as foreign officials for the purposes of the FCPA).

6 Similarly, the U.K. Bribery Act contains (among other prohibitions) anti-bribery provisions similar to those of the FCPA.

7 Press Release, 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) (emphasis added).

8 Violations of the AKS may give rise to liability under the FCA. *See* Patient Protection and Affordable Care Act of 2010 § 6402(f)(1), Pub. L. No. 111-148, codified at 42 U.S.C. § 1320a-7b(g) (2010) (amending the AKS to state that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the FCA). The authors do not address the elements of an FCA violation here, because, in this context, FCA liability is generally predicated on a company's purported violations of the AKS. Avoiding FCA liability, of course, goes far beyond implementing an AKS-focused compliance program.

9 42 U.S.C. § 1320a-7b(b).

10 *Id*.

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 *See* 15 U.S.C. §§ 78dd-1, 78dd-2, 78dd-3.

13 *See* 42 U.S.C. § 1320a-7b(b).

14 *See* 15 U.S.C. §§ 78dd-1(a), 78dd-2(a), 78dd-3(a). For further information regarding the nuances of the FCPA, *see* F. Joseph Warin,

Michael S. Diamant, and Elizabeth G. Silver, *The U.S. Foreign Corrupt Practices Act: Enforcement and Compliance*, Bloomberg BNA (2014).

15 *Bryan v. United States*, 524 U.S. 184, 193 (1998); *see also United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (holding that defendant acts "willfully" if "defendant acted with an evil-meaning mind, that is to say that he acted with knowledge that his conduct was unlawful") (quoting *Bryan*, 524 U.S. at 193); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (holding that defendant acts "willfully" if he acts "with a bad purpose either to disobey or disregard the law").

16 Patient Protection and Affordable Care Act of 2010 § 6402(f)(2), Pub. L. No. 111-148, codified at 42 U.S.C. § 1320a-7b(h) (2010).

17 *Stichting v. Schreiber*, 327 F.3d 173, 183 (2d Cir. 2003) (citations omitted); *see also United States v. Kay*, 513 F.3d 461, 463 (5th Cir. 2008) (upholding jury instruction that defined "corruptly" to mean "voluntarily and intentionally, and with a *bad purpose or evil motive* of accomplishing either an *unlawful* end or result"); *United States v. Liebo*, 923 F.2d 1308, 1312 (8th Cir. 1991) (upholding jury instruction that term "corruptly" meant that "the offer, promise to pay, payment or authorization of payment, must be intended to induce the recipient to misuse his official position…and that an act is 'corruptly' done if done voluntarily and intentionally, and with a bad purpose of accomplishing either an unlawful end result, or a lawful end or result by some unlawful method") (citations and internal quotations omitted).

18 *See, e.g.*, 15 U.S.C. §§ 78dd-2(g)(2)(A), 78dd-3(e)(2)(A). *Cf. United States v. Kozeny*, 667 F.3d 122, 135 (2d Cir. 2011) (assessing "willfully" jury instruction); *United States v. Kay*, 513 F.3d 432, 447–50 (5th Cir. 2007) (analyzing "willfully" element).

19 U.S. Department of Health and Human Services, Office of Inspector General, Compliance Program Guidance for Pharmaceutical Manufacturers (hereinafter, "HHS OIG Compliance Guidance"), 68 Fed. Reg. 23,731, 23,734 (May 5, 2003) (the AKS "extends equally to the solicitation or acceptance of remuneration for referrals"). *Compare United States v. Vernon*, 723 F.3d 1234, 1241 (11th Cir. 2013) (affirming conviction of specialty pharmacy's chief financial officer for approving payments to healthcare professionals to induce referrals) *with United States v. Patel*, 778 F.3d 607, 618 (7th Cir. 2015) (affirming AKS conviction of physician who received remuneration in return for referrals).

20 42 U.S.C. § 1320a-7b(b)(1); U.K. Bribery Act 2010, c. 23 (Eng.) § 2-2.

21 U.S. Department of Justice and U.S. Securities and Exchange Commission, A Resource Guide to the U.S. Foreign Corrupt Practices Act, 12 (Nov. 14, 2012) (hereinafter, "DOJ & SEC, Resource Guide To The FCPA").

22 42 U.S.C. § 1320a-7b(b)(1).

23 HHS OIG Compliance Guidance, 68 Fed. Reg. at 23,738.

24 42 U.S.C. § 1320a-7b(b)(3)(E).

25 The safe harbors are set forth at 42 C.F.R. § 1001.952.

26 *See* DOJ & SEC, Resource Guide to the FCPA, at 15–18.

27 DOJ & SEC, Resource Guide to the FCPA, at 15.

28 42 U.S.C. § 1320a-7b(b); *United States v. Shoemaker*, 746 F.3d 614, 629–30 (5th Cir. 2014).

29 15 U.S.C. §§ 78dd-1(a)(3), 78dd-2(a)(3), 78dd-3(a)(3). By statute, "knowing" means "aware[ness] that [a third party] is engaging in such conduct, that such circumstance exists, or that such result is substantially certain to occur," or "aware[ness] of a high probability of the existence of such circumstance." 15 U.S.C. §§ 78dd-1(f)(2), 78dd-2(h)(3), 78dd-3(f)(3). The courts have construed this language to encompass actual knowledge, as well as deliberate ignorance. *See, e.g., United States v. King*, 351 F.3d 859, 866 (8th Cir. 2003); *Kozeny*, 667 F.3d at 133.

30 HHS OIG Compliance Guidance, 68 Fed. Reg. at 23,734.

31 *See, e.g., United States v. Lahue*, 261 F.3d 993, 1007–08 (10th Cir. 2001) (rejecting defendant's challenge to a jury instruction which stated that jury must find that at least "one purpose" of the remuneration was to gain referrals); *United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) ("Nothing in the Medicare fraud statute implies that only the primary motivation of remuneration is to be considered in assessing [the defendant's] conduct."); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (adopting *Greber's* "one purpose" test, but upholding jury instruction that inducement must be a "material purpose" of the remuneration); *United States v. Bay State Ambulance and Hosp. Rent. Serv., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989). *Cf. United States v. Yielding*, 657 F.3d 688, 709 (8th Cir. 2011) (upholding jury instruction because it "simply informed the jurors that they need not find that such an inducement was the *sole* purpose of the payments").

32 *See, e.g., United States v. Krikheli*, 461 F. App'x 7, 11 (2d Cir. 2012) (upholding jury instructions that included the "one purpose" standard but that also required the prosecution to prove "that the remuneration was offered or paid as a quid pro quo") (internal quotation marks removed).

33 *See* 42 U.S.C. § 1320a-7b(b)(1)(A).

34 H.R. Rep. No. 100-576, at 918 (1988).

35 *United States v. Kay*, 359 F.3d 738, 756 (5th Cir. 2004) (internal quotation omitted).

36 DOJ & SEC, Resource Guide to the FCPA, at 13.

37 15 U.S.C. §§ 78dd-1(a), 78dd-2(a), 78dd-3(a).

38 *See* 42 U.S.C. § 1320a-7b(b)(3)(E); *see also* 42 C.F.R. § 1001.952.

39 The first affirmative defense is for bona fide expenditures directly related to the promotion, demonstration, or explanation of a product or service or to the execution or performance of a contract with a foreign government or agency. 15 U.S.C. § 78dd-1(c)(2). The second affirmative defense relates to payments, offers, or promises that were "lawful under the written laws and regulations" of the foreign official, candidate, or political party's nation. *Id.* § 78dd-1(c)(1).

40 DOJ & SEC, Resource Guide to the FCPA, at 58–59 (explaining that devoting resources and attention to low-risk activities may distract from high-risk activities, and may be an indication that a compliance program is not operating effectively).

41 *See, e.g., id.*, at 57–63 (the "hallmarks" of an effective compliance program are "Commitment from Senior Management and a Clearly Articulated Policy Against Corruption," "Code of Conduct and Compliance Policies and Procedures," "Oversight, Autonomy, and Resources," "Risk Assessment," "Training and Continuing Advice," "Incentives and Disciplinary Measures," "Third-Party Due Diligence and Payments," "Confidential Reporting and Internal Investigation," "Continuous Improvement: Periodic Testing and Review," and "Mergers and Acquisitions: Pre-Acquisition Due Diligence and Post-Acquisition Integration"); HHS OIG Compliance Guidance, 68 Fed. Reg. at 23731 (the "seven elements that have been widely recognized as fundamental to an effective compliance program" are "[i]mplementing written policies and procedures; [d]esignating a compliance officer and compliance committee; [c]onducting effective training and education; [d]eveloping effective lines of communication; [c]onducting internal monitoring and auditing; [e]nforcing standards through well publicized disciplinary guidelines; and [r]esponding promptly to detected problems and undertaking corrective action"); *cf.* U.S. Sentencing Commission, U.S. Sentencing Guidelines § 8B2.1 (listing elements of "an effective compliance and ethics program").

42 *See, e.g.*, U.S. Dep't of Justice and Olympus Latin America, Inc. Deferred Prosecution Agreement (hereinafter "Olympus Latin America DPA"), Att. C, at C-1 – C-7 (Feb. 27, 2016).

43 For example, the OIG Compliance Guidance for Pharmaceutical Manufacturers suggests implementing confidentiality and non-retaliation policies for employees who ask questions or report problems relating to compliance. HHS OIG Compliance Guidance, 68 Fed. Reg. at 23,741. Similarly, the DOJ and SEC FCPA Resource Guide recommends a mechanism for employees to confidentially report misconduct or policy violations without fear of retaliation. DOJ & SEC, Resource Guide to the FCPA, at 61.

44 *Id.* at 57; *see also id.* at 58–59 ("One-size-fits-all compliance programs are generally ill-conceived and ineffective…DOJ and SEC will give meaningful credit to a company that implements in good faith a comprehensive, risk-based compliance program, even if that program does not prevent an infraction in a low risk area because greater attention and resources had been devoted to a higher risk area.").

45 Companies that resolve an FCPA enforcement action with U.S. regulators may find themselves subject to a compliance monitorship. A monitor's recommendations may be as prescriptive as a CIA's (or even more demanding). However, monitors' reports are rarely, if

continued on page 34

continued from page 33

ever, made public, and therefore cannot serve the same benchmarking function as CIAs.

46 *See* Press Release, 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); Criminal Complaint, *United States v. Olympus Corp. of the Americas*, No. 16-3524 (MF) (D.N.J. Mar. 1, 2016); Second Amended Complaint, *United States et al. ex rel. Slowik v. Olympus Am., Inc. et al.*, No. 10-5996 (JLL) (D.N.J. Feb. 4, 2016).

47 Press Release, 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). Last year's SEC enforcement action against Bristol-Myers Squibb ("BMS") also demonstrates some of the ways in which the FCPA may reach interactions between sales personnel and healthcare professionals. *See* Press Release, U.S. Securities and Exchange Comm'n, SEC Charges Bristol-Myers Squibb With FCPA Violations (Oct. 5, 2015) (alleging that certain sales representatives at a joint venture in which BMS was a majority owner made improper payments to healthcare professionals of state-owned and state-controlled Chinese hospitals in the form of cash, gifts, meals, travel, entertainment, and sponsorships for conferences and meetings).

48 *See* Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Olympus Corporation of the Americas (Feb. 29, 2016), *available at* http://oig.hhs.gov/fraud/cia/agreements/Olympus_Corporation_of_the_Americas_02292016.pdf (hereinafter "Olympus CIA").

49 *Id.* at 23–28.

50 *See, e.g.*, Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and DaVita Healthcare Partners Inc., at 10–12 (Oct. 22, 2014), *available at* http://oig.hhs.gov/fraud/cia/agreements/Davita_Healthcare_Partners_Inc_10222014.pdf (hereinafter "DaVita CIA") (mandating training programs of specified lengths for various individuals, including board members).

51 DOJ AND SEC, RESOURCE GUIDE TO THE FCPA, at 59.

52 *Id.* at 58.

53 *See* Olympus CIA, at 24 (requiring review of records in every separate district and/or region in which sales representatives promoted the products under review).

54 *Cf.* HHS OIG Report from February 23, 2012, Pharmaceutical Compliance Roundtable, 8 (Feb. 23, 2012), *available at* http://oig.hhs.gov/compliance/compliance-guidance/docs/Pharmaceutical-Compliance-Roundtable.pdf ("Many participants reported that such ride-alongs do not generally lead to the identification of specific noncompliant conduct by sales representatives.").

55 *See, e.g.*, Lothar Determann and Robert Sprague, *Intrusive Monitoring: Employee Expectations are Reasonable in Europe, Destroyed in the United States*, 26 BERKELEY TECH. L.J. 979 (2011); Karen Ip and Owen Cox, *China: Employers in China obliged to keep personal data confidential*, Lexology (Oct. 4, 2013), *available at* http://lexology.com/library/detail.aspx?g=209cf86c-6793-4b9f-898a-2a80a9745b9a (identifying legal protection of employee personal data in China); *cf.* Article 29 Data Protection Working Party, *Working Document on the Surveillance of Electronic Communications in the Workplace*, WP 55 (May 29, 2002), *available at* http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2002/wp55_en.pdf.

56 *See generally* Betriebsverfassungsgesetz [Works Constitution Act], Sept. 25 2001, BGBI. I at 2424 (Ger.).

57 *See generally id.*

58 The personal service safe harbor, as spelled out in HHS regulations, provides that compensation of third-party agents will not qualify as remuneration for the purpose of the AKS if the agent is retained under an agreement that, among other things, specifically sets forth the services to be performed and arranges compensation to reflect fair market value. 42 C.F.R. § 1001.952(d).

59 *See* Press Release, U.S. Dep't of Justice, Daiichi Sankyo Inc. Agrees to Pay $39 Million to Settle Kickback Allegations Under the False Claims Act (Jan. 9, 2015).

60 *See* Press Release, U.S. Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012).

61 U.S. Dep't of Justice, Press Release, DaVita to Pay $350 Million to Resolve Allegations of Illegal Kickbacks (Oct. 22, 2014).

62 *See id.*

63 *See, e.g.*, U.S. Dep't of Justice and Pfizer H.C.P. Corp. Deferred Prosecution Agreement, Att. A, at A-7–A-9 (Aug. 7, 2012).

64 As detailed above, the FCPA explicitly prohibits companies from making corrupt payments through third parties. *See* 15 U.S.C. §§ 78dd-1(a)(3), 78dd-2(a)(3), 78dd-3(a)(3) (prohibiting issuers, domestic concerns, and others, respectively, from "giving…anything of value to…any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any foreign official…."). Moreover, the DOJ and the SEC have warned of this very risk. *See* DOJ & SEC, RESOURCE GUIDE TO THE FCPA, at 60 ("DOJ's and SEC's FCPA enforcement actions demonstrate that third parties, including agents, consultants, and distributors, are commonly used to conceal the payments of bribes to foreign officials in international transactions.").

65 *See* Press Release, U.S. Securities and Exchange Comm'n, SEC Charges Mead Johnson Nutrition With FCPA Violations (July 28, 2015).

66 *See id.* Similarly, California-based medical device company Bio-Rad Laboratories agreed to pay a $14.35 million criminal fine and $40.7 million in disgorgement and prejudgment interest to resolve allegations under the FCPA that a subsidiary paid above-market commissions to third parties in connection with governmental sales in Russia, Vietnam, and Thailand, even though the third parties allegedly did not and could not perform the services described for those commissions. *See* Press Release, U.S. Dep't of Justice, Bio-Rad Laboratories Resolves Foreign Corrupt Practices Act Investigation and Agrees to Pay $14.35 Million Penalty (Nov. 3, 2014); Press Release, U.S. Securities and Exchange Comm'n, SEC Charges California-Based Bio-Rad Laboratories with FCPA Violations (Nov. 3, 2014).

67 In 2010, for example, the DOJ and the SEC pursued an enforcement action against several participants in a joint venture that allegedly paid bribes to Nigerian officials to obtain business on Bonny Island. *See* Complaint, *SEC v. Halliburton Co.*, No. 4:09-399 (S.D. Tex. Feb. 11, 2009); Information, *United States v. JGC Corp.*, No. 11 CR 260 (S.D. Tex. Apr. 6, 2011); Information, *United States v. Marubeni Corp.*, No. 12 CR 022 (S.D. Tex. Jan. 17, 2012); Consent of Defendant ENI, S.p.A., *SEC v. Eni, S.p.A.*, No. 4:10-cv-02414 (July 7, 2010); Information, *United States v. Technip S.A.*, No. H-10-439 (S.D. Tex. June 28, 2010).

68 *See* HHS OIG COMPLIANCE GUIDANCE, 68 Fed. Reg. at 23,738 ("At a minimum, manufacturers should periodically review arrangements for physicians' services to ensure that: (i) The arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are provided; (iv) the compensation is at fair market value; and (v) all of the preceding facts are documented prior to payment."); PhRMA Code on Interactions with Healthcare Professionals, at 7–8 (outlining indicators of "bona fide consulting arrangements," including written contracts specifying "the nature of consulting services to be provided and the basis of payment for those services[,]…a legitimate need for the consulting services [that] has been clearly identified in advance of requesting the services," pre-determined selection criteria "directly related to the identified purpose" and implemented by individuals with "the expertise necessary to evaluate whether the [candidates] meet those criteria[,]" a number of consultants "not greater than the number reasonably necessary to achieve the identified purpose[,]" and appropriate record-keeping and venues for the services to be provided).

69 Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Daiichi Sankyo, Inc., 11–12, 23–24, 27–28 (Jan. 7, 2015), *available at* http://oig.hhs.gov/fraud/cia/agreements/Daiichi_Sankyo_01072015.pdf (hereinafter "Daiichi Sankyo CIA"); Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and GlaxoSmithKline LLC, 14–15, 35–36, 38–39 (June 28, 2012), *available at* https://justice.gov/sites/default/files/opa/legacy/2012/07/02/hhs-oig-corp-integrity-agreement.pdf (herein-

after "GSK CIA").

70 DaVita CIA, at 12.

71 *Id*. at 13.

72 DOJ & SEC, RESOURCE GUIDE TO THE FCPA, at 60–61.

73 *See* F. Joseph Warin, Michael S. Diamant, and Elizabeth G. Silver, *The U.S. Foreign Corrupt Practices Act: Enforcement and Compliance*, Bloomberg BNA (2014), at A-62.

74 DOJ & SEC, RESOURCE GUIDE TO THE FCPA, at 60–61.

75 *See id*. at 61 (describing "assurances from third parties, through certifications and otherwise, of reciprocal commitments" as one of the "meaningful ways to mitigate third-party risk").

76 DOJ & SEC, RESOURCE GUIDE TO THE FCPA, at 60. Indications that a relationship with a third party may be high-risk include the extent to which the third party will interact with government officials on an entity's behalf and the region in which the third party will operate. Due diligence may result in additional "red flags," including the third party's relative lack of experience in the industry, the third party's pre-existing relationships with government officials, and a third party's history of improper conduct.

77 *See, e.g.*, HHS OIG COMPLIANCE GUIDANCE, at 23,738 (noting "compensation relationships with physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities" as one potential area of concern); OIG Advisory Opinion No. 98-10 (Sept. 8, 1998) (noting "suspect characteristics," including "compensation based on percentage of sales," "direct contact between the sales agent and physicians," and "use of sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients," among other potential concerns); DOJ & SEC, RESOURCE GUIDE TO THE FCPA, at 22–23 (listing "excessive commissions to third-party agents or consultants," consulting agreements with "vaguely described services," consultants in different lines of business from those for which they have been engaged, close relationships between the third parties and foreign officials, and requests of foreign officials to use certain third parties, among other red flags).

78 DaVita CIA, at 12.

79 15 U.S.C. § 78m(b)(6).

80 HHS OIG COMPLIANCE GUIDANCE, at 23,736 ("[R]esearch grants can be misused to induce the purchase of business….To reduce risk, manufacturers should insulate research grant making from sales and marketing influences.").

81 Criminal Complaint, *United States v. Olympus Corp. of the Americas*, No. 16-3524 (MF), at A-2–A-3 (D.N.J. Mar. 1, 2016).

82 *See id*.

83 *See Novartis AG*, SEC Release No. 77431, File No. 3-17177, at 4–5 (Mar. 23, 2016).

84 *Id*.

85 *See* Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Johnson & Johnson, at 15 (Oct. 31, 2013), *available at* http://oig.hhs.gov/fraud/cia/agreements/Johnson_Johnson_10312013.pdf (hereinafter "Johnson & Johnson CIA"); *see also* Olympus CIA, at 9.

86 *See* Johnson & Johnson CIA, at 18–19.

87 *See id*. at 19.

88 *See id*. at 37; *see also* Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Novartis Pharmaceuticals Corporation, 32–33 (Sept. 29, 2010), *available at* http://oig.hhs.gov/fraud/cia/agreements/Novartis_Pharmaceuticals_Corporation_09292010.pdf (requiring prospective budgeting plans and needs assessments for research).

89 *See* Johnson & Johnson CIA, at 37.

90 *See* Olympus CIA, at 14.

91 *See* Novartis CIA, at 33.

92 DOJ & SEC, RESOURCE GUIDE TO THE FCPA, at 60–61.

93 Guidance distributed by the OIG also supports this approach. *See* OIG COMPLIANCE GUIDANCE, 68 Fed. Reg. at 23,735 (outlining best practices for educational grants and research funding, including separation from sales and marketing functions and use of objective criteria that "do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient"); *id*. at 23,738 (outlining "[i]ndicia of questionable research," including "research initiated or directed by marketers or sales agents; research that is not transmitted to, or reviewed by, a manufacturer's science component; research that is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business; and post-marketing research used as a pretense to promote product").

94 DOJ & SEC, RESOURCE GUIDE TO THE FCPA, at 60.

95 *See* HHS OIG COMPLIANCE GUIDANCE, 68 Fed. Reg. at 23,738 (including "post-marketing research used as a pretense to promote product" among other "[i]ndicia of questionable research").

96 *Cf*. DOJ & SEC, RESOURCE GUIDE TO THE FCPA, at 60; Olympus Latin America DPA, at C-7.