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REPORT

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Anti-Kickback Enforcement and Legislation Developments: What Drug, Medical Device and Biologics Companies Must Know

By KAREN A. GIBBS

I. Introduction

Within the past three years, investigation and enforcement activity under the federal False Claims Act¹ (FCA) and the federal Anti-Kickback Statute² (AKS) relating to payments made by medical device companies to their customers, typically physicians, has increased dramatically. The September 2007 highly-publicized orthopedic implant case, involving \$311 million in total civil settlements, is just one ex-

ample of investigations and prosecutions in the medical device industry.³

In July 2007, Advanced Neuromodulation Systems Inc. settled a case relating to a marketing program including kickbacks for patient referrals; the settlement included a three-year CIA. And in July 2006, Medtronic settled another case relating to payments to physicians to use Medtronic's Sofamor Danek division's spinal implants and initiated by a FCA *qui tam* whistleblower. Though not effective because of ongoing litigation involving a *qui tam* relator, the settlement included a payment of \$40 million by Medtronic and a five-year corporate integrity agreement (CIA), including the requirement Medtronic establish detailed procedures and systems to ensure that arrangements with physicians and other potential sources of business are appropriate.

¹ 31 U.S.C. § 3729-33. The False Claims Act is the main mechanism used by the Department of Justice (DOJ) to pursue civil fraud in pharmaceutical and medical device sales and marketing practices, and claims under the FCA often are brought in conjunction with criminal claims under the federal Anti-kickback Statute (see *infra*, note 3 and corresponding text).

² 42 U.S.C. § 1320a-7b(b). The federal Anti-Kickback Statute (AKS) prohibits the offering, payment, solicitation or receipt of any remuneration in exchange for a patient referral or referral of other business for which payment may be made by a federal health care program, including Medicare and Medicaid. Violations of the AKS can result in significant criminal penalties, civil penalties up to \$50,000 for each violation, and imprisonment.

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³ *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007) available at <http://newark.fbi.gov/dojpressrel/2007/nk092707.htm> (last visited Feb. 27, 2008).

Medtronic to Pay United States \$40 Million to Settle Kickback Allegations (July 18, 2006) available at http://www.usdoj.gov/opa/pr/2006/July/06_civ_445.html (last visited Feb. 27, 2008).

OIG Settles Civil Monetary Penalties Law Case Against Medical Device Manufacturer (July 2, 2007) available at <http://oig.hhs.gov/publications/docs/press/2007/ANS%20Press%20Release.pdf> (last visited Feb. 27, 2008).

Alice Dembner, *Plea Bolsters Kickback Against Mass. Medical Firm*, Boston Globe, Jan. 4, 2008 available at http://www.boston.com/business/healthcare/articles/2008/01/04/plea_bolsters_kickback_case_against_mass_medical_firm/ (last visited Feb. 27, 2008). Dr. Chan also settled a related whistleblower suit, requiring Dr. Chan to pay \$1,500,000. *Id.*

The investigations and prosecutions are not limited to companies; physicians also are under scrutiny. On Jan. 3, 2008, in Arkansas, neurosurgeon Dr. Patrick Chan pled guilty to soliciting and receiving kickbacks from a sales representative of Orthofix International and three other companies, facing a potential sentence of five years imprisonment, a \$25,000 fine, or both.

At the same time, FCA- and AKS-related investigations and enforcement activities involving pharmaceutical companies and health care service providers have continued at a steady pace, with some of the largest settlements being reached in the last few years.

For example, on Feb. 7, 2008, the DOJ announced Merck & Company Inc. agreed to pay more than \$650 million to settle allegations that Merck failed to pay proper rebates to Medicaid and paid illegal kickbacks to health care providers to induce prescriptions for the company's products.

And on Nov. 1, 2007, the DOJ reported that fiscal year 2007 settlements with Bristol-Myers Squibb Co., Aventis Pharmaceuticals Inc., Medco Health Solutions Inc., Purdue Pharma L.P. and Purdue Frederick Co. and InterMune Inc. accounted for more than \$800 million.⁴

The primary concerns of investigating and prosecuting agencies are that such company payments to providers may impair the ability of a physician, health care professional, or other decision-maker to select the course of treatment that is in the best interest of the patient or to endorse payment of higher prices for products reimbursed under Medicare, Medicaid, or other federally funded programs.

Many industry stakeholders hope that the DOJ, the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) and the Federal Bureau of Investigation will decrease kickback-related investigation and enforcement activities concerning health care and life science companies, now that the DOJ and HHS-OIG have reached well-publicized, record-setting settlements and verdicts against the full spectrum of stakeholders. However, all indications are that the oversight and enforcement will continue full steam ahead—compliance is big business for the U.S.

⁴ *Merck to Pay More than \$650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks* (Feb. 7, 2008) available at http://www.usdoj.gov/opa/pr/2008/February/08_civ_094.html (last visited Feb. 27, 2008).

government, saving over \$43 billion in fiscal year 2007 alone.⁵

Such oversight and enforcement will not stop with enforcement of the federal FCA or AKS, or state counterparts, “as is,” but also will require manufacturers of drugs, medical devices, biologics and other medical products to be aware of changes in law and recent legislative initiatives requiring increasing levels of control over and disclosure of payments to physicians and other health care professionals. As discussed further below, members of the Senate and House of Representatives increasingly are investigating and proposing legislation to address such payments and implications to Medicare, Medicaid programs, private payers and patient safety.

This further “tightening of the anti-kickback compliance noose,” so to speak, has deep competitive implications for health care companies. To some, it helps level the competitive playing field and spurs innovation. To others, it risks loss of an “edge” due to mandated disclosure of confidential technological developments and corresponding relationships, or it risks imbalance of the competitive playing field due to additional administrative and financial burdens placed on one competitor yet not placed on another in the same market.

As a result, and because drug, medical device, biologics and other medical products companies must work closely with physicians and other health care professionals to be competitive and on that cutting edge, e.g., by engaging them in research and development, consulting, clinical studies and trials, and education and training activities, these companies increasingly will face challenges competing while also ensuring compliance with the anti-kickback laws when it comes to relationships with physicians and other health care professionals. To optimize their ability to obtain or maintain that coveted edge and avoid distraction and a resource drain resulting from investigations, enforcement proceedings and monitoring, it is critical, therefore, that these companies, as well as the physicians, distributors and others involved in the sale, distribution and use of such products, understand recent legal and regulatory developments. It is also critical that these companies understand how to respond to compliance requirements and investigations to avoid negative outcomes.

This article summarizes the recent \$311 million “landmark” orthopedic hip and knee implant case from September 2007 then highlights recent legislative initiatives relating to disclosure of payments to physicians

Justice Department Recovers \$2 Billion for Fraud Against the Government in FY 2007; More than \$20 Billion Since 1986 (Nov. 1, 2007) available at http://www.usdoj.gov/opa/pr/2007/November/07_civ_873.html (last visited Feb. 27, 2008).

⁵ *OIG Reports Record \$43 Billion in Savings and Recoveries* (Dec. 14, 2007) available at <https://oig.hhs.gov/publications/docs/press/2007/SemiannualRelfall2007E.pdf>.

and other health care professionals while strengthening the federal FCA under which violations of the AKS can be prosecuted. This article then closes with an assessment of practical implications and considerations for drug, medical, device, biologics and other medical products companies as well as others involved in the sale, distribution and use of such products.

II. The Landmark Orthopedic Case

Well-publicized in the health care world, this case involved an industry-wide investigation by the U.S. Attorney of the District of New Jersey regarding payments to physicians for the purpose of their exclusive use of artificial hips and knees manufactured by five orthopedic implant manufacturers responsible for 90 to 95 percent of hip and knee reconstruction and replacement implants.⁶ Unlike similar investigations, this investigation was not triggered by a *qui tam* or whistleblower complaint.⁷ The investigation commenced in March 2005, with subpoenas to Zimmer Inc., Smith & Nephew Inc., Biomet Inc., DePuy Orthopaedics Inc. (a division of Johnson & Johnson) and Stryker Orthopedics Inc., and moved rapidly to resolution in September 2007, with each company entering arrangements with the DOJ and HHS-OIG.⁸ The resolution includes eighteen-month deferred prosecution agreements (DPAs) and total payments of \$311 million for four of the device makers; a non-prosecution agreement (NPA) for the fifth device maker (Stryker); and also five-year corporate integrity agreements for all five companies.⁹

The DPAs and NPA each require a federal monitor to conduct a variety of oversight functions,¹⁰ including reviewing all new and existing consulting relationships with the companies, ensuring all new consulting agreements require physicians to disclose their financial engagements with any company to their patients and ensuring the companies disclose the name of each consultant and what they have been paid on the company Web site.¹¹ Additionally, each company must prepare a detailed "Needs Assessment" to determine the commercially reasonable needs for all consultant services to fulfill medical, clinical, training, educational, research and development needs, and also a budget to cover payments unrelated to such services, e.g., honoraria, fellowships and gifts.¹²

While many have written about the compliance and prevention lessons to be learned from this case, including the burden and expense associated with the DPA and NPA requirements,¹³ this case highlights the im-

pact kickbacks and compliance have on competition given the stakeholders—DOJ, HHS-OIG and each of the five companies involved—focused on a resolution that ensured equal treatment and oversight of the five companies, covering 90 to 95 percent of the market(s).¹⁴ Each company insisted that the other companies must be held to the same conditions and requirements to ensure a level playing field. They perceived the DPAs, NPA and CIAs as mechanisms for giving one of their competitors an edge and insisted on assurances to neutralize that risk.¹⁵

As Michele Brown, Counsel for the U.S. Attorney of the District of New Jersey, stated during a Feb. 20, 2008 audio-conference, the orthopedic companies involved with the investigation believed they had to use consulting and other arrangements with surgeons or risk the surgeon would stop using their products. Further, because the practices cut across 90 to 95 percent of the hip and knee implant market(s), the impact to consumers and the industry would be catastrophic if these companies were excluded from Medicare and Medicaid programs. Consequently, the DOJ and HHS-OIG concluded it was not appropriate or fair to exclude one or more of the companies and thus give non-excluded companies a competitive advantage, which risked harm to consumers and patients. The result was the DOJ and HHS-OIG negotiated with all five of the companies at the same time and provided for equal treatment in the DPAs, NPA and CIAs.¹⁶ Counsel Brown also stated that this experience has caused movement from the adversarial process to partnering with companies to reach goals of corporate compliance and a level competitive playing field. She noted, for example, weekly calls with the companies to address competitor compliance and questions regarding interpretation of the agreements.¹⁷

III. The Physician Payments Sunshine Act of 2007

Just three weeks before the announcement of the landmark orthopedic settlement,¹⁸ on Sept. 6, 2007,

available at <http://pascrell.house.gov/issues2.cfm?id=12817> (last visited Feb. 27, 2008). Pascrell expressed unease over the settlement requirement that the companies hire a federal monitor, selected by the U.S. Attorney, because of the lack of transparency surrounding this provision of the agreement. *Id.* According to Representative Pascrell, the lack of transparency "could allow the federal monitor to act with impunity while the manufacturers remain under the threat of prosecution." *Id.* Representative Pascrell expressed concern that, "Under the continued threat of prosecution, any party being investigated seemingly has little choice but to agree to the selection of these federal monitors and their exorbitant fees. Therein the selection of these federal monitors by the U.S. Attorney's Office could give the impression of impropriety and political favoritism." *Id.*

¹⁴ Michele Brown, Counsel to U.S. Attorney Christopher Christie of the District of New Jersey, *National Medical Device Audio-conference: How the Recent Landmark \$311 Million Device Settlements Will Change Industry Practice* (Feb. 20, 2008).

¹⁵ See generally *id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ On June 27, 2007, the Senate Special Committee on Aging, spearheaded by Sen. Herb Kohl (D-Wis.), also conducted a hearing regarding relationships between drug companies and doctors. *Paid to Prescribe?: Exploring the Relationship Between Drug Companies and Doctors: Hearing Before the Sen-*

⁶ See *Five Companies*, *supra* note 4.

⁷ See *supra* notes 2 and 3.

⁸ *Id.*; see also companies' Web sites for the posted agreements with the government.

⁹ See generally *id.*

¹⁰ It has been estimated that monitors cost each company millions each quarter; Zimmer, for example, disclosed that former Attorney General John Ashcroft may charge between \$28 million and \$52 million for 18 months of work.

¹¹ *Supra* note 9.

¹² *Id.*

¹³ For example, on November 26, 2007, Rep. Bill Pascrell (D-N.J.) sent a letter to House Judiciary Committee Chairman Conyers, asking for formal hearings on the use of DPAs and expressing concern over the recent settlement agreements with four of the five hip and knee replacement device manufacturers. See *Pascrell Calls on House Judiciary Committee to Examine Deferred Prosecution Agreements* (Nov. 26, 2007)

Sens. Chuck Grassley (R-Iowa), Kohl, Edward M. Kennedy (D-Mass.), Claire McCaskill (D-Mo.), Charles Schumer (D-N.Y.) and Amy Klobuchar (D-Minn.) introduced legislation (S. 2029) called the Physician Payments Sunshine Act of 2007 (the Sunshine Act)¹⁹ to amend the Social Security Act.²⁰ The legislation parallels several pharmaceutical-related initiatives in the District of Columbia and at the state level in Maine, Minnesota, Vermont and West Virginia.²¹

The proposed legislation provides that each manufacturer of a covered drug, device, or medical supply, on the first day of each fiscal year quarter, must report “a payment or other transfer of value, directly, indirectly, or through an agent, subsidiary, or other third party, to a physician, or to an entity that a physician is employed by, has tenure with, or has an ownership interest in.”²² The term “covered drug, device, or medical supply” means any drug, biological product, device, or medical supply for which payment is available under Medicare or a state Medicaid program.²³ The term “manufacturer of a covered drug, device, or medical supply” means “any entity with annual gross revenues that exceed \$100 million, which is engaged in the production, preparation, propagation, compounding, conversion, or processing of a covered drug, device, or medical supply, or engaged in the packaging, repackaging, labeling, re-labeling, or distribution of a covered drug, device, or medical supply.”²⁴ The term “payment or other transfer of value” means “a transfer of anything of value that exceeds \$25, and includes any compensation, gift, honorarium, speaking fee, consulting fee, travel, discount, cash rebate, or services.”²⁵

Each manufacturer must provide an “Annual Summary Report” of such payments to the Secretary of Health and Human Services (Secretary).²⁶ The required report must include all of the following:

- the name of the physician, and if a payment or other transfer of value was provided to an entity that the physician is employed by, has tenure with, or has an ownership interest in, the entity;
- the address of the physician’s office and, in the case of an entity, the primary place of business or headquarters for the entity;
- the facility with which the physician is affiliated, if any;
- the value of the payment or other transfer of value;
- the date on which the payment or other transfer of value was provided;
- a description of the nature of the payment or other transfer of value, indicated as compensation, food, entertainment, gifts, trips or travel, a product or other item provided for less than market value, participation in a medical conference, continuing medical education, or other educational or informational program or seminar, provision of materials related to such a conference or educational or informational program or seminar, or remuneration for promoting or participating in such a conference or educational or informational program or seminar, product rebates or discounts, consulting fees or honoraria, or any other economic benefit as defined by the Secretary; and
- the medical issue or condition addressed, if any, that was the basis for the payment or transfer.²⁷ The proposed penalty for non-compliance is a civil monetary penalty ranging from \$10,000 to \$100,000 for each failure to comply.²⁸

The proposed legislation also provides that the Secretary must establish procedures to ensure that the information reported by covered manufacturers and the Annual Summary Reports are accessible to the public through a publicly-available, downloadable and searchable website.²⁹ Finally, the proposed legislation requires the Secretary must provide to Congress, by April 1 of each year, a report of the information provided by covered manufacturers in the preceding year and a description of enforcement action taken and penalties imposed during the preceding year.³⁰

IV. The False Claims Act Correction Act of 2007

Compounding the push on the Sunshine Act, just days after introducing the Sunshine Act, Sens. Grassley and Richard Durbin (D-Ill.) introduced the False Claims Act Correction Act of 2007 (“FCACA”)³¹ in response to

ate Special Committee on Aging, 110th Cong. (June 27, 2007), statements of committee members and witnesses available at http://aging.senate.gov/hearing_detail.cfm?id=277848&; (last visited Feb. 27, 2008). On Feb. 27, 2008, the Committee held an additional hearing regarding medical device companies and doctors. *Surgeons for Sale: Conflicts and Consultant Payments in the Medical Device Industry* http://aging.senate.gov/hearing_detail.cfm?id=293677&; (last visited Feb. 27, 2008).

¹⁹ Physician Payments Sunshine Act, S. 2029, 110th Cong. (2007) (Sunshine Act).

²⁰ 42 U.S.C. § 1301 *et seq.*

²¹ D.C. Code § 48-833.03 (2007); Me. Rev. Stat. tit. 22, § 2698-A (2007); Minn. Stat. § 151.214 (2007); Vt. Stat. Ann. tit. 33, § 2005 (2007); and W. Va. Code § 5A-3C-13 (2007).

²² Sunshine Act § 1128G(a).

²³ *Id.* at § 1128G(f)(1).

²⁴ *Id.* at § 1128G(f)(2). Medtronic Inc. is asking the Senate to expand coverage to companies of all sizes, including those companies with annual revenues under \$100 million and physician-owned companies currently excluded from the proposed legislation. Carissa Wyant, *Medtronic Weighs in on Consulting Disclosures*, Minneapolis/St. Paul Business Journal, Feb. 26, 2008 available at http://www.bizjournals.com/twincities/stories/2008/02/25/daily14.html?ana=from_rss (last visited February 27, 2008).

²⁵ Sunshine Act § 1128G(f)(3)(A). Product samples that are intended for patients, a payment or other transfer of value made for the general funding of a clinical trial, and a transfer of anything of value to a physician when the physician is a patient and not acting in his or her professional capacity, however, are excluded. *Id.* at § 1128G(f)(3)(B).

²⁶ *Id.* at § 1128G(b).

²⁷ *Id.* at § 1128G(a).

²⁸ *Id.* at § 1128G(c).

²⁹ *Id.* at § 1128G(d).

³⁰ *Id.* at § 1128G(e).

³¹ False Claims Act Correction Act of 2007, S. 2041, 110th Cong. (2007) available at <http://grassley.senate.gov/public/releases/2007/09122007.pdf>. On October 23, 2007, Senators Grassley and Arlen Specter (R-Pa.) introduced another bill titled the Transparency in Medical Device Pricing Act of 2007; passage of this Act would require quarterly reporting of median and mean sales price data by implantable medical devices to the Secretary of the Department of Health and Human Services and subsequent quarterly publication of such data by the Secretary. Critics of the legislation argue that it is unlikely to decrease prices given the limited number of suppliers of the covered implantable devices, and such legislation may even lead to increases in prices because mandatory disclosure could facilitate price coordination. Robert W. Hahn and Hal J. Singer, *Is Greater Price Transparency Needed in the Medical Device Industry?* (Feb. 19, 2008) (this report was supported by

certain federal court decisions that may serve to limit the reach of the FCA. The FCACA has the support of Judiciary Committee Chairman Patrick Leahy (D-Vt.) and Ranking Member Specter.³² Rep. Howard Berman (D-Calif.), who sponsored the 1986 amendments to the FCA, introduced companion false claims legislation in the House of Representatives on December 19, 2007.³³

The FCACA, if passed, would make two especially significant amendments to the FCA, among others. First, it would remove the requirement that false claims be presented to a government employee to ensure that any government money lost to fraud, waste or abuse can be recovered using the FCA regardless of whether the individual making the false claim directly represents such a claim to a government employee. This correction is proposed in response to the D.C. Circuit Court of Appeals decision in *U.S. ex rel. Totten v. Bombardier Corp.*,³⁴ which held that false claims to government grantees were not “presented” to a government employee and barred government recovery of government funds lost to fraud. Second, passage of the FCACA would amend the FCA to limit the dismissal of claims filed based upon publicly disclosed information (referred to as the “public disclosure bar”). Currently, courts may dismiss claims under the FCA if based upon publicly disclosed information and the *qui tam* relator is not the “original source” of the public information. This amendment is proposed in response to cases like *Rockwell International Corp. et al. v. United States*,³⁵ in which the Supreme Court held that a relator may not recover unless the relator was the original source for all claims brought under the FCA.

V. Practical Implications

Legislation initiatives, investigations and enforcement will continue, so emphasize prevention. Especially if there is turnover in the administration during this election year, given the intensity of the current reformist legislative environment coupled with the DOJ’s and HHS-OIG’s ongoing commitment to enforcement activities in the area of kickbacks, manufacturers and providers should expect increasing compliance requirements, oversight and enforcement. Especially given the burdensome cost of having a monitor assigned to oversee compliance, the focus, therefore, for all stakeholders should be *prevention*. This means prioritizing, establishing and evaluating compliance programs across operations. Companies must not only develop effective compliance programs but also monitor and maintain such programs, which should include written policies and procedures (preferably incorporated into the company’s standard operating procedures or “SOPs”), one or more independent compliance officers with access to senior management and the Board of Directors, functional lines of communication for reporting potential issues, education and training, auditing and monitoring procedures, appropriate and timely investigations of re-

funding of the Advanced Medical Technology Association, known as “AdvaMed” and available at http://www.criterioneconomics.com/docs/Hahn_Singer_Disclosure_final_12-7.pdf.

³² *Id.*

³³ False Claims Act Correction Act of 2007, H.R. 4854, 110th Cong. (2007) (available at http://www.house.gov/apps/list/press/ca28_berman/berman_false.pdf).

³⁴ 380 F.3d 488 (2004).

³⁵ 127 S.Ct. 1397 (2007).

ported issues, and appropriate disciplinary action and enforcement for violations. Especially on financial arrangements with physicians, companies should proactively assess and inventory such arrangements, how they originate and how they relate to company operations.

Most significant here, for purposes of prevention of a kickback claim, is the provision of written guidance and effective education and training for sales, marketing, research, development, clinical education and other teams that may involve interfacing with physicians, consultants or other health care professionals. Such guidance, at a minimum, should address:

- What are the various types of language, conduct or arrangements that could be perceived by investigators as comprising a prohibited kickback;
- What criteria must be met for a physician or other health care professional to be compensated, *i.e.*, what constitutes legitimate consulting or other services such as fee-for-service arrangements, providing training and education, contributing to research and development advances, including what type of deliverables or milestones should be provided;
- What criteria are to be considered in determining the appropriate level of compensation, *i.e.*, what is fair market value given the scope of services;
- What procedures, practices and documentation must be completed for a approval of a service arrangement and review of and payment for achievement of related milestones or deliverables, if applicable;
- What payments may company representatives make for meals, receptions or other hospitality during meetings with physicians or other decision-makers to discuss products or sales terms;
- What types of gifts are permissible, *i.e.*, what gifts benefit patients or serve a genuine educational function;
- What donations or grants are permissible, *i.e.*, what is considered to be support for patient care, medical research or education;
- What are appropriate purposes and venues for conferences being held or sponsored by suppliers, *i.e.*, what are considered scientific and educational activities;
- What payments may be made and how such payments may be made to conference sponsors;
- What honoraria payments may be made to physician faculty members of conferences and what expense reimbursements may be appropriate; and
- What safeguards and procedures are in place for monitoring and auditing all of the above.

Understand the impact of these initiatives, compliance and investigations on competition. The initiatives, if passed, will impact drug, medical device, biologics and other medical supply companies’ dependence on qualified physicians and thought leaders not only to contribute their ideas and clinical feedback on technological or procedural advancements but also to educate and train others regarding such advancements. While some may argue heightened disclosure requirements may discourage physicians and others from accepting consulting, fee-for-service, research, clinical study or trial, development, education, training or other arrangements with

companies for fear such information later being used in a tort case against the physician and in which the technology or product subject to the arrangement is implicated, others would argue that proper implementation of guidelines and heightened disclosure and transparency will spur innovation.

It is also important to note that enactment of the Sunshine Act potentially will permit competitors to get a “peek” into each others’ product and technology pipelines. Especially in the area of medical devices where devices are often the result of close collaboration between engineers and physicians regarding patient needs, and often are the inventions of physicians themselves, this is unpalatable to some wishing to avoid pre-

mature disclosure of developments but highly desirable to others believing it will spur competitors to develop more innovations.

Finally, on investigations and prosecutions, it is critical for company executives to work closely with counsel to ensure any resolution takes into consideration how the terms and conditions of such resolution may impact the company’s competitive edge. Failure to consider competitive impacts during negotiation with the DOJ or HHS-OIG regarding terms and conditions of a DPA or CIA not only may yield a resolution under which drug, medical device or biologics companies cannot comply, but also may yield a resolution which does not address the issue of making the playing field level.