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Mirror, Mirror on the Wall—Evaluating Fair Market Value for Manufacturer-Physician Consulting Arrangements

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INTRODUCTION

Absent adequate forethought, manufacturer-physician consulting agreements implicate Congress's Anti-Kickback Statute and False Claims Act, which criminalizes payments by companies to customers, made in whole or in part, to induce sales.[1] Pharmaceutical companies commonly pay physicians for consulting, advisory, clinical trials and design development agreements. In this post-settlement atmosphere, companies are well served by considering how they devise, implement and maintain a fair market value compensation framework.[2]

Statutory safe harbors, such as the personal services exception, can shelter companies from Anti-Kickback Statute and False Claims Act claims.[3] Establishing such exemptions, however, is complicated and requires a consistently applied, well-formulated and documented fair market value payment methodology. Failure to qualify for an exemption could result in criminal, civil and administrative enforcement actions for violations of the Anti-Kickback Statute and False Claims Act.[4]

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[1] 42 U.S.C. § 1320a-7(b) (2006). The Medicare and Medicaid Patient Protection Act of 1987, as amended, 42 U.S.C. § 1320a-7(b) (Anti-Kickback Statute), provides for criminal penalties for certain acts affecting Medicare and state healthcare (e.g., Medicaid) reimbursable services. The Anti-Kickback Statute criminalizes any payment by a supplier to a customer made, in whole or in part, to induce sales. 31 U.S.C. § 3729-3733 (2007). *See* Beck, J. Randy, *The False Claims Act and The English Eradication of Qui Tam Legislation*, 78 N.C. L. REV. 539 (2000). (In introducing amendments to the False Claims Act in 1985, Senator Charles Grassley explained the purpose behind the Act: "The government needs help—lots of help—to adequately protect the Treasury against growing and increasingly sophisticated fraud … Part of the solution—something I consider essential to any meaningful improvements in cutting down fraud—is the establishment of a solid partnership between public law enforcers and public taxpayers. The Federal government has a big job on its hands as it attempts to ensure the integrity of the nearly $1 trillion we spend each year on various programs and procurement. That job is simply too big if government officials are working alone.").

[2] *See* Press Release, United States Department of Justice (DOJ), *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009); *See* Press Release, DOJ, *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 Aug. 1, 2009).

[3] 42 C.F.R. § 1001.952(d) (2008). The statute creates permissive exclusions for payment practices, which shall not be treated as a criminal offense under section 1128B of the Act. Of those exemptions, part (d) is the Personal-Services contract exception from Anti-Kickback claims for physician consulting agreements.

[4] 42 U.S.C. § 1320a-7(b) (2006); 42 C.F.R. § 1001.952(d) (2008); Department of Health and Human Services (HHS), Office of Inspector General's (OIG's) Compliance Program Guidance (CPG) for Pharmaceutical Manufactures, 68 Fed. Reg. 23,731 (May 5, 2003). Failure to satisfy the requirements of a safe harbor does not result in a violation per se. "Arrangements that do not fit in a safe harbor should be reviewed in light of the totality of all facts and circumstances." […] "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. In addition, to further reduce their risk, manufacturers should structure services arrangements to comply with a safe harbor whenever possible."

Government settlement agreements increasingly focus on fair market value compensation between medical companies and health care professionals. Consider, for example, the following two recent settlement events: 1) Medtronic, Inc. (2006) and 2) New Jersey's Investigation of Hip and Knee Device Manufacturers: Zimmer, Inc., DePuy Orthopaedics, Inc., Biomet Inc., Smith & Nephew, Inc. and Stryker Corp. (2007). In each, government investigators focused on kickbacks and physician consulting arrangements for services that appeared in excess of fair market value.[5] As a result of the government's inquiry, Medtronic agreed to pay $40 million and the orthopedic companies agreed to pay $311 million to settle the government's Anti-Kickback Statute and the False Claims Act allegations.[6]

These settlements represent the first major cases on physician contracting, and provide insight as to what government prosecutors will look for in the future when addressing fair market value compensation issues. But in order to defend against the government on either a personal services safe harbor exemption or a fact-and-circumstance basis, more action is needed. Companies must position themselves to consistently implement fair market value practices, while simultaneously supporting those decisions with adequate documentation. Accordingly, pharmaceutical and medical device companies should carefully evaluate how they arrange, draft and monitor consulting agreements with physicians.

The purpose of this article is to examine the manufacturer-physician arrangements, discuss the evolution of the fair market valuation, and propose a set of standards for calculating fair market value that will enable compliance with legal requirements. Part I of this article discusses the historical development of fair market value and explains how fair market value fits into a legal framework within federal fraud statutes, relevant regulations, directives and guidelines. Part II reviews the major government settlement agreements that have targeted physician-contracting arrangements with medical device companies. Part III explores the barriers to accurately calculating fair market value, and recommends practical principles to use when evaluating fair market value methodologies: 1) use of objective and robust data, 2) pay for health care practitioner's time, 3) provide for differentiated payments based on expertise and 4) document standards for consistent application.

I. HISTORICAL & LEGAL BACKGROUND

Pharmaceutical and medical device companies have long cooperated with physicians to share their knowledge and learn, test and develop products.[7] Collaboration

[5] The five companies include Stryker Orthopedics, Inc. Zimmer, Inc., DePuy Orthopaedics, Inc. Biomet Inc. and Smith & Nephew Inc. Stryker Orthopedics, accepted federal supervision for 18 months. However, it was not subject to criminal charges because it was the first to cooperate in the investigation, according to the government. *See* Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009); *See also* Amended Complaint and Jury Demand at 1, Stryker Corp. v. U.S. Dept. of Justice, et al., No. 08-4111 (D.N.J. (Sept., 11, 2008)); U.S. v. Stryker Corp., No. 1:08-MC-92 (W.D. Mich. (2008)). Stryker's New Jersey action was dismissed by order on Jan. 23, 2009, and the United States' petition for summary enforcement of the Inspector General's Subpoena was granted by order on Jan. 28, 2009. *See* Press Release, DOJ, *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 Aug. 1, 2009).

[6] *See* Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009); *See* Press Release, DOJ, *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 Aug. 1, 2009).

[7] *See generally* Blumenthal, David, *Doctors and Drug Companies*, 351 NEW ENG. J. MED. 18, 1885-1890 (2004). *See* Campbell, Eric et al., *A National Survey of Physician-Industry Relationships*, 256 NEW ENG. J. MED. 17, 1742-1750 (2007). Conclusions: "The results of this national survey indicate that relationships between physicians and industry are common and underscore the variation among such relationships according to specialty, practice type, and professional activities."

exists so that companies can easily determine and identify the needs of patients and physicians. Pharmaceutical companies commonly pay physicians for consulting, advisory, clinical trials and design development agreements.[8] Consulting and advisory arrangements between physicians and pharmaceutical and medical device companies are commonplace and defensible if structured appropriately.[9] In recent years, however, this long-standing payment practice has come under fire due to allegations about arrangements that appear to induce the purchase or prescription of a company's products.[10]

The relevant laws governing physician-contracting and fair market value (FMV) include the Anti-Kickback Statute and the False Claims Act.[11] Both are classified as Medicare and Medicaid fraud and abuse laws and are enforced by the HHS Office of the OIG and the DOJ.[12] In addition, the Food and Drug Administration's (FDA's) Office of Chief Counsel and its Office of Criminal Investigations, enforce the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA).[13] The federal Anti-Kickback Statute's main purpose is to "protect patients and federal healthcare programs from fraud and abuse by curtailing the supposed corrupting influence of money on healthcare decisions."[14] The False Claims Act's main purpose is to counteract fraudulent billings submitted to government regulators by federal contractors involved in healthcare, military or other government spending programs.[15]

Physician consulting agreements that are not carefully constructed may implicate the Anti-Kickback Statute, which criminalizes payments by companies to customers, made in whole or in part, to induce sales.[16] In addition, since the False

[8] Kussecrow, Richard P., OIG, *Promotion of Prescription Drugs through Payments and Gifts*, *available at*, http://oig.hhs.gov/oei/reports/oei-01-90-00480.pdf (last visited Jan. 1, 2010). ("Pharmaceutical companies offer money and other items of value to physician for a range of purposes, from sponsoring important educational activities to actively promoting their products." Offers that have been used for promotional purposes fall into four major categories: Studies, Speaking Engagements, Program Attendance and Gifts.)

[9] HHS, OIG's CPG for Pharmaceutical Manufactures, 68 Fed. Reg. 23,731, 23,738 (May 5, 2003). In the context of consulting and advisory payments "[p]harmaceutical manufacturers frequently engage physicians and other healthcare professionals to furnish personal services as consultants or advisers to the manufacturer."

[10] Press Release, DOJ, *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 Aug. 1, 2009). Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.fel.pdf (last visited Dec. 1, 2009); *See* Blumenthal, David, *Doctors and Drug Companies*, 351 NEW ENG. J. MED. 18, 1885-1890 (2004); *See also* HHS, OIG's CPG for Pharmaceutical Manufactures, 68 Fed. Reg. 23,731, 23,737 (May 5, 2003). "In light of the obvious risks inherent in these arrangements, whenever possible prudent manufacturers and their agents or representatives should structure relationships with physicians to fit in an available safe harbor, such as the safe harbors for personal services and management contracts, 42 C.F.R. 1001.952(d), or employees, 42 C.F.R. 1001.952(i). An arrangement must fit squarely in a safe harbor to be protected. In addition, arrangements that do not fit in a safe harbor should be reviewed in light of the totality of all facts and circumstances …".

[11] 42 U.S.C. § 1320a-7(b) (2006); 42 C.F.R. § 1001.952(d) (2008).

[12] 31 U.S.C. § 3729-3733 (2007).

[13] Totino, MaryAnn, *A Historical Analysis of the FDA's Office of Criminal Investigations*, (May 2007), *available at* http://leda.law.harvard.edu/leda/data/846/Totino_07_%5Bredacted%5D.html.

[14] 42 U.S.C. § 1320a-7(b) (2006). *See also* Fact Sheet, Federal Anti-Kickback and Regulatory Safe Harbors, (Nov. 1999), *available at http*://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm. (last visited Dec. 1, 2009).

[15] 31 U.S.C. § 3729-3733 (2007). *See also* Coordinated Issue—All Industries—False Claims Act Settlements With DOJ (Sept. 5, 2008), *available at* http://www.irs.gov/businesses/article/0,,id=186486,00.html. "The purpose of the FCA is to discourage fraudulent billing practices from occurring, to punish illegal behavior in order to deter similar behavior in the future, and to recover monies fraudulently obtained from the government."

[16] 42 U.S.C. § 1320a-7(b) (2006); 68 Fed. Reg. 23,738 (While these arrangements are potentially beneficial, they also pose a risk of fraud and abuse. In particular, the use of healthcare professionals for marketing purposes—including, for example, ghost-written papers or speeches—implicates the anti-kickback statute.).

Claims Act prohibits a physician from submitting, or causing to submit, a false or fraudulent claim for payment to the government; when claims are submitted pursuant to an otherwise illegal arrangement (such as, Anti-Kickback violations), it is considered a false claim.[17] Thus, consulting arrangements which have fees that appear in excess of FMV for services rendered can trigger alleged violations of both the Anti-Kickback Statute and False Claims Act.[18]

Under the False Claims Act, a person who knowingly submits, or causes the submission of, a fraudulent claim to the government may become subject to substantial penalties. The False Claims Act states that prohibited conduct occurs when a person:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the Government;
>
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid … .[19]

Sanctions for violating the False Claims Act include treble damages, fines and administrative penalties.[20] Violators may be liable for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the government sustains because of the act of that person.[21]

Under the Anti-Kickback Statute, it is illegal to knowingly and willfully solicit or receive anything of value directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual or purchasing, leasing, ordering or arranging for any good or service for which payment may be made in whole or in part under a federal healthcare program.[22] Companies can be charged with criminal penalties, civil monetary sanctions and even exclusion from federal healthcare programs.[23] If a person or entity is found guilty of violating the statute, a fine of not more than $25,000 or imprisonment for not more than five years can be assessed, or both.[24] This provision authorizes a civil monetary penalty of up to $10,000 for each item or service, an assessment of up to three times the amount claimed, and exclusion from participation in the Medicare program and State healthcare programs.[25] For example, in the case of a pharmaceutical company, if exclusion were levied, none of its products could be paid for by Medicare and/or Medicaid.

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[17] 31 U.S.C. § 3729-3733 (2007). United States ex rel. Fry v. The Health Alliance of Greater Cincinnati, No. 1::03-CV-00167 (S.D. Ohio (Feb. 26, 2009)). "The Supreme Court has affirmed an aggressive reading of the FCA. Cook County, Ill. V. United States ex rel. Chandler, 538 U.S. 119, 123 S.Ct. 1239, 155 L.Ed.2d 247 (2003). The court explained that "Congress wrote expansively, meaning to 'reach all types of fraud, without qualification, that might result in financial loss to the government.'" *Id.* (*Quoting* United States v. Neifert-White Co., 390 U.S. 228, 232, 88 S.Ct. 959, 19 L.Ed.2d 1061 (1968))."

[18] HHS, OIG's CPG for Pharmaceutical Manufactures, 68 Fed. Reg. 23,731 (May 5, 2003); OIG & Medtronic Spine, L.L.C. Corporate Integrity Agreement (2006), *available at* http://oig.hhs.gov/fraud/cia/agreements/Medtronic_and_MSD_CIA.pdf.

[19] 31 U.S.C. § 3729(a)1-3 (2006).

[20] 31 U.S.C. § 3729a(7).

[21] *Id.*

[22] 42 U.S.C. § 1320b(1)(A).

[23] 42 U.S.C. § 1320a-7(b).

[24] 42 U.S.C. § 1320a(6)(i).

[25] 42 U.S.C. § 1320a(6)(ii).

Statutory safe harbors such as the personal-services contract exception can shelter companies from Anti-Kickback Statute claims against physician consulting agreements. However, stating that a physician contract payment is calculated at FMV is insufficient to establish the safe harbor exception the company must also show the methodology behind the FMV calculation. Claiming the personal services safe harbor is complicated and requires a consistently applied, well-formulated and documented FMV payment methodology.

The safe harbor for personal services contains specific parameters for what remuneration is allowable.[26] As per the personal services safe harbor, "remuneration" is not considered a "kickback" if the remuneration is a payment made by a principal to an agent as compensation for the services of the agent,[27] as long as each of the following seven requirements are met:

> (1) The agency agreement is set out in writing and signed by the parties.
>
> (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
>
> (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
>
> (4) The term of the agreement is for not less than one year.
>
> (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with *fair market value* in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal healthcare programs.
>
> (6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
>
> (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the *commercially reasonable business purpose* of the services.[28]

In 2003, the HHS OIGs' CPG for Pharmaceutical Manufactures set forth general views on the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.[29] The CPG describes consultant and advisory payments

[26] 42 C.F.R. § 1001.952(d) (2008).

[27] *Id.*

[28] *Id.* (emphasis added).

[29] HHS, OIG's CPG for Pharmaceutical Manufactures, 68 Fed. Reg. 23,731 (May 5, 2003).

as one of the "key areas of potential risk."[30] The rationale behind the risk is that overcompensating physician-consultants may lead to quid pro quo arrangements, which can influence treatment and prescribing, thus creating a conflict of interest.[31] Quid pro quo arrangements that result in reimbursement under federal healthcare programs violate the Anti-Kickback Statute and the False Claims Act.[32]

The CPG also provides guidance to pharmaceutical companies as to the minimum standards for contracting with physician consultants. The CPG states that "at a minimum, manufacturers should periodically review arrangements for physicians' services to ensure that: 1) The arrangement is set out in writing; 2) there is a *legitimate need for the services*; 3) the services are provided; 4) the *compensation is at fair market value*; and 5) all of the preceding facts are documented prior to payment."[33]

It is important to note that the elements for an effective compliance program for advisory and consultant arrangements as explained in the CPG are considerably different than the safe harbor exception as explained in the Anti-Kickback Statute. In creating the CPG the OIG reviewed sources such as 1) previous OIG publications, 2) OIG advisory opinions, 3) safe harbor regulations relating to the Anti-Kickback Statute, 4) Special Fraud Alerts and 5) reports issued by the OIG's Office of Audit Services and Office of Evaluation and Inspections.[34] In addition, the OIG relied on the experience gained from investigations of pharmaceutical manufacturers conducted by OIG's Office of Investigations, the DOJ and the state Medicaid Fraud Control Units.[35]

On balance, the CPG outlines the most accurate compliance program elements companies should follow when dealing with consulting arrangements. It is important to note that the CPG is a guidance document. Guidance documents are used to announce informal regulatory expectations and are more elaborative with respect to the agency's policy and regulatory approaches to an issue.[36] When comparing the two recommendations, the similarities between the CPG and Anti-Kickback Statute safe harbor requirements are that the agreement is set out in writing, there is a legitimate need for services and that compensation is at FMV.

The importance of requiring FMV payments in physician consulting arrangements is supported by the key representative organizations of the contracting parties. For example, industry trade associations such as American Medical Association (AMA), Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association (AdvaMed) incorporated physician compensations changes in to their respective codes of conduct.[37]

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[30] 68 Fed. Reg. 23,734, 23,738.

[31] *See Id.*

[32] *See Id.*

[33] 68 Fed. Reg. 23,738 (emphasis added).

[34] 68 Fed. Reg. 23,731.

[35] HHS, OIG's CPG for Pharmaceutical Manufactures, 68 Fed. Reg. 23,731 (May 5, 2003).

[36] Hoffman, Joel, *Public Participation and Binding Effect in the Promulgation of Nonlegislative Rules: Current Developments at FDA*, 22 ADMIN. REG. L. NEWS, 3 (1997), *available at* http://www.abanet.org/adminlaw/news/vol22no3/hoffman.html.

[37] The AMA is an association of physicians and medical students in the United States whose mission is to advance the interests of physicians and their patients, to promote public health, to lobby for legislation favorable to physicians and patients, and to raise money for medical education. *Available at* http://www.ama-assn.org/ama/pub/about-ama.shtml. PhRMA is an industry trade group representing the pharmaceutical research and biotechnology companies. *Available at* http://www.phrma.org/about_phrma. AdvaMed is an industry trade group representing companies that produce the medical devices, diagnostic products, and health information systems. *Available at* http://www.advamed.org/MemberPortal/About/.

The 1998 AMA Code of Ethics asserted that "[i]t is also appropriate for consultants who provide genuine services to receive *reasonable compensation*."[38] In 2002, the PhRMA Code on Interactions with Healthcare Professionals also called for *reasonable compensation* to be paid to physicians.[39] Furthermore, the 2002 PhRMA Code stated that "[c]ompensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants in connection with their consulting arrangements."[40] In 2009, however, the PhRMA Code revisions stated that "[a]ny compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on *fair market value*."[41] In 2009 the AdvaMed Code was also amended to state that "[c]ompanies may pay consultants *fair market value* compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement."[42]

In addition to the FMV requirement, companies must be able to document a clear and legitimate business need.[43] The absence of a clear business need will

[38] AMA's Code of Medical Ethics, Council on Ethical and Judicial Affairs (CEJA), Gifts to Physicians from Industry Opinion 8.061, *available at* http://www.amaassn.org/ama1/pub/upload/mm/Code_of_Med_ Eth/amacode_home.html (emphasis added) (Report: Issued June 1992, Updated June 1996 and June 1998). GUIDELINE 5: "It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses."

[39] PhRMA Code on Interactions with Healthcare Professionals (Revised 2002), *available at* http://chapter.vc.ons.org/file_depot/0-10000000/0-10000/1337/folder/71753/Pharma+Guidelines.pdf. PhRMA CODE 2002: "It is appropriate for consultants who provide services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants in connection with their consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses."

[40] *Id.*

[41] PhRMA Code on Interactions with Healthcare Professionals (Revised 2008) *available at http://www.phrma.org/files/attachments/PhRMA%20Marketing%20Code%202008.pdf* (emphasis added). SECTION: 6 CONSULTANTS: "It is appropriate for consultants who provide advisory services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on fair market value. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses."

[42] AdvaMed, Code of Ethics on Interactions with Health Care Professionals, *available at* http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf (emphasis added). SECTION: VI CONSULTING ARRANGEMENTS WITH HEALTH CARE PROFESSIONALS: "Companies engage Health Care Professionals to provide a wide-range of valuable, bona fide consulting services through various types of arrangements, such as contracts for research, product development, development, and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. […] Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business." SECTION: QUESTION AND ANSWERS: "How can a Company establish 'fair market value'? There are different valuation methods that may be used to establish fair market value. In all instances, a Company should use objective, verifiable criteria. The method or methods used by a Company should be documented."

[43] HHS, OIG's CPG for Pharmaceutical Manufactures, 68 Fed. Reg. 23,738 (May 5, 2003). The CPG set parameters for consulting and advisory payment relationships: 1) The arrangement is set out in writing; 2) there is a legitimate need for the services; 3) the services are provided; 4) the compensation is at fair market value; and 5) all of the preceding facts are documented prior to payment.

raise significant concern regarding exposure to the Anti-Kickback Statue. While documenting the business need is not difficult, it is a crucial step often missed by companies.[44]

In the context of healthcare there is not a precise definition of FMV. Historically, statutes and regulatory guidance make no recommendations of a specific methodology for accurate FMV determinations.[45] Some general approaches, however, have proven useful. The Internal Revenue Service's (IRS's) definition is most often applied, albeit in the property context. The IRS defines FMV as "the price at which property would change hands between a willing buyer and willing seller, neither being under compulsion to buy or sell and having knowledge of relevant facts."[46] In addition, FMV requires that arrangement be an arm's length transaction between unrelated parties.[47] Regardless of the context, property or healthcare, the FMV objective remains the same—bona fide bargaining at arm's length.[48] Greater clarity regarding FMV could be established after examining the application and enforcement of the principle as it appears in settlements and case law.[49] Part II undertakes such an evaluative analysis.

II. SETTLEMENTS AND CASE LAW

The OIG's mission is to protect the integrity of HHS programs, as well as the health and welfare of the beneficiaries of those programs.[50] The OIG's duties are

[44] HEARING BEFORE THE SENATE SPECIAL COMMITTEE ON AGING—UNITED STATES SENATE, Testimony of Gregory Dempsky, Assistant Inspector General for Legal Affairs, *Examining the Relationship between the Medical Device Industry and Physicians* (Feb. 27, 2008), *available at* http://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.

[45] The most challenging aspects of the safe harbor provisions and CPG guidance is proving the FMV of the contracted compensation. To support the safe harbor exemption companies must accurately document that FMV was applied and that there was a legitimate need for services.

[46] Treasury Reg. 20.2031-1(b) (2009) (valuation of property in general).

[47] *See, e.g.,* Dietrich, Mark, *Correct Fair Market Value Calculation Needed to Avoid Regulatory Challenges*, HEALTHCARE FINANCIAL MANAGEMENT, (Sept 1997), *available at* http://findarticles.com/p/articles/mi_m3257/is_n9_v51/ai_20076548/.

[48] Because of the "arms length" requirement, efforts to define FMV based on historical payment patterns by pharmaceutical/medical device companies to their physician consultant could be flawed due to the multiple commercial relationships existing between physicians and pharmaceutical/medical device companies (e.g., consulting, prescribing, researching and promoting relationships). BLACK'S LAW DICTIONARY 1256 (7th ed. 2002). Fair market value – the price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arm's length transaction; the point at which supply and demand intersect. Arm's Length: of or relating to dealing between two parties who are not related or not on close terms who are presumed to have roughly equal bargaining power [hereinafter Black's Law Dictionary: FMV].

[49] *See* Zimmer, Inc. v. Nu Tech Medical, Inc., N.D.Ind.1999, 54 F.Supp.2d 850. Statutes 219(6.1). (Advisory opinion of OIG of HHS regarding legality, under Medicare/Medicaid anti-kickback statute, of contract between manufacturer of orthopedic products and independent contractor to sell products was entitled to deference as informed judgment to which courts and litigants may properly resort for guidance.) *See* United States ex rel. Ted Kosenske v. Carlisle HMA, Inc., 2007 WL 3490537 (M.D.Pa.) "A party may establish fair market value by demonstrating that: (1) it paid the same amount of compensation in a referral transaction that it would have paid in a non-referral transaction; or (2) it paid fair market value based upon any other commercially reasonable criteria. *See Renal Physicians Ass'n*, 489 F.3d at 1269-1270 (citing Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, 66 Fed. Reg. 856, 944 (Jan. 4, 2001)). This necessitates a fact-intensive inquiry of the circumstances surrounding a particular transaction. *See* 66 Fed. Reg. at 944 ("The amount of documentation that will be sufficient to confirm fair market value (and general market value) will vary depending on the circumstances in any given case; that is, there is no rule of thumb that will suffice for all situations.").

[50] Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101.

carried out through a nationwide network of audits, investigations, inspections and other mission-related functions performed by OIG components.[51] Following its investigation, the OIG often negotiates compliance obligations with companies as part of its settlement arrangement, arising under a variety of civil false claims statutes. In a Corporate Integrity Agreement (CIA), an entity consents to obligations in exchange for the OIG's agreement not to seek an exclusion of that entity from participation in Medicare, Medicaid and other federal healthcare programs.

Few companies have been willing to bear the cost and the risk of exclusion from federal programs by pursuing cases against the federal and state government through the courts. As a result, regulators and prosecutors have substantial leverage to direct targeted companies to a negotiated settlement, the provisions of which often include significant monetary claims as well as non-monetary obligations documented through CIAs.[52]

Moreover, the False Claims Act allows the filing of *qui tam* lawsuits against individuals or companies that have defrauded the government. *Qui tam* lawsuits are initiated by a third party (whistleblower) on behalf of the government.[53] A whistleblower who exposes fraud on the government can receive a share of the recovery as his or her reward.[54] Therefore, *qui tam* provisions have resulted in a large number of filings and are a key source for government cases.[55] Equally problematic is that *qui tam* cases can remain under seal and under investigation for months, if not years, thus contributing to the backlog of cases.[56] With this backlog in mind, *qui tams* set the stage for FMV issues to remain unresolved for years to come.

OIG CIAs serve as guideposts for companies indicating compliance risk areas where the government finds fraud and abuse. Settlements have gone as far as requiring that companies hire independent third party companies to review compliance programs. Over the past five years CIAs have increasingly and intensively focused on the FMV compensation issue.[57] As a result, pharmaceutical and medical device companies should carefully evaluate how they arrange, draft and monitor consulting agreements with physicians.

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[51] About OIG, Office of Inspector General, *available at* http://oig.hhs.gov/.

[52] For examples of CIAs in this field, *See* OIG—Corporate Integrity Agreements, *available at* http://oig.hhs.gov/fraud/cias.asp.

[53] BLACK'S LAW DICTIONARY 1010 (7th ed. 2002). Qui Tam Action—Latin *qui tam pro domino rege quam pro se ipso in hace parte sequitur* "who as well for the king as himself sues in this matter." An action brought under a statute that allows a private person to sue for a penalty, part of which the government or some specified public institution will receive.

[54] *See,* e.g., Lawsuits Under Seal, WASH. POST, (Feb. 27, 2008), *available at* http://www.washingtonpost.com/wp-dyn/content/article/2008/02/26/AR2008022602986.html. ("About 1,000 lawsuits filed by citizen whistle-blowers are under seal at the Justice Department. The actions, known as '*qui tam*' suits, are filed under a provision of the False Claims Act that allows private individuals to sue on behalf of the government as well as themselves. They remain sealed until the Justice Department decides whether to take them up. The breakdown: 630 health care, 230 procurement (mostly military contracts), 140 other.").

[55] *Id.*

[56] *Id.*

[57] In all five CIA's the OIG requires that an Arrangement Database be set up and maintained. That Database contains certain information to assist the companies in evaluating whether each Contractual Arrangement violated the Anti-Kickback Statute. Among other factors the Database must look at: 1) the amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid; 2) The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation; 3) Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties. *See*, *e.g.*, OIG & Medtronic Spine, L.L.C. CIA (2006), *available at* http://oig.hhs.gov/fraud/cia/agreements/Medtronic_and_MSD_CIA.pdf; OIG & Zimmer, Inc. CIA (2007), *available at* http://oig.hhs.gov/fraud/cia/agreements/Zimmer_inc_09272007.pdf; OIG & DePuy Orthopaedics, Inc. CIA (2007), *available at* http://oig.hhs.gov/fraud/cia/agreements/DePuy_orthopaedics_inc_09272007.pdf; OIG & Biomet, Inc. CIA (2007), *available at* http://oig.hhs.gov/fraud/cia/agreements/biomet_inc_09272007.pdf; OIG & Smith & Nephew, Inc. CIA (2007), *available at* http://oig.hhs.gov/fraud/cia/agreements/smith%20_nephew_inc_09272007.pdf.

The government has increased its review of physician consulting arrangements for several reasons. These include: 1) negative media coverage of questionable payments, 2) negative public opinion, 3) congressional oversight, 4) administrative rulings and 5) costly court settlements.[58] It is estimated healthcare fraud costs the federal government billions of dollars a year.[59] In addition, the rising cost of healthcare within the government budget and within the economy as a whole foreshadows the reallocation of significant resources to rein in costs where possible. As a result, the DOJ and HHS are expected to be forceful in their enforcement of the rules. For example, during 2009, Senate testimony referred to pharmaceutical and device manufacturers and stated that the government recovered more than $9.2 billion from such companies in the last decade in connection with criminal and civil cases involving fraud.[60] Two specific settlement events—1) the Medtronic, Inc. (2006) and 2) the New Jersey Investigation of Hip and Knee Device Manufacturers (2007)—specifically detailed physician consulting arrangements for services that appeared to be in excess of FMV for services rendered.[61] These cases show the abusive practices that are sometimes disguised as consulting contracts, royalty agreements, or gifts.

A. *Medtronic, Inc. (2006)*

The DOJ alleged that Medtronic made kickbacks such as inequitable consulting and royalty agreements; trips for doctors, their spouses and families; meetings at lavish venues and company-sponsored adult entertainment.[62] The investigation by the DOJ stemmed from a civil whistleblower (*qui tam*) action filed by a former employee.[63] Medtronic denied any wrongdoing but was accused of paying kickbacks to physicians to induce physicians to select Medtronic's spinal products.[64]

[58] HEARING BEFORE THE SENATE SPECIAL COMMITTEE ON AGING—UNITED STATES SENATE, Testimony of Gregory Dempsky, Assistant Inspector General for Legal Affairs, *Examining the Relationship between the Medical Device Industry and Physicians* (Feb. 27, 2008), *available at* http://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.

[59] U.S. total healthcare spending represents 17 percent of the gross domestic product (GDP). Healthcare costs are expected to increase at similar levels and reach $4.3 Trillion in 2017, or 20 percent of GDP. NCHC Facts About Healthcare—Health Insurance Costs, NATIONAL COALITION ON HEALTH CARE, *available at* http://www.nchc.org/facts/cost.shtml (last visited Aug. 1, 2009). *See also*, HEARING BEFORE THE SENATE SPECIAL COMMITTEE ON AGING—UNITED STATES SENATE, Testimony of Alexander Acosta, US Attorney Southern District of Florida USDOJ, *Fraud in the Medicare and Medicaid Programs*, (May 6, 2009), *available at* http://aging.senate.gov/events/hr208aa.pdf.

[60] In particular, consulting arrangements have been used to induce physicians to refer or prescribe particular products to patients in violation of the Anti-Kickback Statute. In order to comply with relevant guidance documents, regulations and policies, physicians must be paid at FMV for legitimate services. The terms of settlements are not applicable to other companies and their physician consultant arrangements; however, they help identify potentially risky transactions. HEARING BEFORE THE SENATE SPECIAL COMMITTEE ON AGING—UNITED STATES SENATE, Testimony of Alexander Acosta U.S. Attorney Sothern District of Florida USDOJ, *Fraud in the Medicare and Medicaid Programs*, (May 6, 2009), *available at* http://aging.senate.gov/events/hr208aa.pdf.

[61] In addition to examining the FMV of the services rendered, the government examines at whether there was a legitimate need for a particular consulting service and reviews whether there is sufficient supporting documentation of the services rendered. *See* Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009); *See* Press Release, DOJ, *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 Aug. 1, 2009).

[62] *Id*.

[63] Press Release, DOJ, *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 Aug. 1, 2009).

[64] HEARING BEFORE THE SENATE SPECIAL COMMITTEE ON AGING—UNITED STATES SENATE, Testimony of Gregory Dempsky, Assistant Inspector General for Legal Affairs, *Examining the Relationship between the Medical Device Industry and Physicians* (Feb. 27, 2008), *available at* http://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.

More specifically, the DOJ alleged that Medtronic provided improper payments to physicians and companies in connection with the company's spinal products in the form of 1) payments and other remuneration for physicians' attendance and expenses at medical education events, think tanks, VIP/MVP events, and meetings at resort locations; 2) services and payments for services to physicians through other divisions and departments; and 3) payments made pursuant to consulting, royalty, fellowship and research agreements with physicians and entities.[65] As part of this settlement, Medtronic paid $40 million as part of the settlement and signed a five-year CIA.[66]

Under the CIA, Medtronic was required to implement several changes to its policies and standard operating procedure.[67] The CIA required sophisticated procedures and safeguards to ensure existing and future arrangements with physicians and other potential sources of business or referrals are appropriate. Medtronic had to create a database of all existing and new contractual and non-contractual arrangements (including detailed information about the parties and terms of each arrangement).[68] Medtronic created service and activity logs to ensure parties to the arrangement performed required services.[69] Medtronic had to monitor the use of leased space, medical supplies, medical devices, equipment or other patient care items.[70] Medtronic also established and implemented a written review and prior approval process for all arrangements.[71] Transparency though reporting payment relationships cannot ensure ethical conduct, but should inhibit payments that are questionable. Medtronic CIA transparency reporting/tracking requirements for arrangements were the first of its kind and later settlement agreements required similar changes.[72]

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[65] *Id.*

[66] Press Release, DOJ, *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 Aug. 1, 2009).

[67] OIG & Medtronic Spine, L.L.C. CIA (2006), *available at* http://oig.hhs.gov/fraud/cia/agreements/Medtronic_and_MSD_CIA.pdf.

[68] *Id.*

[69] *Id.*

[70] OIG & Medtronic Spine, L.L.C. CIA (2006), *available at* http://oig.hhs.gov/fraud/cia/agreements/Medtronic_and_MSD_CIA.pdf. This provision in the CIA shows the OIG's concern about the provision of equipment and supplies (such as loaner or sample devices) to providers. Effective controls must be in place to ensure loaners and samples are provided for appropriate reasons and not as means of providing free, off-invoice items of value to potential customers.

[71] OIG & Medtronic Spine, L.L.C. CIA (2006), *available at* http://oig.hhs.gov/fraud/cia/agreements/Medtronic_and_MSD_CIA.pdf. ("Arrangements" shall mean every arrangement or transaction entered into by MSD that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between MSD and any actual or potential source of healthcare business or referrals of healthcare business to MSD or any actual or potential recipient of health care business or referral from MSD. The term "source" shall include any physician, contractor, vendor, or agent; and the term "healthcare business or referrals" shall be read to include referring, recommending, or arranging for, ordering, leasing or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal healthcare program. a. "Contractual Arrangements" shall mean every Arrangement that is contractual in nature and shall include all Arrangements related to the provision of services to MSD, including but not limited to, training, education, consulting, research, clinical studies, focus groups, physician advisory boards as well as intellectual property, grants, and charitable contributions. "Non-Contractual Arrangements" shall mean all Arrangements that are not Contractual Arrangements.).

[72] Press Release, DOJ, *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 Aug. 1, 2009). OIG & Medtronic Spine, L.L.C. CIA (2006), *available at* http://oig.hhs.gov/fraud/cia/agreements/Medtronic_and_MSD_CIA.pdf Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009).

B. *New Jersey Investigation of Hip and Knee Device Manufacturers (2007): Zimmer, Inc., DePuy Orthopaedics, Inc., Biomet Inc., Smith & Nephew, Inc. and Stryker Corp.*[73]

The U.S. Attorney's Office for the District of New Jersey conducted an industry-wide investigation of orthopedic companies and physician consultants. As a result, the U.S. Attorney's Office entered to parallel settlements with five companies that made up for nearly 95 percent of the market in hip and knee surgical implants.[74] All five major medical device manufactures settled with the government over federal fraud and abuse claims. Four of the companies entered into CIAs with the HHS OIG. The companies simultaneously entered into Settlement Agreements and Deferred Prosecution Agreements (DPA) with the U.S. Attorney's Office for the District of New Jersey.[75] The suits alleged that the companies had inappropriately paid physician consultants millions of dollars.[76] As a part of the settlement, the companies agreed to pay $311 million to settle the Anti-Kickback Statute and the False Claims Act allegations.[77]

Some of the alleged kickbacks included: 1) overcompensating for consulting agreements and lavish trips; 2) paying for training sessions, which lasted for 1 to 2 hours but paid out as an 8-10 hour workday; 3) purchasing quarterly reports, typically for a fee of $5,000, that included information on market trends, activity in the operating room and product issues that added little or no value to the company; and 4) offering royalty payments and adding consultants to product development teams when those projects were more than halfway completed.[78] Due

[73] Stryker Orthopedics, accepted federal supervision for the next 18 months. However, was not subject to criminal charges because it was the first to cooperate in the investigation, according to the government. Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Aug. 1, 2009).

[74] Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009).

[75] A DPA is entered into and filed simultaneously with the filing of a formal charging document by the U.S. Attorney; in contrast, formal charges are not filed for a non-prosecution agreement, and the agreement is retained by the parties, as oppose to being filed with a court. *See* Craig S. Morford, Acting Deputy Attorney General, Memorandum for Heads of Department, *Selection and Use of Monitors in Deferred Prosecution Agreements and Non-Prosecution Agreements with Corporations*, Criminal Resource Manual 163, (Mar. 7, 2008), *available at* http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/crm00163.htm (last visited Aug. 1, 2009).

[76] Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009). "This industry routinely violated the anti-kickback statute by paying physicians for the purpose of exclusively using their products," Christie [Christie US Attorney] said. The physician consultants also failed to disclose the existence of these relationships with the companies to the hospitals where the surgeries were performed and, more importantly, to the patients that they treated."

[77] Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009).

[78] HEARING BEFORE THE SENATE SPECIAL COMMITTEE ON AGING—UNITED STATES SENATE, Testimony of Gregory Dempsky, Assistant Inspector General for Legal Affairs*, Examining the Relationship between the Medical Device Industry and Physicians* (Feb. 27, 2008), *available at* http://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf. *See also* HHS and The DOJ Heath Care Fraud and Abuse Control Program Annual Report For FY 2007 (Nov. 2008); *available at* http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2007.pdf; ("In particular, the government's investigation found that the firms paid surgeons hundreds of thousands of dollars a year for consulting contracts and lavished them with trips and other expensive perquisites in exchange for using the companies' products exclusively.").

to all of these allegations, the DPAs and CIAs required the companies to implement several changes.[79]

For instance, all of the companies were assigned federal monitors who evaluated compliance measures and reviewed all new and existing consulting relationships with the companies.[80] The companies were required to conduct an assessment to determine the reasonable needs for educational consulting services and new product-development consultants.[81] In addition, all new consulting agreements required physicians to disclose their financial engagements with any company to their patients.[82] The companies were also required to disclose the name of each consultant and what he or she has been paid on the company website.[83]

In March of 2009, in regards to the completion of the DPA pacts, U.S. Attorney Ralph J. Marra, Jr. stated: "[w]e expect [the big four companies] will continue these measures beyond the expiration of the agreements and commit to a continued culture of openness, accountability and compliance."[84] This positive outlook for compliance reformation should inspire other companies to adopt and mirror the government recommended changes in an effort to be transparent, prevent healthcare fraud and abuse, and avoid the potentially inviting intrusive and costly government scrutiny.

These settlements serve as a roadmap to what prosecutors will be targeting in the future. In order to mitigate fraud and abuse risks, companies need the tools to defend against costly investigation. The four principles discussed in Part III will equip companies with a legitimate approach for evaluating FMV solutions.

III. RECOMMENDATION: EVALUATING FAIR MARKET VALUE METHODOLOGIES

Selecting the right comprehensive FMV methodology is as important as adopting and executing a FMV policy. Fundamentally, FMV payment is the result of an arm's length transaction between unrelated parties.[85] However, when pharmaceutical or medical device companies hire a physician to provide consulting, there is potentially

[79] OIG & Zimmer, Inc. CIA (2007), *available at* http://oig.hhs.gov/fraud/cia/agreements/Zimmer_inc_09272007.pdf; OIG & DePuy Orthopaedics, Inc. CIA (2007), *available at* http://oig.hhs.gov/fraud/cia/agreements/DePuy_orthopaedics_inc_09272007.pdf; OIG & Biomet, Inc. CIA (2007), *available at* http://oig.hhs.gov/fraud/cia/agreements/biomet_inc_09272007.pdf; OIG & Smith & Nephew, Inc. CIA (2007), *available at* http://oig.hhs.gov/fraud/cia/agreements/smith%20_nephew_inc_09272007.pdf.

[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009). *See, e.g.*, DePuy, Zimmer, Smith and Nephew and Biomet all report the name and amount paid to consultants. *Available at*, http://www.zimmer.com/z/ctl/op/global/action/1/id/10373/template/CP/navid/10548; http://www.smithnephewdpacompliance.com/; http://www.biomet.com/corporate/consultant_disclosure.cfm; http://www.depuy.com/corporate-information/find-surgeons#/A-Baspx (last visited Jan. 1, 2010).

[84] Press Release, DOJ, *Monitoring and Deferred Prosecution Agreements Terminated with Companies in Hip and Knee Replacement Industry* (Mar. 30, 2009), *available at* http://newark.fbi.gov/dojpressrel/2009/nk033009a.htm (last visited Aug. 1, 2009). Note, each CIA required the company to be subject to monitoring by an independent review organization and OIG, and make periodic reports for a 5-year period.

[85] *See, e.g.,* Dietrich, Mark, *Correct Fair Market Value Calculation Needed to Avoid Regulatory Challenges*, HEALTHCARE FINANCIAL MANAGEMENT, (Sept. 1997), *available at* http://findarticles.com/p/articles/mi_m3257/is_n9_v51/ai_20076548/ (last visited Aug. 1, 2009).

an inherent bias that could act to inflate compensation above FMV. This bias arises because the parties are not truly unrelated and there is an intertwined customer relationship that is created when physicians refer or prescribe products to patients. The industry-physician collaboration is not expected to end, thus parties cannot be unrelated parties in the traditional sense.[86] Pharmaceutical and medical device companies, however, can strive toward an approach that reduces bias and reflects fair market value for services.[87] To satisfy the FMV requirement, some companies have developed fee schedules based on potentially flawed and biased data sources such as 1) historical payment patterns, 2) industry benchmarks and 3) healthcare professional (HCP) speaker requests.

First, companies may have used their own historical payment patterns to identify their most common payment levels.[88] While this may be a well-intentioned effort on the part of the company, it certainly is not a good independent measure of FMV.[89] By looking only at their own payment history, a company is neglecting all payments between physicians and other companies or institutions. In addition, FMV is the price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arm's length transaction. At arm's length means relating to dealings between two parties who are not related or not on close terms who are presumed to have roughly equal bargaining power.

Furthermore, since it can be difficult to prove that payments were made solely for the specific consulting services provided, regulators may argue that the overall internal standard of payments for consulting and speaking engagements may have been inflated over the years. This argument is possible due to the intertwined relationship between the physician and the company. Furthermore, advisory and consulting arrangements can be quite diverse, thus making comparisons among arrangements difficult. The inability to decipher whether those fees reflect FMV payments rates supplies enough uncertainty that other more reliable sources should be used to determine rates.

Second, companies may have used industry benchmarks of payments typically made by the pharmaceutical and medical device industries to physician consultants.[90] These may be provided by formal third party surveys of industry payment practices or may be developed through informal understandings of competitor or industry

[86] *Id.*

[87] HEARING BEFORE THE SENATE SPECIAL COMMITTEE ON AGING—UNITED STATES SENATE, Prepared Testimony of Chad Phipps, Senior Vice President—General Counsel and Secretary Zimmer Holdings, Inc., *Examining the Relationship between the Medical Device Industry and Physicians* (Feb. 27, 2008), *available at* http://www.zimmer.com/z/ctl/op/global/action/1/id/10047/template/CP/navid/10551 (last visited Aug. 1, 2008). "Collaboration with physicians will always be important to clinically meaningful innovation in medical technology. In this industry, the same physician we rely on as a consultant to develop or train on the safe and effective use of our products may also select products for patients. Despite what were then regarded by industry as proper and adequate programs to manage and control these circumstances, with hindsight it now appears that as industry expanded to meet patient needs the use of physician consultants may have been excessive at times. Such excesses fostered a degree of mistrust of the industry and physicians and invited the understandable scrutiny of the government and other stakeholders. The historical model for collaborative relationships requires change to inspire confidence and trust, while preserving the best of the collaboration that drives innovation and advances effective patient care."

[88] Eaton, Fred & Levy, Yoram, *Fair Market Value for Physician Consultants*, PHARMACEUTICAL EXECUTIVE, (Sept. 2005), *available at* http://www.polarismanagement.com/Publications/FairMarketValue.pdf.

[89] BLACK'S LAW DICTIONARY: FMV, *supra* note 48.

[90] Eaton, Fred & Levy, Yoram, *Fair Market Value for Physician Consultants*, PHARMACEUTICAL EXECUTIVE, (Sept. 2005), *available at* http://www.polarismanagement.com/Publications/FairMarketValue.pdf.

practices. Like the historical payments, industry benchmark pricing is a potentially tainted source. Due to the intertwined relationship between the physician and the companies, it can be difficult to prove that payments used for benchmarking were made solely for the specific consulting services provided. As a result, other more reliable sources must be used to determine rates.

Third, companies may have used HCP requested amounts based on 1) what the meeting planning company suggests, 2) feedback from market research survey companies or 3) what an individual requests.[91] Again, theses sources are flawed because it is too intertwined with industry compensation estimations. In addition, the incentives of meeting planning or survey vendors to pay no more than FMV are not well aligned with the pharmaceutical or device company, as these payments to HCPs are typically treated as "pass through" costs billed directly to the pharmaceutical or device company.[92] Since these "pass through" costs do not affect their professional fees and profits, these vendors may be incentivized to over-pay physicians in an effort to more quickly complete their assignments (either meeting or survey) with a minimum of time spent recruiting and negotiating with the physicians.

Well-intentioned companies struggling to comply with the requirements of the personal-services safe harbors have probably implemented all three potentially flawed approaches to FMV. Unfortunately, as discussed above, FMV should not be based on transactions between physicians and pharmaceutical or medical device manufactures due to the intertwined relationship between the two players. Thus, it becomes critical to identify alternative sources for FMV that are recognized as providing independent unbiased data.

For companies attempting to develop methods for applying FMV in the context of the personal safe harbor we recommend evaluating all options using the following four principles: 1) use objective and robust data, 2) pay for HCPs' time, 3) provide for differentiated payments based on expertise and 4) document standards for consistent application.

First, objective and robust data must be used to reference physician compensation rates. In practice, this means that most companies will want to focus on national compensation surveys provided by independent third party institutions. Unlike industry benchmarks of payments between pharmaceutical companies and physician consultants, these surveys examine the annual compensation paid to physicians by their employers (i.e., Hospitals, Group Practices, etc.). Use of these surveys is supported through analogous cases where the government has approved of national surveys for use in Stark analysis.[93] Survey data typically covers thousands of physicians throughout the country and across multiple specialties.[94] Unlike the potential conflict inherent payments between physicians and pharmaceutical and medical device companies, these payments are viewed as being based on an "arms length" transaction between the physician and their hospital or group practice employer.[95]

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[91] *Id.*

[92] *See generally* Bulow, Jeremy & Pfleiderer, Paul, *A Note on the Effects of Cost Changes on Prices*, 1 J. POL. ECON. 91, 181-185, (1983).

[93] The Stark Law 42 C.F.R. § 411.350-389 is related to, but not the same as, the federal anti-kickback law. Stark law, covers three separate provisions, governs physician self-referral for Medicare and Medicaid patients. Physician self-referral is the practice of a physician referring a patient to a medical facility in which he/she has a financial interest, be it ownership, investment, or a structured compensation arrangement. In the Phase II regulations, CMS created a safe harbor that would deem physician compensation amounts that met standards in national compensation surveys as being fair market value. In phase III, CMS eliminated the safe harbor.

[94] Eaton, Fred & Levy, Yoram, *Fair Market Value for Physician Consultants*, PHARMACEUTICAL EXECUTIVE, (Sept. 2005), *available at* http://www.polarismanagement.com/Publications/FairMarketValue.pdf.

[95] BLACK'S LAW DICTIONARY: FMV, *supra* note 48.

Second, FMV payments should be based on reasonably compensating the HCP for his or her time. Payments to HCPs should not be based on the category of activity or the value of HCP services. Here, it is important not to confuse the value gained by the company for the services of the HCPs, with the value the HCP places on his or her time. For example, a physician serving on a one-day advisory board to review effectiveness of market materials should be paid the same fee as he or she would be paid to attend a one-day advisory board to identify the next blockbuster drug. Because the time involved in both meetings is identical, the payment for a particular physician should be the same.

Note in the previous example that we assume the same physician is attending both advisory boards. Usually, an advisory board for setting initial research agenda is staffed by preeminent physicians in the therapeutic area. When evaluating market material, a company should clearly identify the business rationale for using such a preeminent individual to comply with the safe harbor requirements.

In practice, many companies will develop standard fees for standard activities. Rather than attempting to track actual hours for each contract, companies should develop activities standards that the company applies to FMV hourly rates to create standard payment schedules. In these cases, even though the payment schedules are published by activity, the payments are still based on compensating the physicians for their time.

Third, provide for differentiated payments based on expertise. Data used to develop FMV hourly rates (e.g., national compensation surveys) must provide for deferential payments between physicians with different levels of expertise. Many companies provide different fees for local, regional, national and global thought leaders. They will also differentiate payments based on the type of physician specialty and the HCP's license. Theses premiums for expertise must be supported by objective data and the FMV methodology should provide for higher fees for higher expertise (i.e., thought leader status).

Fourth, FMV must provide well-documented and consistently applied standards. This allows companies to demonstrate that their FMV rates and fee schedules are based on unbiased market values and applied consistently in their contracting process and in practice. The use of standard documentation facilitates the consistent application of FMV as well as the means for documenting the rationale or any deviation from the standards. While FMV methodologies may provide some latitude for the specific rates chosen for implementation, once chosen the rates should be applied in a consistent manner. Inconsistent application will cause regulators to question what other factors were involved in determining how the rate was selected.

As companies evaluate methodologies for determining FMV, the four principles discussed above will provide guidelines for indentifying a defensible FMV methodology. It is, however, important to remember that the government has not provided any specific process for calculating FMV. In addition, when evaluating FMV in real world scenarios, outside the theoretical constructs of "perfect competition," most FMV practitioners would identify FMV as a range of payments commonly available in the market place rather than a specific value.[96]

Although, most FMV methodologies should be applicable to the vast majority of physician contracts, they likely breakdown when applied to individuals with unique skill sets. In these situations, a "market price" rarely exists due to the absence of multiple buyers and sellers of the relevant expertise.[97] Therefore, companies need to demonstrate that they have engaged in a true negotiation with the service provider.

[96] Santerre, Rexford & Neun, Stephen, *Health Economics: Theories, Insights and Industry Studies*, 194-201, Thomson 3rd ed. (2004).

[97] *Id.*

Here astute physicians may be able to exercise their "monopoly power" generated by their unique skill set, to extract a higher fees and obtain a larger share of the value that their services generate for the company.[98]

IV. CONCLUSION

Settlement agreements entered into in the past several years have included commitments that the company would pay physicians at FMV. The importance of FMV was further highlighted by the Medtronic and orthopedic companies' settlements where allegations specifically focused on physician consulting arrangements.[99] Clearly, to reduce compliance risk, pharmaceutical and device manufacturing companies should develop a well-documented methodology for determining FMV and then apply the resulting rates in a consistent fashion. In the absence of more detailed guidance from regulators, the four principles for a defensible FMV methodology should include: 1) use objective and robust data, 2) pay for HCPs' time, 3) provide for differentiated payments based on expertise and 4) document standards for consistent application.

[98] *Id.*

[99] Press Release, DOJ, *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 Aug. 1, 2009)**;** Press Release, DOJ, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sept. 27, 2007), *available at* http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited Dec. 1, 2009).