**Testimony**
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# "Examining the Relationship Between the Medical Device Industry and Physicians"

**Testimony of**

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Good morning, Mr. Chairman and members of the committee. I am Gregory Demske, Assistant Inspector General for Legal Affairs in the Office of Inspector General of the Department of Health and Human Services. I appreciate the opportunity to appear before you today to discuss the financial relationships that exist between physicians and the medical device industry. These financial relationships can benefit patients and Federal health care programs by promoting innovation and improving patient care. However, these relationships also can create conflicts of interest that must be effectively managed to safeguard patients and ensure the integrity of the health care system.

In my testimony, I will discuss the risks associated with industry-physician financial relationships; highlight some of our recent investigations that illustrate these risks; and describe ways to mitigate these risks through enforcement actions, outreach to promote compliance, and increased transparency.

Relationships Between the Medical Device Industry and Physicians

Relationships between physicians and the health care industry, including pharmaceutical and device manufacturers and suppliers, can advance medical science and benefit patients. In the development of new technologies and products, the interaction between device manufacturers and health care professionals can be especially valuable because physicians play an essential role in the development, testing, and extensive training involved in producing effective and safe medical devices, such as heart valves, pacemakers, and medical lasers. Physicians also provide ideas and feedback, conduct research and clinical trials, and share their knowledge through participation in medical education programs. Device companies can legitimately compensate physicians for their actual time and intellectual contributions to product innovations and training in the appropriate use of devices.

However, in an environment where physicians routinely receive substantial compensation from medical device companies through stock options, royalty agreements, consulting agreements, research grants, and fellowships, evidence suggests that there is a significant risk that such payments will improperly influence medical decisionmaking. Researchers reporting in medical journals, such as the Journal of the American Medical Association and the New England Journal of Medicine, have found that such financial industry-physician relationships are pervasive and that the impulse to reciprocate for even small gifts has a powerful influence on behavior. Although most physicians believe that free lunches, subsidized trips, or gifts have no effect on their medical judgment, the research has shown that these types of perquisites can affect, often unconsciously, how humans

act.[1] For example, physicians who request additions to hospital drug formularies are far more likely than their peers to have accepted free meals or travel funds from drug manufacturers.[2] Similarly, a device company's largess may influence a physician to favor the company's products. As the American Academy of Orthopaedic Surgeons observed, "[w]hen an orthopaedic surgeon receives anything of significant value from industry, a potential conflict exists which should be disclosed to the patient."[3]

Physicians play a critical role in deciding which medical devices are used in the treatment of their patients. Complex medical devices are generally implanted or otherwise used in a hospital procedure or inpatient stay for which the hospital is reimbursed. The treating physician generally decides or strongly influences the decision regarding which medical device should be used in this hospital setting. Therefore, a device manufacturer has a strong financial incentive to persuade treating physicians to use or recommend the manufacturer's devices.

We do not know how much money device manufacturers pay to physicians. However, the Government's recent investigations of several manufacturers of hip and knee surgical implants offer some insight. In 2005, the orthopedic device market for hips and knees witnessed domestic sales in excess of $5.1 billion and worldwide sales of more than $9.4 billion. We found that during the years 2002 through 2006, four manufacturers (which controlled almost 75 percent of the hip and knee replacement market) paid physician consultants over $800 million under the terms of roughly 6,500 consulting agreements. Although many of these payments were for legitimate services, others were not. The Government has found that sometimes industry payments to physicians are not related to the actual contributions of the physicians, but instead are kickbacks designed to influence the physicians' medical decisionmaking. These abusive practices are sometimes disguised as consulting contracts, royalty agreements, or gifts. The companies and physicians who engage in such kickback schemes are subject to criminal, civil, and administrative prosecution.

Additionally, physician ownership of medical device manufacturers and related businesses appears to be a growing trend in the medical device sector. These business ventures raise substantial concerns that a physician's return on investment from the venture may influence the physician's choice of device. In some cases, physicians could receive substantial returns while contributing little to the venture beyond the ability to generate business for the venture. As we cautioned in a widely-disseminated letter to a medical device trade association, "[g]iven the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device

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[1] See, e.g., The Scientific Basis of Influence and Reciprocity: A Symposium, Association of American Medical Colleges, June 12, 2007; Brennan TA, Rothman DJ, et al. Health Industry Practice that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers. JAMA 2006;295:429-33.
[2] Chren MM, Landefeld CS. Physicians' Behavior and their Interactions with Drug Companies. JAMA 1994;271:684-689.
[3] American Academy of Orthopaedic Surgeons, "Standards of Professionalism, Orthopaedist-Industry Conflicts of Interest," April 2007.

purchasers, we believe these ventures should be closely scrutinized under the fraud and abuse laws." [4]

The financial relationships between device manufacturers and physicians merit scrutiny under anti-fraud statutes because the relationships raise the types of risks that those statutes are designed to address. The consequences of industry-induced bias include risks to patients, health care programs, and scientific research. When a physician's self-interest compromises independent judgment, the patient faces the risk that the physician is making decisions that are not in the patient's best interest. Additionally, excessive payments to physicians increase health care costs and may result in unfair competition. When a device manufacturer pays a physician to influence the physician's use or recommendation of its products, rather than to advance a legitimate medical interest, the additional costs are passed on to the patients, Federal health care programs, and private insurers. Such payments can also distort the marketplace by providing an unfair competitive edge to the company making the payments, regardless of the relative therapeutic value of the company's products. Finally, corrupt payments can compromise medical research independence and the standards of scientific integrity.

Relevant Federal Anti-Fraud Statutes

Several Federal statutes are relevant to manufacturer-physician payment relationships. The False Claims Act is the Federal Government's primary civil enforcement tool for addressing fraud. Under the False Claims Act, the Government may obtain substantial penalties against any person who knowingly submits, or causes the submission of, false or fraudulent claims to the Federal Government. (See 31 U.S.C. §§ 3729-3733.) The False Claims Act allows the filing of *qui tam* lawsuits against individuals or companies that have defrauded the Federal Government. Many people who file *qui tam* lawsuits (called relators) are employees or former employees of companies that committed the fraud.

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer or pay remuneration to induce the referral of Federal health care program business. The statute also criminalizes the knowing and willful solicitation or receipt of remuneration in exchange for such referrals. (See 42 U.S.C. § 1320a-7b(b).) The prohibition applies regardless of the nature or form of the arrangement. If one purpose of an arrangement is to induce referrals of Federal health care program business, the statute is violated. Whether a particular arrangement runs afoul of the statute depends on the specific facts and circumstances of the arrangement, including the intent of the parties.

The anti-kickback statute and regulations contain certain "safe harbors," which describe arrangements that do not violate the statute if every condition of the particular safe harbor is satisfied. OIG's regulatory authority extends to promulgating safe harbor regulations describing categorical practices that are *permissible*. Compliance with a safe harbor is voluntary, however, and arrangements that do not fit in a safe harbor are not necessarily illegal. Rather, they must be evaluated under the statute on a case-by-case basis.

[4] http://oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20(2).pdf.

OIG administrative authorities complement criminal and civil enforcement by providing an additional avenue for sanctioning persons who have defrauded Federal health care programs. For instance, OIG has the authority to exclude individuals and entities from participation in the Federal health care programs for engaging in a range of abusive practices, including false claims and kickbacks. (See 42 U.S.C. § 1320a-7.)

OIG may also pursue violations of the anti-kickback statute under a provision of the Civil Monetary Penalties Law. (See 42 U.S.C. § 1320a-7a(a)(7).) Civil Monetary Penalty (CMP) cases can be attractive alternatives to criminal and civil enforcement for several reasons. For example, relative to the False Claims Act, the CMP provides a more direct vehicle to address parties to a kickback scheme regardless of whether anyone actually submits claims. This makes the kickback CMP particularly relevant in cases in which a device manufacturer is paying a physician to induce the physician to recommend the manufacturer's device for use in a hospital procedure. In such a case, the claim is submitted by the hospital, which is not a party to the financial arrangement. CMP remedies in kickback cases include monetary penalties of up to $50,000 for each act (offer, payment, solicitation, or receipt of remuneration), assessments of up to three times the amount of remuneration, and exclusion from participation in Federal health care programs.

Recent Enforcement Actions

OIG, together with its Government partners, plays a substantial role in enforcing the fraud and abuse laws through criminal, civil, and administrative actions. In recent years, OIG and the Department of Justice (DOJ) have investigated cases involving industry-physician financial relationships in both the pharmaceutical and medical device areas. In these cases, we have seen medical device manufacturers offering physicians lucrative consulting agreements to acquire new business and to maintain physician loyalty. We have also seen instances in which the physicians, in turn, have signaled to the industry that their loyalties and business are for sale to the highest bidder. In some cases, it comes down to how much each company is willing to pay for a physician's business, which is often being simultaneously solicited by multiple competing companies.

Kickbacks offered to physicians by medical device manufacturers take a variety of forms, ranging from free practice management services to all-expense-paid trips and sham consulting agreements. To illustrate these arrangements, I will summarize several settlements with device companies and a recent conviction of a physician.

*New Jersey Investigation of Hip and Knee Device Manufacturers (2007)* – Zimmer, Inc., DePuy Orthopaedics, Inc., Biomet Inc., Smith & Nephew, Inc.
In September 2007, four major medical device manufacturers entered into civil settlement agreements with the Government collectively totaling $311 million to resolve allegations under the False Claims Act. The Government alleged that the four companies provided financial incentives in the form of consulting agreements, lavish trips, and other perks to

induce physicians to use a particular company's artificial hip and knee reconstruction and replacement products.

The investigation found that, although many payments were provided for legitimate services, in certain consulting arrangements the companies derived little value beyond the acquisition of increased sales of artificial hip and knee implants used by the consulting surgeons. The companies also failed to oversee and audit the work performed by the surgeons under the consulting agreements. For example, the surgeons engaged in "work" activities that involved minimal or no actual work being performed, but created a billable event for the consultant, such as the following:

- Consulting agreements required the physicians to report periodically the services that they provided to the company to support the consulting fees. Some consulting agreements had only vague requirements for these reports. When the consulting agreements did include specific requirements, these reports often failed to include the required information or were drafted by sales representatives rather than by the consultants.

- In addition to reports documenting services provided, some companies paid consultants a fee, typically $5,000, for each quarterly report that included information on market trends, activity in the operating room, and product issues. However, these work reports typically included only cursory descriptions and were often duplicated from quarter to quarter. Many of these quarterly reports were of little or no value to the companies.

- The companies sponsored consultant panel meetings at resort locations and reimbursed the physicians for travel expenses. These meetings would only be held for a few hours each day and physician consultants who presented at these meetings typically spoke for a minimal time period, sometimes for as few as 10 minutes. Although the remainder of the day was available for recreational activities paid for by the company, the consultants were compensated $5,000 for a full day of work.

- Consultants billed for training sessions that involved sales representatives observing the surgeon while in the operating room. Some of these training sessions were held for experienced sales representatives who, as part of their jobs, had been servicing the surgeons in their sales regions for some time. These sales representatives were already required to be present in the operating room with the surgeons to assist them with the procedures. These training sessions lasted for 1 to 2 hours, but the consultants billed for an 8- to 10- hour workday.

- Some companies entered into product development agreements with consultant physicians, offering them royalty payments once the products were launched. These agreements provided for annual payments of hundreds of thousands or millions of dollars for up to 20 years. The design teams included up to 20 physicians, some of whom were added after the projects were more than halfway

completed. The companies often did not measure the contributions of individual physicians and up to half the members of some teams appeared to have performed little or no work.

The Government alleged that by offering illegal inducements, the companies violated the False Claims Act by causing hospitals to seek and obtain reimbursement from Medicare. As a part of the global resolution in these cases, the four companies agreed to certain prospective remedies. To avoid criminal prosecution, the companies each entered into an 18-month Deferred Prosecution Agreement (DPA) with the United States Attorney's Office in New Jersey. Under the DPAs, the companies agreed to be subject to oversight by a Federal monitor appointed by the U.S. Attorney, to disclose any other bad acts, and to post on their Web sites the names of company consultants, along with payments made to those consultants. Separate from the DPAs, each of the companies also entered into a Corporate Integrity Agreement (CIA) with OIG in exchange for OIG releasing its exclusion authority. Each CIA requires the company to put in place compliance systems, be subject to monitoring by an independent review organization and OIG, and make periodic reports for a 5-year period.[5]

*Medtronic, Inc. (2006)*
In another case, OIG worked with DOJ to investigate allegations that Medtronic, Inc., a medical device manufacturer, paid kickbacks to physicians. The Government alleged that Medtronic offered kickbacks to spine surgeons to induce them to choose devices marketed by a Medtronic subsidiary specializing in spinal implant devices. The kickbacks took various forms, including consulting and royalty agreements for which little or no work was performed; trips for doctors, their spouses, families, or girlfriends; consultant meetings held at lavish venues; and company-sponsored adult entertainment. In July 2006, Medtronic agreed to pay $40 million to settle the False Claims Act case and enter into a 5-year CIA.[6]

*Advance Neuromodulation Systems, Inc. (2007)*
In July 2007, OIG entered into a kickback CMP settlement with Advanced Neuromodulation Systems, Inc. (ANS), a device company specializing in spinal cord stimulation. OIG alleged that ANS engaged in a marketing program in which it paid a number of physicians $5,000 for every five new patients tested with an ANS product. To resolve allegations that ANS paid kickbacks, ANS paid $2.95 million in a CMP settlement and entered into a 3-year CIA with OIG.

OIG alleged that ANS's program did not provide any significant clinical value but rather served as a marketing tool to increase ANS's sales. The program was developed by ANS's Vice President of Sales and Marketing. The $5,000 "data collection fee" was not

[5] An additional company, Stryker Orthopaedics, Inc., entered into an 18-month Non-Prosecution Agreement (NPA) with DOJ. The NPA requires Stryker to implement all of the reforms imposed on the other companies under the DPAs. Stryker did not enter into any civil settlement with DOJ or OIG and has not been given any release from civil or administrative liability.
[6] Although the settlement agreement and CIA have been fully executed, they have not become effective because of ongoing litigation involving a *qui tam* relator.

set through a fair market value analysis of the physicians' time, and ANS's clinical research department did not use the data collected. In addition, OIG alleged that ANS's sales and marketing personnel provided physicians with sports tickets, trips for physicians and their families, dinners, and other gifts. For instance, the investigation found that ANS sponsored 3-day conferences at resort locations (Napa Valley, Alaska, Colorado Springs) in which physicians were invited to participate in roundtable discussions. The agendas for these conferences indicated that much of the time at these conferences was spent on recreational activities, including wine tasting, skiing, golfing, and canoeing. Further, in many instances, the physicians' spouses and children were invited to these conferences and participated in recreational activities at the expense of ANS.

*Dr. Patrick Chan (2008)*
Although criminal prosecutors have historically targeted their limited resources on companies paying kickbacks, a physician who accepts a kickback from a medical device manufacturer in return for using the company's products can be as culpable as the device company that provided the kickback. In January 2008, Dr. Patrick Chan, an Arkansas neurologist, paid a $1.5 million civil settlement and pled guilty to soliciting and accepting kickbacks from Blackstone Medical, a medical device company that sells devices and implants used in back surgery. The kickbacks included gifts and payments for sham consulting agreements and fake research studies. The investigation found that Dr. Chan stopped using one company's products after it refused to pay him kickbacks. Soon thereafter, Dr. Chan signed a $25,000 consulting agreement with Blackstone and switched to using its products.

Mitigating the Risks Inherent in Physician-Industry Financial Relationships

As I have mentioned, physician-industry interactions can provide tangible benefits to patients and the advancement of medical science. These interactions can also create conflicts of interest that, if not managed effectively, can pose significant challenges to medical professionalism and undermine the integrity of the Nation's health care system. Criminal, civil, and administrative enforcement is an important facet of an overall strategy to discourage financial arrangements that distort physicians' professional judgment. However, it would be both inappropriate and impractical to rely solely on Government enforcement to address an issue of this complexity. The health care industry, medical community, and the Government must develop and implement additional approaches to reduce the risks raised by these arrangements.

For this reason, OIG commits substantial resources to encourage the health care industry to adopt voluntary anti-fraud and compliance measures. OIG promotes these efforts by providing a range of comprehensive guidance, including advisory opinions, compliance program guidance, and special fraud alerts and bulletins. All of these resources are publicly available on OIG's Web site at www.oig.hhs.gov. OIG also engages in extensive industry outreach efforts, including providing speakers at major trade association, legal, and compliance conferences.

As reflected in the Government's recent enforcement actions involving the medical device industry, the anti-kickback statute plays a central role in addressing excesses in physician-industry relationships. Because the anti-kickback statute is a criminal, intent-based statute that requires a case-by-case analysis to determine whether the law has been violated, OIG's ability to issue general guidance about the statute is limited. The safe harbor regulations issued by OIG immunize certain conduct from prosecution and provide guidance on relevant risk factors. In addition, OIG offers an advisory opinion program under which parties can obtain OIG's legal opinion about the application of the anti-kickback statute and other OIG fraud and abuse authorities to their existing or proposed business arrangements.

Further assistance is available from OIG in the form of compliance program guidance for various health care sectors. OIG's Compliance Program Guidance for Pharmaceutical Manufacturers (CPG) (68 FR 23731 (May 5, 2003)) provides detailed information that drug manufacturers and medical device manufacturers can consider when establishing and operating an effective internal compliance program. The CPG identifies fraud and abuse risk areas, including many of the risks associated with financial relationships between medical device manufacturers and physicians. With respect to kickbacks, for example, the guidance discusses risks associated with manufacturers providing discounts, product support services, educational grants, research funding, and certain consulting arrangements. Medical device companies and physicians can use this guidance as a tool to help identify and manage the risks associated with their own arrangements.

Another strategy for promoting integrity in industry-physician financial relationships is subjecting those relationships to reporting requirements and greater transparency. For example, several states have recently enacted laws that require pharmaceutical companies to report payments made to physicians. Additionally, in the DPAs with the medical device manufacturers, the United States Attorney for New Jersey has required that the companies maintain on their Web sites the names of the physicians to whom they make payments and the amounts paid. OIG is considering requiring similar disclosure requirements in future CIAs with device manufacturers and pharmaceutical companies.

Academic institutions are also taking steps to manage their relationships with the health care industry in response to the growing concern that financial conflicts of interest are interfering with physicians' professional judgment. Both the Association of American Medical Colleges and the Association of American Universities have promulgated recommendations for the protection of human subjects from the effects of conflicts of interest on the part of academic investigators and their universities. In the Journal of the American Medical Association, a group of physicians from many of the Nation's most prestigious academic medical centers has called for more stringent regulation of physician-industry relationships. Alarmed by the adverse impact that financial conflicts of interest have on patient welfare and research integrity, they have called for the

elimination or modification of common practices related to gifts, drug samples, continuing medical education, speakers bureaus, and consulting and research contracts.[7]

A number of academic medical centers and health systems also are taking affirmative steps to address the conflicts of interest created by accepting gifts from the pharmaceutical and medical device industries. In addition to barring gifts and free food, some medical centers are restricting the distribution of drug samples and limiting sales representative access to physicians. For example, just this month, the University of Pittsburgh Medical Center and Schools of the Health Sciences announced a policy that bars faculty, staff, and students from accepting any gifts, regardless of value, from the pharmaceutical or medical device industries. The policy also requires that any consulting arrangements be reviewed and approved in advance by the University. Additionally, the American Medical Student Association has launched a campaign to encourage medical schools and academic medical centers to develop policies that limit the access of pharmaceutical company representatives to their campuses and prohibit medical students and physicians from accepting gifts of any kind from these representatives.

## Conclusion

In conclusion, financial relationships between the medical device industry and physicians are pervasive and can create both benefits and risks to patients and health care programs. Effectively managing the risks associated with these financial relationships is a challenge that warrants a comprehensive strategy by Government, the health care industry, and physicians.

OIG will continue to work with DOJ and other partners to investigate and pursue cases against device manufacturers and physicians who violate fraud and abuse laws. At the same time, we will continue our outreach to the medical device industry and physicians to increase awareness of the compliance risks and the resources available to assist them in managing those risks. OIG is also considering ways to promote increased transparency of financial relationships. Efforts by Congress, industry, physicians, and academia to promote awareness of the risks of conflicts of interest, increase the transparency of these financial relationships, and implement appropriate policies to manage these risks would go a long way to safeguard patients and health care programs.

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This concludes my statement. Thank you for the opportunity to testify today. I would be pleased to answer any questions that you may have.

[7] Brennan TA, Rothman DJ, Blank L, et al. Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers. JAMA 2006;295:429-433.