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SURGEONS FOR SALE: CONFLICTS AND CONSULTANT PAYMENT IN THE MEDICAL DEVICE INDUSTRY

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

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SURGEONS FOR SALE: CONFLICTS AND CONSULTANT PAYMENT IN THE MEDICAL DEVICE INDUSTRY

WEDNESDAY, FEBRUARY 27, 2008

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, D.C.

The Committee met, pursuant to notice, at 10:36 a.m., in room SD–628, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senators Kohl, Salazar, McCaskill, Smith, Coleman, Vitter, and Corker.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. This hearing will come to order. We welcome all of you who are here today, and we welcome our witnesses for taking time to be with us.

Last June, I chaired a Special Committee on Aging hearing that examined the financial and gift-giving relationships that exist between the pharmaceutical industry and physicians. What we learned then is that there is a need for more disclosure relating to doctors accepting gifts from drug companies.

Following that hearing, Senator Chuck Grassley and I introduced the Physician Payments Sunshine Act, which would create a national data base of payments and gifts to physicians from a variety of medical sources. Now today, we will focus on the tangled, murky and sometimes conflicting financial relationships between the medical device industry, surgeons and physicians.

It is important to note that these relationships can play an important role in product innovation. In areas where these relationships are legitimate and productive, we do not wish to disturb them.

However, over the past decade, it has become clear that interactions between medical device companies and surgeons often involve substantial payments, taking the form of consultant fees, educational grants, royalties, funding for clinical trials, travel and gifts. Some of these payments have been alleged to be grossly excessive, illegitimate and often not properly documented. It is not hard to see that these financial relationships can create conflicts of interest and can exert inappropriate influence over medical decisions. In some documented cases, they do break the law.

We will hear testimony today that these types of frequently unethical payments are not anecdotal but rather have been pervasive

and industry-wide for too long. We will hear that both the medical device industry and the physicians who take their money are equal participants and are equally culpable.

One witness will relate that some physicians make it known to these companies that they will be loyal to the highest bidder. If these physicians are essentially putting their medical judgment up for sale, then where does the patient's well-being fit into the equation?

Over the past several months, Committee staff has interviewed dozens of surgeons and medical device industry sales representatives to learn more about the conditions surrounding these payments. Disturbingly, some physicians related that they felt shunned when they declined to take part in financial relationships with the industry. One surgeon provided a written statement to the Committee concerning payment offers explicitly intended to induce her to use particular medical device products. To speak to this, we have with us today a clinical professor of surgery and an industry executive to offer their perspectives on the problems raised by these types of payments.

We will also hear from HHS Office of the Inspector General. The Justice Department and OIG have been examining in depth these troubling and widespread conflicts for at least 3 years. In September of last year, the Justice Department reached settlement agreements with the top five orthopedic device makers which dominate their industry. According to Committee staff's calculations, the five orthopedic companies which settled agreements with the Justice Department last fall spent the combined total of at least $230 million on these consultant and other payments. While these companies have admitted no wrongdoing, they collectively paid the government more than $310 million in settlement fines related to their handling of these types of payments.

Officials from two of these companies, Stryker and Zimmer, are here today. I would like to thank their representatives for agreeing to testify before the Committee, and I want to emphasize that the concerns we raise today pertain to the entire range of firms that dominate the industry and not just to these two manufacturers.

A witness from AdvaMed will also speak on behalf of the medical device industry today. In fairness, this investigation has also shown that surgeon-owned medical device companies also have potentially serious conflicts of interest as we will hear from the Inspector General's Office.

The Committee has sent detailed questions and document requests to a number of these firms asking for the same type of information and disclosure that we required from the larger medical device companies. Most have responded, and we intend to continue this line of inquiry to ensure that the entire industry is accountable in these conflict-of-interest matters.

In closing, I am well aware that the medical device associations and physician groups have written voluntary ethical guidelines addressing these areas, but the issue before us today is whether they have been or are being followed. There will be ample evidence presented today indicating that they are not. We look forward to working with cosponsors, Senators Grassley, McCaskill, Klobuchar, Ken-

nedy and Schumer, along with my colleagues in the Senate to get our important disclosure legislation passed.

So once again, we thank everyone for their participation and now we turn to other senators who are with us today who may wish to make a statement.

Senator Vitter.

OPENING STATEMENT OF SENATOR DAVID VITTER

Senator VITTER. Thank you very much, Mr. Chairman. I am going to pass for now and look forward to the testimony.

The CHAIRMAN. Thank you so much.

Senator Salazar.

OPENING STATEMENT OF SENATOR KEN SALAZAR

Senator SALAZAR. Thank you very much, Chairman Kohl, for holding this hearing on this very important subject. I want to thank the witnesses from both the government and the companies for being here and sharing their expertise with us.

Patients place a great deal of trust in their doctors. The integrity of our health care system is grounded in this trust relationship. But today we are here to examine some troubling allegations that the relationship between medical device manufacturing companies and surgeons have created conflicts of interest. Some media reports show that surgeons choose to use certain medical devices in exchange for consulting fees, royalties or other gifts. These are serious charges. Companies spend millions of dollars a year in providing these monies to physicians in so-called in-kind payments, much of which are not disclosed to the public.

I understand that surgeons and medical device companies maintain close relationships due to the complex nature of the devices that are produced. However, it is critical that the doctor-patient trust never be compromised and that the relationship is carried out in compliance with a strict code of ethics.

I agree with many of my colleagues, that increasing transparency with regards to payments to physicians is essential. Transparency will enable patients to be more informed and disclose potential conflicts of interest.

At the same time, we should consider a disclosure system that is uniform, that is easy to understand and accessible. As we move forward in this process, we must keep this balance in mind. I want to thank Chairman Kohl again for his leadership on this issue. I look forward to learning more about the issues that are at stake in this very important issue of life and death and—sometimes can involve the important issue of life and death. I look forward to working to see whether we get to some resolution to this issue.

Thank you, Chairman Kohl.

The CHAIRMAN. Thank you, Senator Salazar.

Senator Corker.

OPENING STATEMENT OF SENATOR BOB CORKER

Senator CORKER. Mr. Chairman, in order to listen to the witnesses, I will pass and wait to hear the testimony.

The CHAIRMAN. Thank you so much.

Senator CORKER. Thank you for having the hearing. I appreciate it, yes, sir.

The CHAIRMAN. Thank you so much.

We are pleased at this time to welcome our first panel. Our first witness will be Gregory Demske, assistant inspector for Legal Affairs in the Office of Health and Human Services Inspector General. Mr. Demske is responsible for administrative health care fraud actions on behalf of the HHS/OIG. He has worked at the OIG counsel's office for the past 17 years and also served as a special assistant United States attorney in the District of Columbia.

Our next witness will be Dr. Charles Rosen, who is the president and founder of the Association for Ethics in Spine Surgery and also a clinical professor at the University of California, Irvine. The stated purpose of AESS is to promote patient care and evidence-based medicine and to provide increased public awareness of the detrimental and pervasive influence—the financial influence—of industry on many health care providers and patients. Dr. Rosen has been in practice for more than 17 years. He is a specialist in spinal disorders.

Then we will have Said Hilal, president and CEO of Applied Medical Resources Corporation. Mr. Hilal will testify to his perspectives on the attitudes and practices of larger orthopedic device companies in regard to conflicts of interest and also paying surgeons.

We welcome you all here today, and Mr. Demske, we will start with your testimony.

STATEMENT OF GREG DEMSKE, ASSISTANT INSPECTOR GENERAL FOR LEGAL AFFAIRS, OFFICE OF INSPECTOR GENERAL, US DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, D.C.

Mr. DEMSKE. Good morning, Mr. Chairman and members of the Committee. I appreciate the opportunity to appear before you this morning. Relationships between the medical device industry and physicians can benefit patients and Federal health care programs by providing for innovations and improved patient care. However, these relationships can also lead to conflicts, which must be managed to safeguard the interests of patients and the integrity of our health care system.

Physicians receive substantial compensation from medical device companies in the form of grants, fellowships, royalties and various types of consulting agreements. These companies also provide physicians with a variety of non-cash benefits, such as travel, meals and gifts. We do not know the amount of these monetary and in-kind benefits, but we did learn in our investigation of hip and knee manufacturers that over the course of a 5-year period, four manufacturing companies paid physicians over $800 million in consulting fees related to the hip and knee devices alone.

There is a significant risk that such payments will improperly influence medical decisionmaking. A substantial body of research

shows that money and gifts influence the behavior of people in general and physicians in particular. Industry-induced bias presents risks to patients and the health care system. When a physician's self-interest compromises independent judgment, the patient faces risks that the physician will make decisions that are not in that patient's best interests.

Payments by companies also can create an uneven playing field and give an unfair competitive advantage to the company making the payments. Finally, excessive payments to physicians increase the total costs to our health care system. Some financial relationships that raise these risks also violate the law.

In September of last year, the government entered into settlements with four manufacturers of hip and knee reconstruction and replacement devices. The government alleged that these four companies offered inducements to surgeons to entice them to use the particular company's products. We found that, for example, in the largest types of consulting agreements involving the most money—product development agreements—physicians could be paid up to millions of dollars a year in royalties.

Despite the amount of money involved in these agreements, we found that some of the companies did very little to monitor the actual contribution of individual physicians. We also found that it appeared that members of some of these product development teams did little or no work in contributing to the development of products. To resolve these cases, the four companies paid a total of over $310 million. They entered into deferred prosecution agreements with the U.S. Attorney, and they entered into 5-year corporate integrity agreements with OIG.

This type of enforcement is an important facet of an overall strategy to discourage financial arrangements that distort physicians' professional judgment. However, it would be both impractical and inappropriate to rely solely on government enforcement actions to address this complex issue. The health care industry, medical community and government must develop and implement additional approaches to reduce the risks raised by these arrangements.

OIG, for its part, provides guidance to the health care community about how to comply with laws and implement voluntary compliance programs. We publish safe harbor regulations, advisory opinions, compliance program guidance, fraud alerts and bulletins, and we reach out to stakeholders in the industry. At the same time, many academic medical centers are implementing policies designed to limit the financial influence of the industry at their institutions.

Finally, we are aware of the efforts to increase transparency of industry-physician financial relationships. We will monitor these efforts and are considering imposing transparency requirements in future corporate integrity agreements. Government, industry and physicians need to look at this type of requirement and other means to address the risks raised by financial relationships between the device industry and physicians.

Thank you for the opportunity to testify today. I will be happy to answer any questions.

[The prepared statement of Mr. Demske follows.]

Testimony
Before the Senate Special Committee on Aging

United States Senate

"Examining the Relationship Between the Medical Device Industry and Physicians"

Testimony of

Gregory E. Demske

Assistant Inspector General for Legal Affairs

February 27, 2008
10:30 a.m.
628 Dirksen Senate Office Building

Daniel R. Levinson
Inspector General
Department of Health and Human Services

Testimony of:
Gregory E. Demske
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

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

[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.

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.

The CHAIRMAN. Thank you, Mr. Demske.

Dr. Rosen.

STATEMENT OF CHARLES ROSEN, CLINICAL PROFESSOR, UNIVERSITY OF CALIFORNIA, IRVINE, CA; PRESIDENT, ASSOCIATION FOR ETHICS IN SPINE SURGERY

Dr. ROSEN. Good morning, I am Dr. Charles Rosen, a clinical professor of orthopedic surgery at the University of California, Irvine, School of Medicine. My expertise is in spinal surgery. I have been asked to testify today as president of the Association for Ethics in Spine Surgery.

My tale is of the influence medical device makers exert to sell their product and how this hinges on a small minority of highly paid spine surgeons who have become nothing more than marketing men disguised as independent researchers. This all began in 2005 when I was shocked after reviewing the FDA approval of an artificial lumbar disk replacement made by a major device manufacturer. The FDA approved a study that was small in number, short in follow-up and actually eliminated the first 26 percent of patients receiving the replacement.

The disk replacement operation needs to be at least as good as the control operation it was compared to in order to gain approval. This control operation had a 60 percent failure rate, not a high bar to exceed by any standard. At the end of the study, two-thirds of the disk replacement patients, namely the majority, were still on daily narcotics for pain but still rated as successes due to the questionable design of the study.

Now in wondering how this was allowed, I noted that some members of the FDA voting panel had conflicts of interest, and many authors of the paper itself were paid consultants of the device manufacturer. As an aside, it was this last conflict of interest among authors of another disk replacement that recently became the focus of a Department of Justice probe. I was similarly concerned about the data and the cozy relationships with the first disk replacement, so I contacted the FDA as well as my own professional societies, including the North American Spine Society. I was politely rebuffed by all.

Then unfortunately in 2005, my prediction of disk replacement failures came true. I began seeing patients in a horrible type of pain that I had never seen before in all my years of practice, pain that often led to their loss of employment, marriage, family life and sometimes prompted thoughts of suicide. Getting no response from organized medicine nor the FDA, I voiced my concerns to the Wall Street Journal in June 2005 in an article that appeared on the front page.

I also felt compelled to start the Association for Ethics in Spine Surgery to help expose this unseemly influence of industry, which resulted in profits over patients, not to mention the huge waste of the health care dollar. Thinking that I might be the only member, I find quite surprisingly that now, a year and a half later, we have over 250 spine surgeon members and members-to-be requesting enrollment, all of whom were required to sign an affidavit stating that they do not have any financial ties to industry. This sudden groundswell of grassroots support by surgeons is accelerating be-

cause I believe the association has tapped into the pent-up frustration of the silent majority of our profession who refuse to violate the Hippocratic oath and sacred trust of their patients for the sake of their pocketbook.

Unfortunately, this is in stark contrast to many of those on industry's payroll who then began to attack me however they could. For example, after 8 years of being continually promoted in good standing at the University of California, I suddenly received a bad evaluation from the department chairman and was told that I would probably be fired shortly. It was later revealed to me that he was a paid consultant of a major device manufacturer and was even on a 1998 FDA Committee to evaluate disk replacements.

Since then, and fortunately for me, he left the department under a cloud of controversy to be replaced by a new and highly ethical chairman without industry ties. However, even the new chairman is approached repeatedly by professors and chairmen from all parts of the country as well as my own university to have me fired. Little reason is given. Not surprisingly, all seem to be paid consultants of industry.

Attacks on me have reached into the Internet chat rooms and Web sites, many of which are covertly sponsored by industry to lure in new patients and mold public thinking. Unfortunately, industry consultants infiltrate the boards of medical journals and professional societies which control the flow of medical information. I have even speculated that maybe this accounted in part for their rejection of my papers on failed disk replacements, as well as my opinions on ethics in industry.

High-profile industry physicians also influence the nature of obscure disclosure rules that reveal little of industry reimbursement, lest the research lose the enormously valuable appearance of having independent validation. I believe that getting enormous sums of money from a company about whose product you are writing—money that might go away if you write a negative paper—makes the research neither objective nor independent.

I have heard repeatedly from physicians on industry's payroll that those millions don't affect one's judgment. Nevertheless, the details shouldn't be revealed because that is private, though the sales pitches are very public. A recent front-page New York Times article about financial ties in a particular spine study is a perfect example of this rampant practice in the spine surgery world of which few outside are aware.

Before finishing, I would like to make a few recommendations. First, disclosure of complete financial compensation should be made in the case of authors publishing public papers about medical devices, in the case of the governing bodies of all 501(c)(3) medical societies and all paid medical consultants of both big and small device companies so it is a level playing field.

Second, industry money going to individual physicians at universities must be more tightly regulated, particularly public universities, such as the University of California, where I believe the regents know little of the undeclared financial violations of policy. The public, as do I, look toward academia for the unbiased truth, and this should be the standard.

Third, I will mention briefly device distributorships owned by surgeons. Here, profit is garnered by all the surgeon owners agreeing to only implant their distributorship's devices. Patients usually don't know this conflict, which leads frequently to unnecessary implants and surgery, and it should be stopped.

Last, the FDA should not have any paid consultants on its voting panels. To say this is impossible is a dubious claim of the FDA since there are many honorable and willing spine surgeons out there. I personally answered an FDA call for volunteers, yet my letter wasn't even acknowledged.

Thank you for the privilege and honor of addressing this Committee.

[The prepared statement of Dr. Rosen follows:]

Written Testimony of Dr. Charles D. Rosen
President of the Association for Ethics in Spine Surgery

I am Dr.Charles Rosen. I am a Clinical Professor of Orthopaedic Surgery at the University of California, Irvine, School of Medicine, specializing in spinal surgery which I perform, teach, and research.

My testimony is in my capacity as president of the Association for Ethics in Spine Surgery which I founded in 2006 in response to the ever increasing negative influence of industry on the treatment of back pain and spinal disorders in this country, and in particular on spinal surgery and research. Influence is exerted by device manufacturers who are enabled by a small but growing minority of spine surgeons on their payroll. To join my association, spine surgeons must declare in an affidavit that they do not accept compensation in any form from device manufacturers. We currently have close to 250 members enrolled or in the process of enrolling.

I will give you an inside view of the influence peddling of device makers and its effects, what happens if one voices concerns over this issue, and lastly, my recommendations to address the problem.

Spinal surgery for back pain costs billions of health care dollars every year and is increasing. In a single routine 2 hour spinal operation a surgeon can easily implant $25,000 worth of hardware in the form of multiple $1200 screws, $5000 cages, $12000 disc replacements, $5000 bone graft substitutes, spacers, or $20,000 spinal cord stimulators. Multiply this times a hundred surgeries per year for just one spine surgeon and then times the thousands of spine surgeons in the country, and one can see the enormous financial incentive for a device company to influence a surgeon to implant their products.

To exert this influence, companies often pay large sums of money, sometimes in the millions, to high profile spine surgeons who can write favorable papers about their products under the guise of unbiased research. In the last few years DOJ actions have led to 5 major companies being ordered to reveal the surprising size and extent of these amounts on their websites. As revealed in the New York Times a few weeks ago, the Department of Justice is investigating whether such surgeons on the payroll revealed to the FDA these conflicts of interests when they submitted evidence for approval of a certain brand of lumbar disc replacement.. Many such surgeons are also in governance positions of the professional societies and on the editorial boards of journals. This allows them to influence the choice of presentations in society meetings, choice of educational workshops, as well as papers chosen for publication. Sometimes company stock is used by smaller companies to incent surgeons to promote their product, giving them a bias for surgical results to appear favorable. Also, companies frequently pay surgeons just to continue being exclusive users of their products, or to switch over to them from a competitor's since one single surgeon can generate millions in sales each year. Because such behavior is illegal, it may be disguised as a fee for a sham consulting arrangement, for a royalty of little significance, or a hollow title such as key decision maker.

Now, the effects of this strategy are very successful. For example, most of the 4000 members of a large educational society called the North American Spine Society (NASS) do not take money from any company, and only want to do what's best for their patients. They rely on the information they receive from their professional society - in this case NASS - to be unbiased and to help them decide what implants to use, if any at all. Yet, few know of the enormous sums of money that many board members and well known authors are paid by industry. So called ethical disclosure rules are obscure in revealing the real extent of these financial rewards. For example, NASS has levels of disclosures indicated by categories without details. The highest category means that a surgeon receives greater than $10,000 per year or owns greater than 10% of a company. This does not reveal if it is $11,000 or one Million dollars. I submit to you that if this were fully exposed, then most surgeons, as well as patients, would reconsider their choice of procedures, and whether many should even be done at all.

I believe another problem is device distributorships, which are growing rapidly. Here, surgeon shareholders will form companies to manufacture or purchase their own devices at a fraction of the retail price of the major companies. All agree to implant only these devices. Then they share in the subsequent profits. This is an incentive for over utilization of implants and procedures, as well as limiting patient choice to one manufacturer of products that may not be the one best for the patients. These patients in my experience know nothing of the substance of these relationships, if even of their existence. .

Industry and its consultants cultivate a public mind set for selling that which is propagated by direct patient advertising, media announcements touting medical breakthroughs, and vast use of the internet to plant information on searches and in chat rooms that are covertly sponsored by industry. In this mind set, every new expensive high tech, device and procedure is an

advancement in surgery, even if results are only good for a year or two before the need for revision operations set in. It's a world where testimonials by doctors and patients over- rule independent studies and are enough to demand that payment be made for even the least validated procedure. Voicing concerns is labeled as impeding medical advancement or as a sign of ulterior motives. This leads to efforts at silencing the critic by underhanded attacks.

And attacked I was.

In 2004, the first lumbar disc replacement approved for implantation in this country was approved by the FDA in what I criticized as a poor study. I'll briefly mention my reasons because they're so easily grasped if the veneer of long words and the dubious stamp of FDA approval is stripped away. And remember, studies can be designed anyway one desires. This particular study was a small one with only a few hundred patients ; 2/3's of patients were still on narcotics 2 years after the disc replacement and this belies claims of success ; the first 25% of all the patients – those usually with all the complications - were eliminated by design from the final results; the control operation it was compared to was one with a 60% failure rate – a low bar to clear; and even the function of the device - namely continued motion– was not correlated with pain relief. One study in Europe even showed that over 90% of successful disc replacement patients had pain relief because paradoxically the device had spontaneously frozen up, acting as a conventional fusion.

In trying to understand how this was all allowed, I wondered whether the full financial involvement of the authors of the study was revealed to the FDA, which is the precise focus of the current Department of Justice investigation into the more recently approved lumbar disc replacement. Based on those recent questions, I wonder if the situation isn't similar with the first lumbar disc replacement that was approved.

After I voiced my concerns, an email went to almost every orthopaedic surgeon in the country saying I was doing this because I was in cahoots with Jim Cramer of Mad Money TV fame to short the stock of one of the largest multi-national companies in the world which happened to make the first disc replacement that was FDA approved. The email was from a highly visible industry consultant who publishes a weekly orthopaedics newsletter and one who organizes many disc replacement symposiums. After I contacted him to say this was absurdly untrue, I was threatened with a law suit for libel if I defended my self publicly. Even last week, I was attacked and libeled again by him in the same fashion because of the recent New York Times article. However, interestingly, he appears forced to revel that his newsletter is partly funded by the Viscogleisi brothers who are part of the recent Department of Justice probe into the FDA's approval of the latest disc replacement. In any case, this modus operandi appeared to be the new theme for much of what lay in store for me. Namely, money trumps truth and science.

As I started seeing dozens of patients with failed disc replacements in some of the most horrible, unremitting pain I have seen in all my years of practice , in patients whose lives are effectively ruined, I was deeply moved. The Association for Ethics in Spine Surgery was born

to make surgeons and the public aware of the often negative influence of industry and the doctors on their payroll.

The attacks on me continued. Down to the last person, they all were by surgeons or others on industry's payroll. After 8 years of being continually promoted in good standing at the University of California, Irvine I suddenly received a bad evaluation and was told I might be fired soon. I later was told the person at UCI initiating this was a paid consultant of a major disc replacement manufacturer and was even on a 1998 FDA committee to evaluate disc replacements.

Additional attacks continued. Our current department Chairman notes the numerous occasions he was accosted by various people within the orthopaedic and neurosurgical world with the same message --- fire Rosen from the department. The chairman recognized that they were trying to discredit me, with no actual proof or comment of wrong doing. No hard reason is ever given except that essentially I am somehow "disrupting" the spine world. Such people include surgical department chairmen from UC campuses, including my own, as well as various academics in spine surgery from out of state. The request to have me fired has come from the head of a prominent orthopaedic foundation under a not – for – profit charter for education and research who is , as all they all are, a highly paid industry consultant. (Incidentally, for me, this also begs the question of whether industry funded foundations, funded either directly or indirectly, yet still influence ultimate product use by surgeons, should have tax exempt status.). One well known academic spine surgeon even approached a colleague of mine at UCI and spread the rumor that I am critical of disc replacements only because of a desire to get paid for testifying in malpractice suits against surgeons, which is untrue. I have not now, nor in the last 16 years of practice, testified against any surgeon in any malpractice case. Nor do I intend to. It seems the main thing all these personal attacks have in common is that they are by the minority of spine surgeons on industry's payroll.

The attacks worsen. At one point, the national weekly orthopaedic newsletter I mentioned , sent a reporter to try and associate me with the a local scandal of sorts that had nothing to do with me at all.

The attacks through the internet increase by companies utilizing their industry sponsored "chat" rooms and websites to discredit me. They are effective because the public does not know of the paid promoters and posters involved in what poses as patient education. Despite the financial purpose, many tout 501c 3 status as evidence of their purely charitable nature. One such site discusses disc replacement arthroplasty. On this site I am said to be critical of replacements because I am paid millions by a competing manufacturer. This is untrue.

Some of the fallout from these attacks is in other areas, including locally where I work. At UCI, neuroscience research is internationally renowned, and a ground breaking research program for spinal cord injury victims was begun. However outside our department are those that wish me fired, and commensurate with this, will not allow my directing such a program

despite the fact .that my fellowship training was specifically in spinal cord injury. Such actions do an injustice to the American public and citizens of California who look to the University of California to advance science, not to use it as a personal weapon. It is even more unfair to those who suffer life in a wheelchair, longing for research to free them of their bonds.

My research and opinions are difficult to get published in the spine literature. I sometimes wonder if it's the subject matter itself.

Before finishing, I will give you my recommendations.

Firstly, I believe the exact dollar amount of any type of industry compensation from all companies to surgeons, particularly those who are writing papers and running professional societies, should be available for all to see. Their claim of right to privacy is hollow when it occurs in the context of making very public their opinions on devices to buy. And this disclosure should not be limited to only big cap companies as this will just move the game to the dozens of smaller ones. Frankly, I don't see how putting a yearly payroll on line is a troublesome reporting burden either.

Secondly, physicians running not-for-profit medical organizations for research or education should not be on industry's payroll. I suggest that the hidden agenda is in fact ultimately for profit in many cases, and thus the tax exempt status is improper.

Thirdly, device distributorships owned by spine surgeons where they profit from implanting their own devices, is in effect, selling product to unknowing patients. In my opinion, this leads to excessive device implantation and surgery that may not otherwise occur without the profit from this.

Fourthly, industry money going to individual physicians at universities must be more tightly regulated. The public, as do I, look towards academia for the unbiased truth, and this should be the standard.

Finally, no one on the FDA panels should be a paid consultant. Industry has too much influence designing studies to get the desired results. What seems to be a familiar pool of favored consultants should be eliminated. Although a recent outside consultant for the FDA claims that there are not enough doctors without conflicts to be on the panels I say that this is patently untrue. At least 2/3 of spine surgeons in this country takes no money from industry, and haven't been really approached to volunteer for FDA work. Last year I responded in a certified letter to a request for volunteers for spinal issues. I never received even the slightest acknowledgement, though I certainly believe I 'm qualified.

The CHAIRMAN. Thank you very much for being here, Dr. Rosen. Mr. Hilal.

STATEMENT OF SAID HILAL, PRESIDENT/CEO, APPLIED MEDICAL RESOURCES CORPORATION, RANCHO SANTA MARGARITA, CA

Mr. HILAL. Chairman Kohl, thank you, and Ranking Member Smith and the Committee for kindly extending an invitation for me to testify. My name is Said Hilal. I represent Applied Medical from Orange County, CA. I have been in this field from the time it was health and care and before it became mostly industry. I am here this morning to outline the serious concerns I, and my fellow Applied Medical officials, have about conflicts of interest and ethics we have observed in America's health care system.

Applied Medical has supplied enhanced clinical outcomes, although not in orthopedics, coupled with value since its founding in 1987. We offer advances in minimally invasive procedures that reduce recovery time, pain and complications and typically does that for less. I mention this because it is both important and possible.

In the interest of full disclosure, Applied has pursued litigation related to antitrust and intellectual properties against many organizations. I have previously had the honor of testifying about antitrust issues before the Senate Judiciary Antitrust Subcommittee. While those issues harm upcoming companies, U.S. companies, they do not compare to the damage caused by unethical practices and quid pro quo.

Because Applied and its products are used by surgeons, we sell to hospitals. We, therefore, are directly affected by how business is done in hospitals. Because we pioneer new modalities and techniques, we support surgeon training and peer-reviewed scientific studies. Therefore, university hospitals and thought leaders are exceptionally important to us.

Additionally and in my opinion, medical device companies have an obligation to support research and education, but this must be accomplished with no strings attached. Sadly, support has mutated into a quid pro quo instrument. We believe the correlation between payments and purchases is astoundingly and embarrassingly high. We believe this clandestine correlation has a significant impact on market economics.

We also believe some surgeons and other medical personnel have become inextricably beholden to device companies. Enticements in such situations go past corrupt to become corrupting. Some clinical personnel become gatekeepers for manufacturers.

Corrupting influences are not really limited just to university hospitals. We hear of large manufacturers approaching hundreds of surgeons with the invitation to become "consultants," an extension of the sales divisions, it turns out, of these large companies.

Years may go by without any follow-up activity until a new competitor shows up at the gate of a hospital. It is then that the so-called consultants are activated and paid to lecture, proctor and consult. As the money flows, these consultants become ardent opponents of change that impacts their sponsors, often adopting "sponsor-designed" lists of objections to challenge the new supplier.

With some hope, we watched large companies adopt codes of ethics to address interactions with surgeons and others. But our hopes have actually evaporated.

I would like to share with you a firsthand experience here. We got invited to a meeting where large device companies put on a presentation to leading surgeons, allegedly to educate the audience on new AdvaMed guidelines and ethics codes for receiving grants and other payments from these companies. The presentation was entitled, "Is the Party Over?" The title alone is alarming in my opinion, and I believe encapsulates the impropriety of this situation.

According to the presenters, the party is far from over. Surgeons were coached on how to act in a safe manner and continue to receive lucrative payments. Amazingly, surgeons were reminded that the grants are "all about ROI, the return on investment" for the granting company. I ask: How are these companies planning to capture that ROI and what strings are attached?

To a large extent in these United States, our surgeons and medical organizations remain the most respected around the world, but we see corrupting influences every day. This is precisely why Applied continues to enthusiastically support the efforts of this Subcommittee to keep the corrupting influences from undermining the well-earned respect.

Unfortunately, voluntary codes from industry have not sufficed. Gentle, slap-on-the-wrist settlements and penalties have not been effective. Many large device companies hide behind credos, skirt the edge and break promises of ethical conduct. As long as the penalty for making billions of unethical dollars for years is a few million dollars every few years, these corrupting behaviors are not going to recede.

We welcome legislation and enforcement that can get us past this unhealthy situation. There is little that ethical companies can do alone. We hope and trust these unethical practices will get the necessary scrutiny. This great nation's health care deserves the best, and it is our duty to aim for the best.

I thank you very much.

[The prepared statement of Mr. Hilal follows:]

Testimony of

Mr. Said Hilal
President and Chief Executive Officer
Applied Medical Resources Corporation

United States Senate
Special Committee on Aging

February 27, 2008

Statement of

Mr. Said Hilal

President and Chief Executive Officer
Applied Medical Resources Corporation

Before the US Senate Special Committee on Aging

February 27, 2008

Thank you, Chairman Kohl and Ranking Member Senator Smith for holding this hearing. My name is Said Hilal, and I offer this statement on behalf of Applied Medical of Orange County, California. I appreciate the opportunity to outline the serious concerns I and my fellow Applied Medical officials have, about conflict of interest and ethics we have observed in America's health care system.

Applied has supplied improved clinical outcomes coupled with value since shortly after its inception in 1987. Our company offers sixteen surgical products lines, many of which represent significant advances in laparoscopy and minimally invasive surgery. We lead the market in hand access surgery for colorectal and abdominal procedures. Another one of our product lines protects incisions during abdominal procedures, especially C-Sections, and shows promise in reducing both infection rates and the need for follow-up pain medications. Yet another one of our product lines is "trocars." Trocars are access tubes equipped with advanced seals through which a surgeon inserts surgical instruments while maintaining pressure within the body cavity of a patient undergoing "minimally invasive" surgery. This type of surgery, using trocars, also is referred to as "keyhole" surgery, because the hole made by the trocar is about the size of an old-fashioned keyhole. Typically, the trocar provides a half-inch or smaller aperture for surgical instruments and a television camera to negate the need for large, open incisions and the lengthier recovery time typically associated with conventional open surgery.

In the interest of full disclosure, Applied has been in litigation related to antitrust and intellectual property against several other companies in the medical device industry. I have previously testified about issues relating to some of these matters before the Senate Judiciary Antitrust Subcommittee. While those issues are serious hurdles facing the smaller U.S. companies and start-ups, they do not compare to the challenges and damage of unethical practices and quid pro quo, given in return for sales. Manufacturers' rebates to hospitals, and fees and other payments, exaggerate the cost of individual procedures to Medicare accountants, and funnel funds through the backdoors of the institutions. Opaque pricing and bundling is gaming the American health care system every single day.

Because our products are used by surgeons, we sell to hospitals. We therefore, are very much affected by how business is conducted in hospitals. And because we pioneer new modalities and techniques, we support surgeon and resident training, as well as peer-reviewed scientific studies. Therefore, university hospitals are exceptionally important to us.

Ethical relationships between surgeons and device innovators are critical to the collective mission of improving clinical outcomes. New devices could not be developed without appropriate cooperation with clinicians. To us, medical device companies have an obligation to support research and education through unrestricted grants – but they must be unrestricted, with no strings attached.

Sadly, grants have deteriorated, often quite creatively, into quid pro quo instruments. We believe the correlation between grants and purchases is exceptionally and astoundingly high. We believe this clandestine correlation has a significant impact on market economics – and some surgeons have become inextricably beholden to suppliers. Such relations go past "corrupt" and become "corrupting". Clinicians become gatekeepers for suppliers, for the wrong reasons.

Corrupting influences are by no means reserved for teaching hospitals alone. While there are many appropriate consultant relationships that exist between medical technology companies and physicians during the development phase of a product, we hear of large suppliers approaching hundreds of surgeons with invitations to become "consultants". However, these physicians appear to be no more than an extension of the sales and marketing efforts of the large companies. Years may go by without any follow-up activity – until a new competitor is at the gates of the hospital. It is then that the so-called consultants are activated by the large supplier and paid to lecture, proctor and consult. As money starts flowing, the so-called consultants become ardent opponents of any change that threatens their sponsor's business, often adopting sponsor-designed lists of objections to challenge the new supplier.

With some hope, we watched as large companies adopted codes of conduct in an attempt to address their interactions with clinicians. But, since then, our hope has evaporated. My colleague, Gary Johnson, and I attended a meeting where large manufacturers put on a presentation to leading surgeons, allegedly to educate the clinicians on new AdvaMed guidelines for receiving "unrestricted" grants from suppliers.

The presentation was entitled "Is the Party Over?"

It turns out the party is far from over, if the presenters are right. At the presentation, surgeons were coached on how to act and communicate in a "safe" manner. The surgeons were actually reminded that grants are "...all about ROI, the return on investment." Although the words were often very carefully chosen, the message was clear – don't use the wrong words in your communications, don't e-mail, grab the phone

and call us, and you can still get the grants, and you just have to know what is expected in return, because that cannot be discussed.

To the credit of most surgeons, they deemed the effort inappropriate and distasteful. This is one reason U.S. clinicians and medical organizations remain the most respected around the world. They are believed to be mostly resistant to improper influences and pay-offs. Unfortunately, the reaction by many clinicians is not deterring manufacturers from searching for those who will "listen and cooperate." It is time to restrain the corrupting influence of big money and remedy this unhealthy situation.

Sadly, voluntary codes from industry, self-governance, and gentle slap-on-the-wrist settlements and "penalties" have been ineffective. Many manufacturers still feel comfortable skirting the edge and breaking promises of ethical conduct, while hiding behind superficial credos and codes. And as long as the penalty for making billions of unethical dollars for years is a few million dollars once every few years, these corrupting behaviors will not recede. Rather, these practices will continue to keep cost high, stifle competition and innovation and defer or prevent these cost-saving improvements from reaching our aging population.

In our opinion and experience, a multibillion-dollar medical supplier does not consider $40 million or $ 400 million in penalties, after years of violations, as painful or prohibitive or even painful. The reward far outweighed the consequence of the improper conduct. Settlements of this nature simply inform abusers how to better proceed with caution to obscure their tactics. This is what my colleague and I witnessed at the meeting I described – an invitation for participants to be more careful and covert.

We believe the country has unintentionally made available an affordable "Get out of Jail" card for these situations. Given the disproportional nature of profit to penalty, these monoliths do not even feel the slap.

Applied continues to enthusiastically support the efforts of this Committee. There is little that ethical companies can do alone. We hope and trust these unethical practices will continue to have your attention.

Given a level and honest playing field, we – and many American companies like us – can bring exceptional value to healthcare in the U.S. and around the globe. This great nation deserves the best healthcare, and it is our duty to aim for the best.

ADDITIONAL INFORMATION

I. APPLIED IS AN INNOVATOR IN SEVERAL SURGICAL FIELDS

Founded in 1987 and headquartered in Orange County, California, Applied designs, develops, manufactures, licenses, markets, and sells seventeen lines of specialized devices for general, colorectal, obstetrics, urology, laparoscopy, cardiovascular and vascular surgery. Our products are 99 percent manufactured in the United States.

At its inception, Applied recognized that the national trend of rapidly escalating healthcare costs would reach 20 percent of GDP within a decade. This presented a serious national problem and an opportunity for innovative companies that could affect improved clinical and financial outcomes concurrently. Accordingly, Applied's business strategy has been to develop products and practices that enhance performance while reducing the cost of products and procedures. Since 1988, Applied has evolved as a prolific developer of products and technologies that fulfill this dual requirement, resulting in 645 pending and issued medical device patents worldwide.

Our products have been safely, successfully, and satisfactorily used in many hospitals throughout the globe and for many years. Millions of our devices have been sold and used as testament to their acceptance and performance. Our outstanding record with the FDA also attests to the quality and performance of our products.

Applied maintains one of the highest commitments to innovation and quality in its industry. Over the past decade, Applied has spent 20 percent of its revenues on R&D, resulting in impressive clinical results and financial savings. One example of the results of Applied's investment is our device named GelPort ™ System, used in advanced laparoscopic procedures to reduce the trauma of open surgery in colorectal procedures. The GelPort product is rapidly expanding the field of minimally invasive hand access surgery. We were awarded Innovation of the Year 2002 by The Society of Laparoendoscopic Surgeons. The Acucise® product is another proud innovation for dealing with ureteral strictures. Peer-reviewed clinical papers attest to the fact that the Acucise® product eliminated hospital stay, reduced costs by $14,000 per procedure and replaced a 210-minute surgery under anesthesia with a 42-minute minimally invasive procedure under sedative and achieved a hundred percent success rates in secondary procedures. Applied also has introduced new generations of atraumatic, minimally invasive surgical devices for occluding blood vessels and grasping tissue, and has eliminated sometimes life-threatening latex from its products.

Applied's trocar seal technologies set the standard for seals used in minimally invasive surgery and are utilized in the majority of trocars currently on the market. The Applied

trocars were the first to accommodate instruments with a wide range of diameters to traverse the seal without adaptors, leakage or excessive friction. The patented seal technologies developed by Applied have resulted in real improvements in patient care in minimally invasive surgery by reducing time in the operating room and improving surgeon control during the procedure.

Applied introduced the Separator™ product, a new generation of access products that uniquely separates the abdominal wall layers along their natural lines without the use of traumatic plastic or metal blades.

II. SOLUTIONS/CONCLUSION

We urge you to push forward with efforts to draft and enact legislation that permanently reforms behavior in this area and restores grants and research funds to their proper and constructive role in the process, for the sake of patients and hospitals, healthcare and improved clinical outcomes, and the continuing competitiveness of innovative U.S. manufacturers in world markets.

We also urge you to exercise your oversight responsibilities to encourage enforcement of the existing laws by the Federal Trade Commission and Department of Justice and at the same time as you act to strengthen those existing laws. Progressive European and Australian agencies are way ahead of us on these issues, and are often dealing with violators promptly and firmly.

We believe the U.S. has some catching up to do. Our nation has led the world in many fields where as capabilities increased, cost decreased, and, as volumes went up, so did availability, choice and competitive spirit.

At the risk of repeating the Applied mantra one more time, these favorable economic trends and accomplishments have not had the same opportunity to positively impact medical devices and healthcare. Clandestine practices and anti-competitive bundling of grants with products continue to take their toll.

On behalf of Applied Medical and its 1,200 team members, I urge you to restrain quid pro quo practices from the medical field.

Thank you.

The CHAIRMAN. Thank you very much, Mr. Hilal.

We turn now to the Ranking Member in this Committee, the senator from Oregon, Gordon Smith.

OPENING STATEMENT OF SENATOR GORDON SMITH, RANKING MEMBER

Senator SMITH. Thank you, Mr. Chairman. In the interest of time, I will put my statement in the record.

The CHAIRMAN. Without objection.

Senator SMITH. The thrust of that statement relates to balance, and this hearing is in the great tradition, the bipartisan tradition, of the Aging Committee, which tries to put light and heat on bad practices while at the same time not in any way wanting to restrain or stifle innovation or impede good practices. That is the balance I think we all strike here.

But as I have listened to each of your testimonies, I have been struck by the circumstance you describe, and it is alarming. I guess what I am hearing from you is that these aren't exceptional circumstances, that this is becoming so pervasive as to become alarming.

Is that your judgment, Dr. Rosen?

Dr. ROSEN. Yes, over the last 20 or 30 years, I think it has become ingrained where it is OK. The leaders in the field that are heading the societies, editing the journals are probably for the most part the biggest offenders, which sends the message that this is OK. So yes.

Senator SMITH. So, Mr. Hilal, I assume you are a medical doctor as well?

Mr. HILAL. No, I am not.

Senator Smith. No, Mr. Hilal, then your point is that codes of ethics and conduct and voluntary agreements just aren't providing enough protections? I think that is the thrust of your testimony.

Mr. HILAL. Yes, sir.

Senator SMITH. Dr. Rosen, it would seem to me, were I a physician, and I have a relationship with a manufacturer of some surgical product, that I would have in the back of my mind the potential that I may have a conflict in interest in putting in to someone that may be an inferior product—this would really give me pause because of the potential malpractice implications. But are you saying that that is not a sufficient deterrent to a financial conflict of interest?

Dr. ROSEN. No, I don't think that enters the picture really at all. Should it? I think that among——

Senator SMITH. Let's say, I am doing a hip replacement, and I have got an inferior product in which I have a financial interest. The patient as you describe is in pain, and it is just inferior to what else I could have put in. It just seems to me that that is a lawsuit ripe with liability.

Dr. ROSEN. Well, most of the implants, whether it is total hips or spine, they are all generically good. I mean, they have all passed 501—they have all passed through some type of approval. They are generally the same, and people can make arguments for one product over another based on some aspects of them, but it is rarely one is felt universally inferior to any of the others.

So it doesn't usually take that sort of discussion. It is usually about the particular aspects of one versus the other, and you can justify using most any of the products out there in some fashion.

Senator SMITH. So the current circumstance just doesn't work sufficiently to protect patients or to sever the conflict-of-interest relationship between a manufacturer and a physician. Is there any other marketing model that would protect older Americans and all Americans?

Dr. ROSEN. I think that disclosing the exact amounts that someone gets from a company, precisely, in the papers they write, in the presentations they give——

Senator SMITH. How about before the operation they give?

Dr. ROSEN. Well, I think as well as that to the patient, that there should be signed consent that they acknowledge the doctor has this amount of compensation from this company. So——

Senator SMITH. Nothing like that happens now?

Dr. ROSEN. Oh no, not at all. I mean, most of the time patients—have no clue. Most of the doctors don't have any clue because—including me. In some cases I will know because I have heard, but the majority of the time that is obscured effectively.

Senator SMITH. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Mr. Demske, in your written testimony, you state that we have seen instances in which physicians, in turn, have signaled to the industry that their loyalties 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,".

So what you make clear is that there are two groups of players here in this unethical conduct, the companies as well as the doctors. What is the OIG office doing to detect and address wrongdoing on the part of surgeons and physicians?

Mr. DEMSKE. OIG is working with the Department of Justice to follow up on the investigations in New Jersey and other cases to identify whether we can pursue criminal, civil or administrative cases against physicians who are in this situation where they have demanded payments in exchange for their patients. One of the difficulties that we face in prosecuting these cases is that our primary tool is the Federal anti-kickback statute, and that statute requires knowing and willful conduct on behalf of the defendant in order for the government to get a conviction. This is often difficult—it means we have to prove the state of mind of the defendant. Absent evidence that the physician made statements such as those reflected in my testimony or the existence of witnesses that can make statements as to that physician's intent, these cases are very difficult to prove.

But we are working with the U.S. Attorney's Office to identify cases in New Jersey and elsewhere in the country against physicians as part of that case. You can anticipate in the future that we will be bringing additional cases against physicians.

The CHAIRMAN. Is it fair to say that we need some additional legislation to root out the problems that we are discussing today?

Mr. DEMSKE. I would say that the anti-kickback statute itself is insufficient to address the influence of money in this industry. Be-

cause of the high burden of proof that the government must meet, it cannot reach many of the arrangements that can influence medical judgment in an inappropriate way.

The CHAIRMAN. Thank you.

Dr. Rosen, we expect to hear from witnesses on the second panel that many of these questionable and unethical payments to physicians and surgeons have been identified and are being addressed. Do you believe that that is correct? To your knowledge, what is the state of the problem today?

Dr. ROSEN. I don't believe they are being really addressed in any substantive way at all. I think it is mostly been a reactive action taken by many of the medical societies and organizations, such as AdvaMed, to give lip service to ethics and the concerns just to the point where it sort of satisfies the public. But really as far as disclosing the amounts of money, stock, royalty options that people get, I don't think it happens at all.

In fact, one of the—for example, one of the main societies, the North American Spine Society, has said it is pioneered ethics, and yet the highest level of disclosure on a five 'A' through 'E' is letter 'E,' which means someone gets over $10,000 from a company or owns more than 5 percent of a company. Now that doesn't tell you whether it is $11,000 or $1 million, which can often be the case. So it is sort of piecemeal trying to throw out that we are dealing with the ethics. No, I don't think it is being really addressed at all.

The CHAIRMAN. So it is fair to say that you do not believe that voluntary industry guidelines can resolve this problem?

Dr. ROSEN. Embarrassingly, I don't believe the medical societies are capable of doing it nor industry. As in the previous question, it is so embedded now among most of the people that are running these societies, including educational foundations, that I don't think it is possible to change that without something from the outside happening.

The CHAIRMAN. Mr. Hilal, do you agree with that, that voluntary guidelines are not going to resolve the problem?

Mr. HILAL. I wholeheartedly agree. They have not so far. They have simply forced the groups that are practicing their quid pro quos to just go more covert and more careful. I have seen it with my own eyes where they were coached on that.

I just don't see it going away. It doesn't kick in where the product is best and the value is fair. It kicks in when the product is marginal and the value is high. For the competition, that is not best for free markets. What distorts free markets, in my opinion, is the act of the kickback.

The CHAIRMAN. Thank you.

Senator Corker.

Senator CORKER. Mr. Chairman, thank you, and I want to thank the panelists for great testimony. I think that the comments by the Ranking Member about achieving balance is what we all wish to do.

I know we are going to hear from some other panelists in just a moment, but it does seem to me that disclosure would be a no-brainer. I mean, I think that people should know. I will tell you, on the other hand, that all of us see physicians, and I think even if my physician told me that they had a major financial relation-

ship regarding a particular procedure, I don't know if it really would affect me that much. I just wonder if you would expand on that a little. But I mean, just honestly, I go to these little specialty facilities, and I know the doctors are making money off of those, and yet if they tell me I need a procedure, then I suppose I am going to have it anyway. I just wonder if you might respond to that.

Dr. ROSEN. I don't think it necessarily will change that much either. In some cases, though, if there is a new procedure that came out and it is a little questionable, and the person is not sure and they see that, well, this doctor owns 10 percent of the company that brought this public, and he is suggesting the device in putting—I think that might affect them. For the most part, probably not, but I think the patient would be and the doctor would be better off protected as well, if the patient knew. Certainly with things like distributorships, though, where the money is made by putting in implants, I think the patients should know that there is really a close correlation between the profit and putting in the implants versus not using them, because many operations can be done without them.

The main thing, really, is for papers and presentations that the rest of the doctors in this country read. I really believe 95 percent of the spine surgeons in this country have really nothing to do with industry. They just want to do the best for their patient, but they rely on the 5 or 10 percent of high-profile people that are writing papers to decide what to do. If they knew that these people had a million dollars in salary from so-and-so company, when they read a paper that proposes using a certain device, they will realize this is not an independently validated paper, and that is a big difference.

Independent validation is when somebody looks at it in an unbiased fashion, and that is the keystone goal in medicine. That would be the most valuable thing, because this all happens with products that are not so great, and that is the reason they have to sort of make a pretense that they are independently validated. But as far as the person in the office, maybe some difference, but mostly for other doctors.

Senator CORKER. I would imagine it might affect the utilization rate in many cases, but more than—you know, you talked about that products were actually, in some cases, very comparable, but I would think that just from the standpoint of utilization, that could be driven up greatly by having the financial relationship. I know it applies in most other business, but——

Dr. ROSEN. Absolutely.

Senator CORKER. OK.

Mr. Hilal, the issue, on the other hand, it seems to me that physicians who are using products—I know some physicians that are inventor-types, if you will, and they have an imagination, and they are able to figure out ways that products can provide a better service, and so they do work with companies, you know, to make those products better. Could you talk just a little bit about that?

I think, at the end of the day, we all want innovation to take place, and we want to make sure that the products that are sold are products that physicians know will do a better job for the pa-

tients involved. Again, I think as Ranking Member Smith mentioned we do need a balance here. So how do we keep that from being perverted, if you will?

Mr. HILAL. Absolutely, I truly believe that the best innovation is the innovation that starts from the clinical need itself. As a matter of fact, we at Applied would argue that 80 percent of the solution may be in the proper definition of the need or the problem. Therefore this correlation, this cooperation, between surgeons and companies is very important for the development of products.

Surgeons are the users. They are the champions of the patient. In that term, they really need to be listened to. They need to be allowed to innovate and help the companies develop new products. That is a far cry from pushing and hawking the product. That is a far cry from getting a kickback to favor a product. I think that is really what the concern is.

I believe that disclosure is helpful, but I would take the time to differentiate between "disclosure" and inadvertently turning it around to the patient and saying, "Patient, protect thyself," because patients cannot protect themselves. I agree with you. A patient is not going to look at the financial statement of his or her doctor and decide whether that doctor is acting in the patient's best interest. This is why I delved a little bit on what I call the corrupting influence.

I agree with Dr. Rosen. Most surgeons dedicate their lives to taking care of patients, to doing the right thing. Why tempt them? Why walk up to them and say, "You can make an extra buck if you use this product?" How does that help a free market compete, innovate and continue to be the leading force in the world health endeavor?

Senator CORKER. Mr. Demske, what are your specific concerns about the physician-owned facilities? I know you mentioned that just in passing in your testimony. I wonder if you would expand on that particular issue.

Mr. DEMSKE. Certainly. The OIG has for many years given guidance about the risks that are inherent when health care providers enter into joint ventures with physicians, because there is a risk that the physicians are being brought in as investors as a way to funnel profits back to the physicians to induce them to send their business to a facility. So physician ownership raises those sort of risks.

One has to look at how those investors are selected, whether they are a major source of business for the entity and whether it is a bona fide investment at all. We have recently been looking at physician involvement in distributors of medical equipment and group purchasing organizations. Those types of investments can be additional ways device manufacturers can funnel money to physicians. These payments may not be for the service that a GPO or distributor would usually provide but is essentially money being paid to influence the physician's choice of devices.

Senator CORKER. Mr. Chairman, thank you. It is a very good panel, and thank you for your testimony.

The CHAIRMAN. Thanks, Senator Corker. I want to reiterate what he said. This has been a very, very good panel. You have really shed light on some of the issues and the problems that we face and

given some indication as to the direction in which you believe we need to go. In that sense, it has been really good to have you. You made a great contribution, thank you so much.

At this point, we would like to call the second panel. Our first witness on the second panel will be Ned Lipes, who is the executive vice president of Stryker Corporation. Mr. Lipes has worked at Stryker for nearly 20 years, and he will discuss how his company is now addressing conflicts of interest and potential violations of law by its employees.

Then we will hear from Chad Phipps, who is the senior vice president and general counsel at Zimmer Holdings, Incorporated, one of the largest medical device companies in the industry. Mr. Phipps' global responsibility for Zimmer's legal affairs, and he also serves as secretary to the board of directors.

Finally, we will be hearing from Christopher White, who is the executive vice president and general counsel at AdvaMed. AdvaMed's member companies produce nearly 90 percent of the health care technology purchased annually in the United States, and its mission is to, "advocate for a legal regulatory and economic climate," on behalf of medical device manufacturers.

Gentlemen, we welcome you here today.

Mr. Lipes, we will take your testimony.

STATEMENT OF EDWARD LIPES, EXECUTIVE VICE PRESIDENT, STRYKER CORPORATION, MAHWAH, NJ

Mr. LIPES. Good morning, Chairman Kohl, and Senator Corker. My name is Ned Lipes. You are not the first one that has made that mistake, sir.

The CHAIRMAN. Thank you.

Mr. LIPES. I am the executive vice president of Stryker Corporation, and I would like to take this opportunity to thank you for the invitation to appear here on behalf of Stryker Corporation in connection with the committee's efforts to explore the relationship between medical device companies like Stryker and physicians.

As you may know, Stryker is one of the world's leading medical technology companies, with the most broadly based range of products in orthopedics and a significant presence in other medical device areas or medical specialties. Our corporate headquarters and the majority of our manufacturing operations are headquartered right here in the United States. Stryker has grown into a Fortune 500 company based on our offering of an unparalleled variety of high quality products and services as well as the dedication of each of the company's more than 15,000 employees around the world.

In the late 1930's, Dr. Homer Stryker, who was a resident in orthopedic surgery at the University of Michigan, found that certain medical products were not meeting his needs or the needs of his patients. He put his inventive mind to work and created new products to solve real clinical problems that he faced with his patients. Some of his inventions included the walking heel for leg casts, the turning frame for immobile patients and the oscillating saw to remove casts for broken bones.

Dr. Stryker's devices gained attention of other medical professionals, and in 1941, the demand for the products grew so large that Dr. Stryker founded the company to make those products. The

company became Stryker Corporation when Dr. Stryker retired from his medical practice in 1964. Dr. Stryker was a great example of the role that surgeons can play in the development of new products to meet the challenges and needs of patients.

Since its founding, Stryker has focused its attention on continuing to meet and surpass the needs of medical professionals and patients. Working with the medical professionals who use our products, we have continued to improve the quality of care available to patients by solving real clinical problems and finding better ways to make products that will last longer and perform at higher levels. In the past year, 2007, Stryker's sales were over $6 billion.

As for me, I started working at Stryker in 1988. In 1989, I became president of Osteonics Corporation, which was the orthopedic implant division of Stryker Corporation. In 1998, Stryker purchased Howmedica Corporation from Pfizer and became Howmedica Osteonics Corporation, which is now known as Stryker Orthopaedics, based in Mahwah, NJ.

Early in my career with Stryker Orthopaedics, I recognized that one of the keys to success was to have close interactions with a select and small number of thought-leader surgeons who have good ideas about how to better treat their patients. Throughout the 1980's, the 1990's and continuing to today, Stryker has had consulting contracts with a select group of orthopedic surgeons. For example, surgeons from Indiana and Pennsylvania assisted Stryker in developing a new hip implant system designed to secure initial fixation in the implanted patients. These same surgeons have been involved in following the clinical results of this product in their patients to demonstrate that our design goal has actually been achieved. Another orthopedic surgeon from California helped Stryker design a new knee implant system to give patients a greater range of motion with their new knee.

Because these surgeons contributed their time and their ideas to Stryker, we paid them for their efforts. How much did Stryker pay? We paid what we believed to be fair market value for the services that they provided.

Stryker has other types of contractual relationships with surgeons as well. For example, some surgeons are great teachers. One surgeon from Massachusetts has a very strong interest and understanding of ceramic technology. He uses that knowledge and that expertise to help other surgeons understand when that technology may be appropriate for their patients. Another surgeon from Georgia helped Stryker teach Japanese surgeons about the benefits of a new knee design that can help patients kneel and squat more easily.

Finally, other surgeons are outstanding peer-to-peer teachers of implant techniques. One surgeon from Michigan regularly teaches his peers—in sawbones, cadaver laboratories and in his operating room—by demonstrating the proper use of our newly developed computer navigation technology for hip and knee replacement surgery, all with the goal of enhancing outcomes for patients.

We retain these consultant services because they help us teach the proper use of our products, and this helps our business grow. In the late 1990's, our industry began to change and certain abuses emerged as the use of consultants became more of a marketing

tool. Stryker did not change its business model and instead adhered to the traditional approach to contracting with surgeons. We required our business leaders—excuse me—to have clearly defined procedures, systems and controls in place to ensure compliance with our business model.

In March 2005, the United States Attorney for New Jersey issued subpoenas to five orthopedic companies, including Stryker, as it began its investigation into the relationship between these companies and surgeons. The September 2007 settlements related to this investigation have provided our industry with a level playing field so that each company will play by the same set of rules regarding contracting with health care professionals.

Surgeons who are absolutely crucial to product design, development and clinical studies will be paid fair market value for their services. Other surgeons who are great teachers will be paid fair market value to train their fellow health care professionals about the features and benefits of the products that we sell. Stryker firmly believes that all the competitors in our industry can and should compete on a level playing field. The recent settlements with the U.S. Attorney provide a strong framework to ensure that this occurs, and Stryker intends to honor its commitments to the U.S. Attorney in both spirit and principle.

In the years ahead, we look forward to competing on the basis of how our products and services meet the demands of surgeons and patients. We look forward to continuing to interact with consulting surgeons who have so much to offer in terms of enhancements to treatments for patients everywhere. These collaborations will continue to bring innovation and improvements in patient care.

Thank you for the opportunity to express Stryker's views, and I look forward to any questions that you may have.

[The prepared statement of Mr. Lipes follows:]

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SENATE SPECIAL COMMITTEE ON AGING

FEBRUARY 27, 2008

STATEMENT BY

EDWARD B. LIPES

EXECUTIVE VICE PRESIDENT

STRYKER CORPORATION

Good Morning Chairman Kohl, Ranking Member Smith and Committee Members:

My name is Ned Lipes and I am the Executive Vice President of Stryker Corporation. I want to take this opportunity to thank you for the invitation to appear here today on behalf of Stryker Corporation in connection with the Committee's effort to explore the relationships between the medical device industry and physicians.

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Since its founding, the Company has focused its attention on continuing to meet and surpass the needs of medical professionals and patients. Working with the medical professionals who use our products, we have continued to improve the quality of care available to patients by solving real clinical problems and finding better ways to make products that will last longer and perform at a higher level. In 2007, the Company's sales topped $6.0 billion.

As for me, I started working at Stryker in 1988 and in 1989, I became the President of Osteonics Corporation, the orthopaedic implant part of Stryker Corporation. In late 1998, Stryker purchased the Howmedica orthopaedic implant business from Pfizer and Osteonics became Howmedica Osteonics Corporation, which is now known as Stryker Orthopaedics and is based in Mahwah, New Jersey.

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paid them for their efforts. How much did Stryker pay? Stryker paid what it believed to be fair market value for the services that had been provided.

Stryker has other types of contractual relationships with surgeons as well. For example, some surgeons are great teachers. One surgeon from Massachusetts has a strong interest and understanding of ceramic technology. He uses that knowledge and expertise to help other surgeons understand when this technology might be appropriate for their patients. Another surgeon from Georgia helps Stryker teach Japanese surgeons about the benefits of a new knee design that can help their patients kneel and squat more easily. Finally, certain surgeons are outstanding peer-to-peer implant technique teachers. One surgeon from Michigan regularly teaches his peers – in sawbones classes, in cadaver labs, and in his own operating room – by demonstrating the proper use of our newly developed computer navigation technology for hip and knee replacement surgery – all with a goal of enhancing patient outcomes. We retain these consultants' services because they help us teach the proper use of our products, and this has helped our business grow.

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The September 2007 settlements related to the investigation have provided our industry with a level playing field so that each company will play by the same set of rules regarding contracting with health care professionals. Surgeons, who are absolutely crucial to product design and development, will be paid fair market value for their services. Other surgeons who are great teachers will be paid fair market value to train their fellow healthcare professionals about the features and benefits of certain products.

Stryker firmly believes that all of the competitors in our industry can and should compete on a level playing field. The recent settlements with the U.S. Attorney provide a strong framework to ensure that this occurs and Stryker intends to honor its commitments to the U.S. Attorney in both spirit and principle. In the years ahead, we look forward to competing on the basis of how our products and services meet the demands of surgeons and patients. We look forward to continuing to interact with consulting surgeons who have so much to offer in terms of enhancing the treatment of patients everywhere. These collaborations will continue to bring innovation and improvements in patient care.

Thank you again for the opportunity to express Stryker's views. I would be pleased to answer any questions that Members of the Committee may have.

The Chairman. Thank you, Mr. Lipes.

Mr. Phipps.

STATEMENT OF CHAD PHIPPS, SENIOR VICE PRESIDENT, GENERAL COUNSEL AND SECRETARY, ZIMMER HOLDINGS, INC., WARSAW, IN

Mr. PHIPPS. Mr. Chairman and members of the Committee, my name is Chad Phipps, and I am senior vice president and general counsel of Zimmer Holdings, based in Warsaw, IN. I am pleased to testify today on behalf of our company. Your Committee has taken a real leadership role on this important issue, and it is a privilege to be able to provide our insights and to describe our strong support for the chairman's legislation. I will make brief, summary comments in this oral statement and ask that my written testimony be included in the record.

We at Zimmer are proud of our 80-year record as a worldwide leader in providing orthopedic and other medical devices. We serve millions of patients who suffer from debilitating conditions, and we contribute to health care systems in over 100 countries.

The subject of this hearing—the relationships between physicians and the medical device industry—warrants some historical context.

The industry has transformed patients' lives through a combination of clinical knowledge and engineering. This combination brings the insights of highly skilled physicians who work directly with patients together with the technical knowledge of engineers who design and build safe and effective devices. Surgeon training on the use of products has also been central to the significant benefits that patients have experienced with these devices.

Over the years, as devices and procedures expanded in number, complexity and impact, so too did the industry's investment in the collaboration that made them possible. Despite what were then regarded by industry as appropriate programs to manage these circumstances, with hindsight it now appears that as industry expanded to meet patient needs, the use of consultants may have been excessive at times. Such excesses fostered a degree of mistrust 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.

Zimmer's continuous consideration of our own compliance standards, combined with measures taken beginning in 2003 by the HHS I.G. and AdvaMed, prompted Zimmer that year to reevaluate our model for the management of conflicts of interest and led to the implementation of our enhanced 2005 corporate compliance program. Now, as we buildupon that foundation, we are applying further discipline to ensure we align collaboration strictly with necessity.

In September 2007, Zimmer and four other orthopedic companies signed agreements with the Federal Government to resolve a DOJ investigation that began in March 2005 pertaining to past consulting relationships with health care professionals.

Under the resolution, Zimmer entered into a deferred prosecution agreement, without admitting any liability. We agreed to pay a

civil monetary sum and to be subject to oversight for 18 months by a federally appointed monitor. The U.S. Attorney's Office acknowledged that the agreement does not allege that our company's conduct adversely affected patient health or patient care. As part of the settlement, Zimmer also entered into a 5-year corporate integrity agreement with the HHS I.G. We are taking our obligations under these resolution agreements extremely seriously, and they are a top priority for our company.

Zimmer welcomes the opportunity to outline the additional progress we have made since signing these agreements. We also wish to express our commitment to go beyond their requirements, to set a new industry standard that will meet the needs of both patients and the health care system.

Our broader commitment includes fundamental changes in product development, marketing, surgeon training, educational and research funding, and transparency. Let me share just a few examples of the changes we are putting in place while we continue to define the full scope of Zimmer's program.

First, our sales and distribution teams, and individuals with daily responsibility for sales support, will have no involvement with physician consultants concerning agreements, services and payments.

Second, we are reviewing our existing royalty-bearing hip and knee development agreements to ensure that they are consistent with the fair market value principles of our corporate compliance program.

Third, with respect to Zimmer's future funding of medical fellowships, residencies and general educational programs, we plan to make cash donations to independent, third-party institutions. They will choose the programs that will receive Zimmer funding globally, and we will have no influence over the selection of the recipients.

Fourth, Zimmer's future charitable activities will include product donations to independent, third-party charitable institutions. They will distribute the donated products in areas of the world with great medical need. Again, Zimmer will have no control over their distribution and no influence over who receives them.

Finally, while the industry code of ethics currently allows certain educational, practice-related or branded company gifts to health care professionals, Zimmer restricted such gifts as part of our 2005 compliance program, and we will now move to prohibit them altogether.

As we continually improve our compliance program, we will implement the changes globally across our entire business, which also goes beyond the requirements of our resolution agreements with the government.

Mr. PHIPPS. In closing, we acknowledge that initiating change is often difficult. Nevertheless, we will carry these initiatives forward because it is the right thing to do for patients, our company and the industry as a whole.

Mr. Chairman, we appreciate the committee's consideration of our views, and I look forward to your questions.

[The prepared statement of Mr. Phipps follows.]

Prepared Testimony of Chad F. Phipps
Senior Vice President, General Counsel and Secretary
Zimmer Holdings, Inc.

U.S. Senate Special Committee on Aging
Hearing on "Examining the Relationships
between the Medical Device Industry and Physicians"
February 27, 2008

Mr. Chairman, Senator Smith, and members of the Committee, I am pleased to testify in front of you today on behalf of Zimmer, as this panel examines the relationships between the medical device industry and physicians. Your Committee has taken a real leadership role in examining this important issue, and it is a privilege to be able to provide our Company's insight as part of the information you are gathering in this area.

Zimmer was founded more than 80 years ago and is a worldwide leader in designing, developing, manufacturing, and marketing orthopaedic reconstructive and other medical products. More than 7,500 Zimmer employees are at work today all around the world, and their commitment is to provide effective, innovative solutions to relieve the pain of arthritis, other debilitating musculoskeletal conditions, and traumatic injuries experienced by millions of patients, and to restore their mobility and productivity. Our hip and knee joint replacement systems and our wide range of other products and services make us valuable contributors to healthcare systems in over 100 countries, and it is that global perspective I hope to bring to the Committee today.

The world of medical devices is on the threshold of change. In the near future, our aging population will create a surge in demand for innovative products that meet clinical needs. A dramatic increase in the prevalence of arthritis, obesity, and other chronic conditions, combined with the ongoing incidence of debilitating acute conditions, will significantly increase the need for joint replacement and other medical technologies that maintain quality of life and productivity.

As a leader in the medical device industry, Zimmer is focused on how to meet the profound needs of an aging population at a time when the rise of these chronic conditions and the ongoing burden of acute conditions will drive healthcare consumption and productivity losses to unprecedented levels. We believe it is essential to understand and address what it will take for our Company and our industry to meet the needs of the patients of the future and the healthcare systems that serve them.

The subject of this hearing – the relationships between physicians and the medical device industry – warrants some historical context at the outset before we detail how our Company is responding to the challenges these relationships present, and why we are supporting the Physician Payments Sunshine legislation co-sponsored by Chairman Kohl.

The medical device industry has transformed patients' lives through a rare combination of clinical knowledge and engineering, bringing the insights of highly

skilled physicians who work directly with patients together with the technical knowledge of engineers who design and build safe and effective devices.

This collaboration has been the heart of a product development model that continues to identify and address profound unmet patient needs. Because physician skill level is a key driver of successful patient outcomes, physician training on the safe and effective use of today's complex products and procedures has also been central to the significant benefit patients have experienced with medical devices. We note that the federal government recognizes the importance of collaboration in our industry and is focusing its efforts not on eliminating collaboration, but rather on determining models for appropriate and necessary collaboration.

Over the years, as devices and procedures expanded in number, complexity, and impact, so too did the industry's investment in the collaboration that made them possible. Expansion in collaboration increased consulting relationships between industry and physicians, so that physicians could be paid for their intellectual property contributions as well as the services they provided while developing products and conducting the physician training necessary for successful patient outcomes.

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.

In April 2003, the Department of Health and Human Services' Office of the Inspector General issued voluntary compliance guidance to pharmaceutical manufacturers, to help them prevent healthcare fraud and abuse by promoting a high level of ethical and lawful corporate conduct. In January 2004, a new Code of Ethics on Interactions with Healthcare Professionals, developed by our industry association, the Advanced Medical Technology Association, became effective.

Zimmer's continuous consideration of our own compliance standards, combined with these measures taken by OIG and AdvaMed, prompted us to re-evaluate thoroughly our model for the management of conflicts of interest that may result from collaboration. This re-evaluation, which we started in 2003, led to the implementation of our enhanced Corporate Compliance Program in 2005. Now, as we build upon that foundation, we are applying further discipline to ensure we align collaboration strictly

with necessity and aggressively reduce the risk of actual, potential, or perceived conflicts of interest.

As the Committee is aware, in September 2007, Zimmer and the four other leading U.S. orthopaedic companies signed agreements with the federal government to resolve a Department of Justice investigation that began in March 2005, pertaining to past consulting arrangements with healthcare professionals.

Under the terms of the resolution, Zimmer entered into a Deferred Prosecution Agreement, without admitting any liability. We agreed to pay a civil monetary sum and to be subject to oversight for 18 months by a federally appointed monitor. The government granted Zimmer a civil release and agreed not to pursue any criminal charges against our Company if we comply with the Deferred Prosecution Agreement. Further, the U.S. Attorney's office acknowledged that the agreement does not allege that our Company's conduct adversely affected patient health or patient care.

As part of the federal settlement, Zimmer also entered into a five-year Corporate Integrity Agreement with the OIG.

We are taking our obligations under the Deferred Prosecution and Corporate Integrity Agreements extremely seriously and they are a top priority for our Company.

Zimmer welcomes the opportunity to share with this Committee today the progress we have made since signing these resolution agreements and especially our commitment to go beyond their requirements. We are dedicated to setting a new industry standard that we believe will meet the needs of both patients and the healthcare systems that serve them.

At the time of the settlement, the U.S. Attorney acknowledged that Zimmer's 2005 Corporate Compliance Program provided many of the requirements contained in the agreements the five companies entered into with the Department of Justice. Our new initiatives in the area of compliance further enhance our 2005 Program and exceed the requirements of those resolution agreements.

We believe these new compliance initiatives will allow us to continue to deliver industry-leading products of the highest quality backed by business practices that inspire confidence and trust. Ultimately, our goal is to ensure that patients benefit from innovations focused on their needs, and that everyone with a stake in quality healthcare can trust that physicians choose products based on what they believe is best for patients. For this reason, we now endeavor to prevent even the appearance of impropriety.

As a market leader, it makes sense to us that our leadership position should extend to include best practices in the areas of compliance and ethics. We believe these best practices are necessary to ensure a vibrant future for medical technology and for the patients our industry serves – creating principles and systems that drive greater

transparency, innovations that solve unmet patient needs, and value to the healthcare system over the long-term.

Our broader commitment includes fundamental changes in product development, marketing, surgeon training, educational and research funding, and transparency. We are currently finalizing the specific strategies that will comprise this broader plan.

Today I would like to share with the Committee a few examples of the changes we are putting in place while we continue to define and communicate the full scope of the program:

First, our sales and distribution teams and individuals with daily responsibility for sales support will have no involvement with physician consultants concerning the agreements we enter into with them, the services that the consultants provide for us, and the payments we make to them.

Second, we are reviewing our existing royalty-bearing hip and knee development agreements to ensure that they are consistent with the fair market value principles of our 2005 enhanced Corporate Compliance Program and the terms of our resolution agreements. We have initiated this process and are currently communicating with consultants who hold these royalty-bearing agreements.

Third, with respect to Zimmer's future funding of medical fellowships, residencies, and general educational programs, we plan to make cash donations to one or more appropriate, independent third-party institutions. These third-party institutions will choose the programs and applicants that will receive Zimmer funding globally. Zimmer will have no control or influence over the selection of the ultimate recipients of these funds. This approach makes it possible for Zimmer to continue to provide worthy support to the education of orthopaedic surgeons around the world, while eliminating any possibility for inappropriate influence.

Fourth, Zimmer's future charitable activities will include product donations to one or more appropriate, independent, global third-party charitable institutions. These institutions will determine the distribution and application of these donated products in areas of the world with great unmet medical need. Again, Zimmer will have no control over the distribution of these products and no influence over who receives them.

Finally, while the current AdvaMed Code of Ethics allows for certain educational, practice-related, or branded company gifts to healthcare professionals, Zimmer further restricted such gifts as part of our 2005 Corporate Compliance Program, and will now move to prohibit them altogether. In lieu of providing gifts to individual healthcare professionals, Zimmer may make cash donations to appropriate, independent third-party institutions that will then determine the dissemination of education-related items.

As we work to make these and other changes, and continually improve our Compliance Program, we will implement these improvements globally across our entire business, a commitment that also goes beyond the requirements of our resolution agreements. We will enhance our efforts to align all business units consistently throughout the world behind these best practices. We are pursuing these priorities with a commitment to ensure that when our products are chosen, it is because they are the best solution for patients. That is the sole basis upon which we want to compete, and the surest path forward to ensuring confidence and trust in our industry.

Given these commitments, we are strongly supportive of the Physician Payments Sunshine Act, introduced by Chairman Kohl and Senator Grassley, that aims to provide for the appropriate disclosure of relationships between medical technology companies and physicians. We believe that the goals of this legislation mirror the ideals of Zimmer and the medical device industry. Together, our collective goal is to ensure the highest quality care for patients.

Earlier this week, we sent a letter to Chairman Kohl, expressing our strong support for the Bill, and setting out our more detailed views on its provisions. I would appreciate if the letter could be made part of the record of this Hearing.

We acknowledge that initiating change is difficult. Nevertheless, we will carry these initiatives forward because we believe it is the right thing to do for our Company, our stockholders, and for the industry as a whole. Implementing these

enhancements will make it possible for us to focus entirely on what we do best, bringing to market products that enhance patients' lives.

Mr. Chairman, Senator Smith and members of the Committee, it has been a privilege to be able to outline the steps we are taking in this critically important area. As a company and as an industry leader, we believe our efforts demonstrate a firm commitment to a new standard for relationships between the medical device industry and physicians. We appreciate the Committee's consideration of our views as it exercises its important leadership on this issue.

I look forward to your questions.

The CHAIRMAN. Thanks a lot, Mr. Phipps.

Mr. White.

STATEMENT OF CHRISTOPHER WHITE, EXECUTIVE VICE PRESIDENT, GENERAL COUNSEL AND ASSISTANT SECRETARY, ADVAMED, WASHINGTON, DC

Mr. WHITE. Thank you very much, Mr. Chairman. My name again is Christopher White. I am the executive vice president, general counsel and secretary of AdvaMed, the Advanced Medical Technology Association. AdvaMed represents more than 1,600 of the world's leading medical technology innovators and manufacturers. These are companies that together produce the most advanced technologies, improving health outcomes across the entire continuum of care, from wound care to diagnostics to orthopedics, cardiovascular and beyond.

However, over 70 percent of our member companies are relatively small, with annual sales of less than $30 million per year. But taken together, our member companies' constant innovation in the United States leads the world in cutting-edge medical technologies.

Mr. Chairman, I wish to be clear. AdvaMed supports the appropriate disclosure of relationships between medical technology companies and physicians. We recognize that strong ethical standards are critical to ensuring the valuable collaboration between the medical device industry and health care professionals. We have been very pleased to work with you, Mr. Chairman, your staff, Senator Grassley and the Physician Payments Sunshine Act, and we thank you very much for your openness to our recommendations.

This morning, I would like to highlight three points specific to the legislation and its relation to the medical device industry. One, I would like to further highlight industry's unique interactions with physicians. Two, I would like to highlight our commitment to compliance. Three, I would like to provide some thoughts relative to the legislation itself.

First, as you have heard today and on the earlier panel, medical device companies develop ongoing relationships with physicians. These relationships are essential to developing new treatments and ensuring medical technology can be used safely and effectively. In short, physicians are inventors of new medical technologies. They are skilled advisers to medical device companies in improving existing technologies. They are researchers. They are trainers of other health care professionals. They are trainees themselves by companies who develop new, breakthrough technologies requiring sophisticated deployment or activation.

Of course, physicians are also our member companies' customers. In short, physicians play a central role in our health care delivery system. They wear many hats in their interactions with medical device companies. As the Congress examines these relationships, we urge the Committee to approach the matter with surgical precision to avoid any inadvertent harm to the many beneficial collaborations detailed further in my written testimony.

Second, while the close and ongoing collaboration is necessary to develop new medical technologies, we recognize and respect the need for health care professionals to render independent decision-

making relative to product selection. That is why we developed a code of ethics to help distinguish those interactions that contribute to the advancement of medical technology from those that could be viewed as influencing the medical decisionmaking process inappropriately.

Let me assure you that this is not merely lip service. Our industry's commitment does not stop with the code of ethics itself. We have taken aggressive steps to educate the health care industry about the code. We will be presenting before medical specialty societies in the very near future, including next week. We have engaged in outreach on a sustained basis over time. It is a continued priority as we move ahead on this issue and in this area.

Sometimes we present alongside enforcement agencies to underscore that adherence to the code of ethics is beneficial to all stakeholders. Recently, our industry has adopted a code logo program to ensure that the code of ethics is not merely words on paper but rather to ensure that companies institute effective and lively compliance controls to implement the code of ethics. This is consistent with guidance from the OIG and its compliance effectiveness documents. In short, compliance is an ongoing process. It is a priority for our association, for our industry and for our member companies.

Finally, Mr. Chairman, we understand and we appreciate your desire to increase public understanding of industry relationships with physicians, and we, too, wish to ensure that patients get clear and meaningful information about how these relationships improve patient care.

In closing, I would like to highlight our four top priorities as we move forward.

First, we believe that the legislation should specifically preempt State laws requiring disclosure of relationships with physicians. Simply put, a patchwork of 50 laws all with different standards, different definitions of payments, different details, different contexts required in different formats on different systems on different Web sites will only cloud the transparency we all seek to promote. Instead, we support one comprehensive Federal standard so that patients will have clear information available on reportable payments from one source.

Preemption in the case of a new, strong Federal reporting standard, such as the one envisioned by this legislation, makes eminent sense, and it is not new. In fact, it is consistent with the preemptive effect of a similar national requirement to report the results of clinical trials overwhelmingly approved by the Congress last year in the FDA Act amendments.

Second, we are concerned, Mr. Chairman, that your legislation requires disclosure only from companies that exceed $100 million in annual revenues. We believe the goals of your legislation would be better served by adopting a threshold tied to a company's annual level of physician payments, regardless of company size. We advocate a metric requiring companies making $250,000 in reportable physician payments annually to participate in the disclosure program. This would provide an important level of transparency while still meeting your goal of exempting smaller companies that make relatively few payments to physicians.

Third, as outlined in our correspondence to the Office of the Inspector General and as discussed in the earlier panel, the emergence of physician-owned entities raises very important legal and policy questions regarding the potential effect on clinical decisions by physicians. As opposed to the collaborations addressed in our testimony among physicians and industry, which yield important advances in medical technology, these arrangements simply seek instead to leverage device purchasing into income-generating opportunities for physicians. The Office of the Inspector General, as you heard last year, in correspondence to AdvaMed stated that these arrangements should be closely scrutinized under the fraud and abuse laws, and the disclosure program proposed in your legislation should apply to these physician-owned entities as well, regardless of their size.

Finally, Mr. Chairman, I described the many hats that physicians wear in their interactions with medical device companies. We think that any legislation creating a public data base should give companies the opportunity to provide the context of those payments. If Sunshine is going to work, then patients need to understand what they are looking at and what it means. The absence of any context could serve as a disincentive for physicians to participate in the development and improvement of medical technology.

We believe that these recommendations together—creating an alternative threshold, including physician-owned entities, providing context to patients and preempting State laws to create a strong, central, Federal reporting standard—are all essential ingredients that must be included if the disclosure program is to meet the needs of patients and to be one that the medical technology industry can support. In addition, we have provided a number of more technical suggestions to the Committee that we have discussed with your staff. They have been attached to my written testimony and submitted for inclusion in the record.

Mr. Chairman, AdvaMed and our member companies want to stress again that we support appropriate disclosure of relationships between medical technology companies and physicians. We believe that the positions and recommendations set out in our testimony are constructive, reasonable and designed to make a Federal disclosure program work well for patients, for industry and to protect the essential collaboration that you have heard this morning.

Thank you very much for your openness to our recommendations. We look forward to continuing to work with you, your staff and Senator Grassley as this legislation moves ahead.

[The prepared statement of Mr. White follows:]

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SENATE SPECIAL COMMITTEE ON AGING

FEBRUARY 27, 2008

STATEMENT BY

CHRISTOPHER L. WHITE

EXECUTIVE VICE PRESIDENT, GENERAL COUNSEL AND SECRETARY

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

We thank the Committee for inviting AdvaMed to participate in today's hearing on the medical device industry's relationships with physicians. My name is Christopher White, and I am Executive Vice President, General Counsel and Secretary of AdvaMed.

Mr. Chairman, let me be clear that AdvaMed supports appropriate disclosure of relationships between medical technology companies and physicians. We and our member companies recognize that strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and health care professionals to produce the world's most advanced medical technologies. We have been pleased to work with you and your staff on the Physician Payment Sunshine Act, and we thank you for your openness to the recommendations we have offered to enhance the Federal disclosure program envisioned by your legislation. With some reasonable modifications to ensure a fair and level playing field for our companies, to provide clear, meaningful information to patients, and to preserve the relationships beneficial to patients and continued medical innovation, we believe our industry could support your legislation.

The Advanced Medical Technology Association (AdvaMed)

AdvaMed, the Advanced Medical Technology Association, represents more than 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of our member companies are relatively small companies with sales of less than $30 million per year. Our members are committed to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members manufacture nearly 90 percent of the $86 billion in life-enhancing health care technology purchased annually in the United States, and nearly 50 percent of the $220 billion in medical technology products purchased globally.

The medical technology industry is a critical component of the U.S. health sector. In addition to the profound contributions of medical technology to the health and well-being of the public, in 2006 the industry employed 357,700 workers; paid $21.5 billion in salaries; and shipped $123 billion worth of products. Taking into account the national multiplier impacts, the industry created: 1.96 million jobs; payrolls that totaled $93 billion; and $355 billion in sales. However, we are not just a major contributor to the U.S. economy based on revenues and jobs. The devices we make also help patients stay healthier longer as well as recover more quickly after treatment, thus allowing patients to participate more fully at work and in the community.

The medical technology industry is fueled by intense competition and the innovative energy of our member companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

Medical Device Company-Physician Collaboration is Essential to Safe and Effective Patient Care

Physicians are key partners in the development and improvement of medical technology. The innovative nature of medical device research and development involves on-going collaboration with physicians. Physicians have the critical field experience and expertise that guides our industry in creating new advanced technologies and procedures for patients.

Physicians are partners in many aspects of innovation. They are often the inventors of new devices, and it is critical that our industry work closely with them to move their innovative ideas from concept to reality. Other physicians make valuable recommendations on how to improve existing devices and provide ongoing consulting to provide expert technical assistance and feedback to companies in the development and refinement of those improvements. In short, physician expertise, feedback, and experience are critical to a robust and innovative medical technology industry.

In addition, device companies forge important training arrangements with physicians, essential for the safe and effective use of medical devices. How well a medical device works depends, in large part, on the skill and training of the physician utilizing the technology. A physician's technique with a complex medical device is critical. For many medical devices, physicians need hands-on education and training in order to perform medical procedures that utilize a device. This technique-specific nature of devices also makes physician involvement crucial to the training and education required after market approval, as specific techniques often need to be taught, and physician operators are best suited to provide this training to their fellow physicians. Moreover, because medical technologies undergo rapid, next generation improvements, some technologies require re-trainings with each advance. Some training on medical technologies requires travel to central facilities that can accommodate large medical technologies or specialized training facilities, such as simulated operating rooms or other health care facilities.

We should not forget that physician innovation and collaboration with the device industry has led to groundbreaking advances in patient care. Physicians have worked successfully with medical device companies to create technologies that benefit millions of American patients. Such advances include technologies to manage debilitating diseases like diabetes and heart disease, avoiding complications like amputation and long term disability; advance minimally invasive surgeries and instruments, allowing patients to recover faster and return to daily routines; restore basic functions such as hearing and vision; provide precise early diagnosis with in vitro diagnostics, often before clinical symptoms appear; and improve the speed, accuracy and availability of diagnostic imagery and x-ray equipment.

AdvaMed's Code of Ethics Guides Ethical Industry Collaboration with Physicians

AdvaMed and our member companies take very seriously our responsibility to ensure ethical interactions with our physician partners. We recognize that adherence to ethical standards is essential to the industry's ability to continue its collaboration with health care professionals. That is why AdvaMed developed a Code of Ethics to distinguish interactions that result in bona fide contributions to the advancement of medical technology, from interactions that may inappropriately influence medical decision-making. AdvaMed has taken aggressive steps to educate the industry and health care professionals about the Code, ethical interactions and compliance. A 2006 independent report found that nearly 100 percent of medical device companies surveyed have adopted the Code; it has been embraced by some health care professional societies; and has served as a template for international device industry codes of conduct.

The AdvaMed Code specifically addresses arrangements with consultants, member-sponsored product training and education, support of third-party educational conferences, sales and

promotional meetings, the limitation of gifts to modest, occasional items that benefit patients or serve an educational purpose and have a fair market value of less than $100, provision of reimbursement coding information, and grants and charitable donations.

AdvaMed makes it a top priority to ensure all of our members and the industry at large are educated about the Code and its importance in preserving essential relationships with our physician partners. Our member company compliance and ethics officers meet regularly to discuss compliance best practices and share ideas and experiences in operationalizing the AdvaMed Code. We speak regularly before provider groups, physician societies and industry groups to stress the importance of ethical collaborations and to further educate and inform regarding the Code of Ethics. More recently, development of our Code Logo program demonstates our leadership role in ethical practices and compliance. Under the program, companies that certify they meet the eight requirements outlined in a "Conditions of Use" agreement will be granted a license to display the "AdvaMed Code of Ethics Logo" on their corporate Web site, business cards, event displays and marketing materials.

The eight elements of our Code Logo Program align with the HHS Office of the Inspector General's (OIG) Compliance Program Effectiveness Standards and outline specific programs and processes firms must maintain to ensure effective compliance. Further, to reinforce that a company's commitment to ethical practices must originate at the highest levels, AdvaMed requires that the Code Logo certification be signed by a high-ranking corporate executive. Now, at a glance, health care professionals, patients and others can know they are dealing with a company that is committed to the highest ethical standards and has solid compliance programs in place.

Our industry's commitment does not stop with the Code. Member companies have dedicated substantial resources and put additional compliance procedures in place to make the Code even more specific for their employees and establish clear boundaries of acceptable practices. This is an ongoing process and a priority for our companies.

AdvaMed's Positions on S. 2029, The Physician Payment Sunshine Act

Mr. Chairman, after you introduced your bill, AdvaMed began a process with our companies to think through all of the issues that could arise from a disclosure program. It was important to our industry to approach this process in a thoughtful and comprehensive manner so we could provide very specific feedback and recommendations to your bill. As you know, we have developed a list of positions and recommendations that we believe will make a disclosure program work well for patients, physicians, and our industry. We thank you and your staff for your willingness to work with us on several provisions that are a top priority for AdvaMed.

- First, we believe the legislation should expressly preempt State laws requiring disclosure of relationships with physicians. A patchwork of 50 State laws - all with different standards of what types of payments must be disclosed, different details and context provided, all published in different formats and for different time periods – would be confusing for patients to interpret and burdensome for companies to comply with. Our industry supports one comprehensive Federal standard for disclosure (described further below) so that patients have clear information on reportable payments.

We understand preemption in certain contexts can be controversial, but in this case, it makes sense. The new Federal standard established by this legislation is a strong and robust one. It is simply unreasonable to expect companies to put in 50 different accounting systems to collect and report expenditures when a strong federal standard exists, particularly when the result would be to confuse rather than inform patients.

Congress recognized the importance of preemption under similar circumstances just last year, in the FDA Amendments Act, passed by both the House and Senate with overwhelming bipartisan support. Among other measures, the Act requires manufacturers to register drug and medical device clinical trials in a Federal database. This enables patients and physicians to have access to a single database to learn more about the details of clinical trials. The disclosure program under consideration in your legislation is similarly intended to serve as a central repository for information that patients can access easily. The FDA legislation's preemption serves the important purpose of preventing patients from having to navigate potentially conflicting and confusing State clinical trials databases; your legislation should do the same for patients seeking clear information about physician-industry collaborations.

- In addition, we are concerned that your legislation requires disclosure only by companies with more than $100 million in annual revenue. We believe the goals of your legislation would be better served by using a threshold that is based on the level of payments a company makes to physicians each year. Our view is that the legislation should require disclosure by any company that makes more than $250,000 in reportable physician payments annually. We believe this would provide an important level of transparency while still meeting your goal of exempting companies, such as many smaller companies, that make few of the payments covered by the legislation.

- Third, companies in which physicians both have an equity ownership interest and generate a substantial portion of the companies' revenues through ordering (or influencing orders for) devices sold or manufactured by the company, or through improperly influencing such orders or purchases in some other way, such as physician owned manufacturers, distributors, and group purchasing organizations that sell devices to hospitals at which the physician-owners treat patients, should not be exempt from disclosure under your legislation. As we explain today, AdvaMed recognizes the important and beneficial role of physician collaboration with device companies. On the other hand, the emergence of companies with equity investments by physicians who are also major revenue generators for the companies, raises important legal, conflict of interest and policy issues relating to the potential effect on clinical decisions by physicians.

  AdvaMed is concerned that at least some of the physician equity investments in device manufacturing or distribution entities for which physicians generate substantial revenues have the potential to create conflicts of interest between physicians' responsibility to provide the best care and physicians' equity interests which may compromise (or appear to compromise) the physician-patient relationship and could further serve to restrict patient access to the most appropriate advanced medical technologies. As opposed to the collaborations addressed in our testimony among physicians and industry, which yield

advances in medical technology, these arrangements instead seek to leverage device purchasing into income generating opportunities for investing physicians. The Office of the Inspector General last year stated in correspondence to AdvaMed that these arrangements pose a strong potential for improper inducements and should be closely scrutinized under the fraud and abuse laws. The disclosure program proposed in your legislation should apply to these physician owned entities regardless of their size.

- Finally, we think that any legislation creating a public database that reports payments to physicians should give companies the opportunity to provide the context of those payments. If "sunshine" is going work, then patients need to understand what they are looking at and what it means. As I described earlier, collaboration with physicians is essential to medical technology innovation. Our companies work with physicians to invent new devices, to improve existing devices, and to make sure physicians are trained to use our devices safely and effectively. That information needs to be clear to patients. A system that implies – even inadvertently – that all physician relationships are inappropriate would be a disservice to our physician partners who take very seriously their role to bring new technologies to patients. Even worse, a poorly designed disclosure program could serve as a disincentive for physicians to participate in the development, improvement, and training for medical devices at all. That would be a disservice to patients who are looking for the next breakthrough in medical technology that could improve their lives.

I've attached our full set of positions and recommendations, as adopted by our Board of Directors, to this testimony for inclusion in the record. We believe that these recommendations, including the key points I've made today – creating an alternative threshold, including physician-owned entities, providing context to patients, and preempting State laws to create a strong Federal standard for disclosure – are all essential ingredients that must be included if the disclosure program is to meet the needs of patients and is to be one that the medical technology industry can support. In addition, we have provided a number of more technical suggestions to the Committee – included in our full set of positions and recommendations – that are important in making the program workable for companies and useful for patients.

Mr. Chairman, AdvaMed and our member companies want to stress again that we support appropriate disclosure of relationships between medical technology companies and physicians. We believe our recommendations for the legislation are constructive, reasonable, and designed to make a Federal disclosure program work well for patients, while continuing to foster essential collaboration between the medical technology industry and our physician partners in innovation. We have appreciated your openness to our recommendations, and we look forward to continuing to work with you and Senator Grassley as your legislation moves forward.

I'll be happy to answer any questions you or other members of the Committee may have.

The CHAIRMAN. Thank you very much.

Mr. Lipes, in the agreement Stryker entered into with the Department of Justice it is mandated that your company adhere to the AdvaMed code of ethics on interactions with health care professionals, as you know. Was the company not complying with this code prior to entering into its non-prosecution agreement?

Mr. LIPES. No, sir, the company was complying, both the spirit and the intent of the AdvaMed guidelines from the time that they were issued.

The CHAIRMAN. Based on information Stryker provided to the Committee, it appears that your company provides very large payments for clinical trials. In fact, you reported $3.4 million in total clinical trial payments on your Web site. This is quite disproportionate to what other companies provide for clinical trials. One of your competitors only spends roughly $127,000 on clinical trial payments. Can you explain to us the discrepancy between your large payments for clinical trials and what appears to be typical industry practice?

Mr. LIPES. We are confused by that as well, Senator. We have asked the U.S. Attorney's Office to help us understand how other companies may have accounted for their clinical studies. Because for us, clinical studies are a vital part of us determining how well our products are performing. We are required to do clinical studies for the approval of some of our products, whether it is through a 510(k) or through the PMA process. The PMA requires that we continue to follow those patients after the product has been approved.

We make every effort to perform some type of clinical study on all of the products that we have developed so that we have some context for understanding how well that product is performing in patients and whether or not we have achieved the clinical or the design goals that we set out. So I am very surprised at the discrepancy, and I think that further understanding of how different companies have accounted for that will clear up the discrepancy.

The CHAIRMAN. Good.

Mr. Phipps, in its written statement, the HHS OIG outlined a wide variety of specific violations of law and unethical practices it uncovered prior to the settlements entered into by your company with the Department of Justice. Throughout an interview with Committee staff, you maintained that Zimmer had little if any specific knowledge of the evidence or charges that the U.S. Attorney might bring against your company. So I find it surprising that Zimmer still agreed to pay the government $170 million in its deferred prosecution agreement. Is it still your view that you were largely unaware of what specific wrongdoing had been discovered? If so, why did you agree to pay $170 million?

Mr. PHIPPS. Yes, Mr. Chairman, that is true that we did not receive any facts from Mr. Christie's investigation at the time of the settlement or since. He has never provided any facts to our company as to what they uncovered in the course of their 2-year investigation.

As far as why we settled, it starts with, as a public company, first and foremost what is in the best interest of our shareholders and also what is in the best interest of employees and patients. We deemed that the settlement was in the best interest of these stake-

holders. We negotiated a settlement that allows us to continuously strengthen our compliance practices while still allowing us to move forward with necessary and appropriate collaboration, and we felt that it is important that we have the ability to continue to do that in a proper manner.

The resolution agreement also incorporates many of the features of Zimmer's corporate compliance program, which was important to us, and the U.S. Attorney imposed requirements of Zimmer's program across our industry through these agreements. The fact that we were able to settle without admitting to any wrongdoing—and if we comply with the DPA for 18 months, then we will have a Federal release. Those are all important factors.

Then the flipside of that is what if we didn't settle? Maybe that is even more important when you are in our shoes at that point. It would have been a long, drawn-out investigation taking multiple years most likely. We would not want to be in a situation where we are the only company of the five that did not settle. There would be a cloud of uncertainty hanging over our company and our stock for a long period of time.

The ultimate risk for a company in our position is that if you face prosecution and ultimately do not prevail in your defense, you may be excluded from participation in the Federal health care reimbursement system, which is in effect a death penalty for a company such as ours. Then finally, the U.S. Attorney looked me in the eye and said, I have a case that I can prove against your company beyond a reasonable doubt. I had to take him for his word on that, even though I don't have their facts——

The CHAIRMAN. All right.

Mr. White, as you have testified, your association created a voluntary list of ethical guidelines to address the questionable practices that we have been discussing today. As part of its settlement with five of the orthopedic device manufacturers, Justice Department mandated that companies follow the AdvaMed code of ethics. Why would it take the government's legal intervention to force compliance with your code by some of the industry's largest companies?

Mr. WHITE. The AdvaMed code of ethics is a voluntary code, however it does have meaning in our industry. It has been replicated internationally by other trade associations abroad. It has been borrowed from and adopted by medical trade associations.

As a voluntary trade association, we lack the resources and don't have the ability to enforce the code itself. However, we do have a sustained outreach and a real commitment to bring the words to life within organizations, and we have implemented a number of programs including the code logo program that I have described to you to ensure that the code of ethics has meaning within our member companies and within our industry.

The CHAIRMAN. Thank you.

Senator Corker. Then Senator McCaskill.

Senator CORKER. Mr. Chairman, again thank you for a great panel. It appears to me that you have created a piece of legislation that is addressing a need. It appears to me that people on both sides of the equation agree generally with it. It appears to me that Mr. White in his four points has addressed some things we might

want to look at in making the legislation even better. I would have to say this has been an excellent hearing.

You know, I am aware that we live in a world that if you can make a little money doing something a little bit, you can make a whole lot more doing something a whole lot. That is obviously what we have seen in our credit markets right now. We are seeing a lot of corrections take place throughout our country, and it is going to take some time for that to settle out.

I guess, you know, seeing that both industry and those proponents of stronger ethics agree on this legislation, I just would like to ask the two industry folks who are here, will this legislation, in your opinion, truly be time tested and will it, in fact, solve the problem of over-utilization and zealous sales, if you will, as it relates to consulting arrangements? Do you think this will adequately address the problem for the long term, or are there other things we ought to look at in this regard?

Mr. LIPES. Senator, I believe that the proposed legislation, with the amendments Mr. White spoke about in combination with the AdvaMed guidelines and in combination with the changes that all the companies have made in the orthopedics industry as a result of this Department of Justice investigation, will result in a significant reduction if not elimination of the kinds of abuses that we have seen in the past.

Mr. PHIPPS. Yes, we have a unique experience here because we have been posting, as you know, under our deferred prosecution agreement, our hip and knee consulting payments as part of that agreement since October. I think the reaction to that has been mixed, but I think it is a positive. I think most surgeons understand it. We understand it. It has been a good way for us to take a look at our business and where we are spending money and using consultants.

I do think one thing I would suggest, and it is in our letter, Mr. Chairman, to you, that we think is important is that there not be exemptions for companies that are smaller. We think that if there is going to be transparency, it needs to be across the board. There should not be an exemption, we don't think, for companies based on not having large revenues or not using consultants as much. It should be fully transparent across the industry. That is important for us, and we wanted to put that on the record as well.

Senator CORKER. Mr. Chairman, I would just like to make a comment. I know that we will be able to work with your staff privately in this regard, but I would have to agree. I think one of the comments yesterday in just going through your legislation, which it seems to me that truly you have done something here that needs to be done, and it looks like something that we ought to pass through with unanimous consent in the Senate. I am sure that will happen very quickly.

But it does seem to me that, "being able to abuse your way to a certain level and then have to comply in a different way doesn't make a lot of sense."

It seems to me that we ought to have transparency at all levels, and that does make a lot of sense to me, and I hope that we will be able to work with you in that regard.

I want to thank you again for what I think has been an excellent hearing that has vetted your piece of legislation, which it seems to me is most needed. I want to thank you for addressing that need. Thank you, sir.

The CHAIRMAN. Thank you very much, Senator Corker.

Senator McCaskill.

Senator MCCASKILL. Thank you, and I meant to tell you, I think one of you all is responsible for something that is in my right knee, and some days—I am glad I don't know which one of you it is, because some days I would like to say thank you. Today is a day I would not say thank you to you, so it is a good thing that I don't know which one of you is responsible for the device that was my complete knee replacement that I had about a year ago.

I am a little incredulous about some of this. I don't mean to pick on you, Mr. Phipps, but I am going to talk a little bit about your company. Based on the testimony that you just gave the chairman, what you are basically saying is that your company thought it was a good deal to pay $170 million to the government even though you have done nothing wrong?

Mr. PHIPPS. Senator McCaskill, I did not say we did nothing wrong. What I said in response to the question was that the U.S. Attorney never provided us any facts for what they uncovered under their investigation. We have done our own reviews and investigations internally over the years. We have made significant improvements as we have had experiences and learned more information.

In 2003, for example, we learned that these inherent conflicts of interest, where you have customer, vendor—consultant being the same people, that this is an area that is subject to abuse. We put in place a very robust compliance program that was implemented in 2005. This investigation, it is important to note, covered 2002 through 2006. Our compliance program came into place in 2005.

So in the past we think there were excesses, and frankly, we have found some of those excesses and addressed them with our program. We are using this settlement phase of our investigation to turn the dial up another couple of notches and to continuously improve. It has been an evolution.

But there were excesses in the past; there were abuses in the past, not unique to Zimmer, but across our industry. I believe all companies that face that inherent conflict of interest are subject to the same problems, and I think people that say that there weren't excess have had their head in the sand, frankly, and it was a problem. We feel like we have addressed it.

Senator MCCASKILL. So the issue wasn't that there weren't facts there. The issue was that you all found the facts yourself that indicated that prosecution was a real problem, and somebody could maybe go to jail, and therefore it wasn't necessary for your company to demand the facts? Because, I mean, I have spent a lot of time as a prosecutor in my life. I can't imagine getting a defendant to pay $170 million without producing anything to convince them that they have done something they might go to jail for. So what you are saying is that you all didn't demand those facts from the U.S. Attorney because you had done the internal investigation and

conceded that there could be potential criminal liability for what you all had done.

Mr. PHIPPS. We did respectfully request those facts, both before we settled as well as we have done that since. Because in my position, I would like to know if they found things that may involve individuals still with our company or relationships with doctors that we still have; I would want to know that.

They have declined in each instance to provide that statement of facts. I am not sure if it exists or not, but they have not provided it. But we believe, based on our own reviews that we have done, that there were excesses in the past and we feel that it was important to settle this investigation.

Senator MCCASKILL. I guess it is possible they may be holding their version of what they have found because this is a deferred prosecution agreement. There has been no agreement; there has been no dismissal with prejudice of any criminal charges. This is merely agreement that says—it is kind of like, you know, what we call probation. When somebody robs a bank, they get probation. When it is sometimes a big company, they get deferred prosecution, as opposed to actually having to establish that you have to plead guilty to something. Is that a fair——

Mr. PHIPPS. That is fair. There were three other companies. All four of us had a criminal complaint filed against us. If you look at that complaint, you will see it is very bare bones. There are no facts alleged in that complaint whatsoever, but——

Senator McCaskill. OK. Let me ask you this. There is $170 million that you are paying out of your company, and I know your stockholders are aware of that. Aren't you also paying tens of millions of dollars to former Attorney General Ashcroft for monitoring this?

Mr. PHIPPS. Over the course of the 18 months, we do expect to pay tens of millions, yes.

Senator McCaskill. How much do you think—what have you told your shareholders that you are going to have to pay? It is my understanding this was not a competitively bid contract, and that your company is on the hook for it. What are you estimating that you are going to have to pay former Attorney General Ashcroft for monitoring your company?

Mr. PHIPPS. Based on the estimates that they provided to us, which is $1.55 million to $2.9 million per month, that ends up being in the range of $28 million to $52 million over the course of 18 months.

Senator McCaskill. I have looked at some of your disclosures for 2007. That seems to me much higher than any of the money you are paying any of the doctors, correct?

Mr. PHIPPS. That is correct. On an hourly basis, we pay surgeons $500 per hour. I am not sure what it equates to with our monitor.

Senator McCaskill. You know, the reason that this is obviously a concern to us is because we deal with constituents all the time that can't get health insurance, that can't afford health insurance, and we know that Medicare is one of the most incredible train wrecks that is coming in terms of our entitlements in our Federal budget, that Medicare costs are escalating, and obviously the taxpayers are on the line for that. I understand that this $170 million

and between $30 and $50 million you are going to pay Attorney General Ashcroft for a year and a half is not taxpayer money, but it all ends up getting into the mix because obviously the costs of your company are passed on, in terms of the cost of what you sell to the people that are performing these surgeries.

I want to focus for a minute on your disclosures. It seems to me if you have avoided prosecution by saying, "We are going to fully disclose," that it is really incumbent upon you all to decide you are really going to disclose. Now, here is what is confusing to me. I am looking at the document where you are admirably disclosing and what this law is going to require you to disclose, that for example you paid in 2007 a doctor in Deerfield, IL, $1.875 million. Now, I am assuming that that is for some kind of consulting. That is not for him doing—he is getting paid for doing the surgeries, too, correct?

Mr. PHIPPS. Yes, 75 percent of our disclosure is for royalties that people receive from being a developer of a product. So when you see our posting, about 75 percent in the aggregate is royalties. We have nothing to do with what he is being paid by his hospital or anyone else for procedures, if that is your question.

Senator MCCASKILL. So these big numbers are people who have been involved in the development of the product?

Mr. PHIPPS. Seventy-five percent of the total. If you tell me a particular doctor's name, I can——

Senator MCCASKILL. Well, like all the ones that are over a million and a half dollars?

Mr. PHIPPS. Yes, there may be some there that have also done, you know, training, so that would be a standard consulting fee. But in the aggregate, 75 percent roughly is for royalties.

Senator MCCASKILL. I would like to focus on the plane flights. What kind of corporate plane do you have?

Mr. PHIPPS. We have a Challenger and a Hawker.

Senator MCCASKILL. They are both jets?

Mr. PHIPPS. They are jets. We lease——

Senator MCCASKILL. Now——

Mr. PHIPPS. We lease at least one of them, maybe both.

Senator MCCASKILL. OK, we have spent a lot of time talking about the cost of private corporate jet travel around here as we passed the ethics bill, because some of us who just got here were really frustrated that some folks used to be able to hop on one of these corporate jets and travel around for pennies on the dollar as United States Senators and as Members of Congress. So we have now changed that, and now you must pay charter rate. So I am aware what it costs to fly one of these. Could you explain to me how a jet flight, a private jet flight, from San Diego to Indiana, is disclosed at $138?

Mr. PHIPPS. Yes, that is based on the IRS's standard industry fare level or the SIFL rate. I do not know anything about that area other than that is the normal way to calculate those rates using the IRS's standards.

Senator MCCASKILL. Well, you know, I don't get the word normal. I mean, to me that ought to be in quotes. This is about full disclosure. This is about the public understanding. I mean, if this

is your idea of full disclosure—there is no requirement that you disclose the IRS rate. It seems to me you ought to let people know.

You can't park a jet at an airport for $138, much less fly it across country. We are talking about tens and thousands of dollars per flight. I bet that flight from Indiana to San Diego cost between $20,000 and $30,000 easily. You know, wouldn't you want to fully disclose what you are actually paying as a corporation for the benefit of these doctors? Isn't that the idea behind this disclosure?

Mr. PHIPPS. Yes, none of those flights are for the doctors' benefit. Those are all for the company's benefit. They perform services on our behalf. They are taking time out of the O.R. to do a service that we need for training or for development, and it is not compensation to them. This is the first time we have disclosed any of that information. It is not 1099-type income to them.

Senator MCCASKILL. I understand—all the more reason not to use the IRS number. That is what that figure is for. That is an IRS number for purposes of computing income. But this is about public disclosure. I understand—you can make the argument that every single thing you pay to these doctors is not for the benefit of the doctors but rather it is for the benefit of getting their time and expertise.

The whole purpose of this disclosure and the whole purpose of the law we are proposing is so the public can get a true picture of the kind of money that is being put out in connection with these doctors so they can draw their independent judgment as to whether or not there is a conflict of interest. Will you all make a commitment that you will begin disclosing the actual costs of private jet flights for these doctors in the future?

Mr. PHIPPS. I will take that back and we will consider it. I personally am not an expert in that area, but I will take that under advisement and go back and talk to our people, yes.

Senator MCCASKILL. Mr. White.

Mr. WHITE. I represent AdvaMed, the Advanced Medical Technology Association, and speaking on behalf of industry, we have communicated our views that it is critical to have the context surrounding these disclosures described. The companies are in the best position to provide that description, and for that reason we have offered our recommendations to this legislation that would provide the context, so that you are not only looking at a physician name and address and a dollar amount but the context of that payment.

Senator MCCASKILL. You know, nothing is keeping any of your members from disclosing a whole lot right now. I mean, if you really want the public to understand what is going on, all you have got to do is tell them. It doesn't take an act of Congress, candidly. It shouldn't take a threatening criminal prosecution.

I mean, the disclosure that we are talking about today, frankly, it is kind of discouraging that we even have to get government involved. It ought to be something that you ought to see as the right thing to do in terms of the public fully understanding this relationship because of the allegations that are naturally going to rise up from this kind of relationship.

What about your company, Stryker, are they willing to disclose the actual cost to the company of these jet flights that these doctors are taking?

Mr. LIPES. From 1989 till 2003, when I ran the orthopedics business at Stryker, I am not aware of a single time when we flew a surgeon on a private jet.

Senator McCaskill. OK, I think you all understand the point I am making. If you are worried about context, you know, they can context right now to their hearts' content. They can get on their Web site and they can start telling the public exactly what they are paying, who they are paying, how much and for what. There is nothing we are going to do to stop you.

So I think it is kind of ironic that you are worried about this legislation not having context. You can provide context without a government mandate, and we would hope that you would.

I thank you, Mr. Phipps, for taking back to your company the fact that I think it is a little disingenuous to call a private flight less than 100 bucks when the cost is many, many, many times that. I hope your company will consider doing the right thing in that regard.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator McCaskill.

Senator Coleman.

Senator COLEMAN. Thank you, Mr. Chairman.

First, let me thank you and Senator Smith for holding this hearing. Let me also thank you for your leadership on this issue. I think as a Ranking Member on the Permanent Subcommittee on Investigations, we have focused on rooting out waste, fraud and abuse in our health care system. We have a hearing coming up on Medicare fraud in a very short period of time. So I just want to personally thank the chairman for his leadership here.

I am a firm believer that sunshine transparency is the best disinfectant, and certainly this hearing is about that. Today, the Physician Payments Sunshine Act may be a good place to start but should be improved in ways that will actually provide greater transparency and greater oversight. So I look forward to working with you and my other colleagues, Mr. Chairman, on this issue.

In terms of transparency, Mr. White, AdvaMed has a code of ethics, but clearly there has been discussion today that says we have got to go beyond that. As you reflect on the code of ethics, are there areas now where you think you may want to kind of push further than where you are at today?

Mr. WHITE. Absolutely, I agree with the comments expressed earlier that the code of ethics needs to be more than words on paper, and we share the concerns and will rise to the challenge of ensuring that the code of ethics is more than words on paper. I think in the context of the deferred prosecution agreements, we have seen those agreements break new ground on the legal front. There are arrangements that are addressed in those agreements that are not addressed in any other legal authority, specifically royalties, and I think that is an area that is potentially ripe for inclusion in the AdvaMed code of ethics.

As I indicated earlier, we have a dedication to the code of ethics. We have a three-part infrastructure within our association that

brings together CEOs, lawyers and compliance officers within 2 weeks of the deferred prosecution agreements. We convene meetings of our compliance officers to discuss seriously next steps in this area, and we would look forward to advising you, your staff and the Committee as we move forward.

Senator COLEMAN. I think it would be extremely helpful to kind of look beyond royalties as one area, but I think that is—you may have stated this before; I may have missed it—but in terms of adherence to code of ethics or enforcement of code of ethics, what sort of powers do you have there? Then how do you actually ensure that members comply with codes of ethics?

Mr. WHITE. Well, quite frankly, we are limited in that area. We are a trade association. We are bound by the antitrust laws and other authorities, and so we don't have specific legal authority or we are not deputized as an enforcement agency to undertake specific enforcement actions. Instead, we educate, we provide outreach and we have implemented the code logo program to ensure that there is a commitment of the top-level executives of our member companies to the code of ethics to ensure that there is robust training and education, auditing and monitoring and so forth.

So we believe that the code of ethics together with these other procedures to make it come to life within organizations is an important step forward. Can we do more? We can, and we pledge to work with you.

Senator COLEMAN. One of the things that I have noticed here is if you don't do it yourself, government may tell you how to do it. So it becomes critically important to make sure that there is a very robust and broad code of ethics with transparency, including many of the issues that have been raised today, or certainly we may find the need to require that, and then it becomes a whole different process.

There is no question, though, that collaboration is important, as my concern on so many of the things is you get a few bad actors and then you have a reaction to that—doctors reluctant to collaborate with device manufacturers to improve product and patient care. My State medical device industry is one of the giants. We pride ourselves on being the center of medical technology, and a lot of the tremendous enhancements in quality of life have come about because of innovation.

Talk to me a little bit about the other side. Perhaps this is Mr. Phipps and Mr. Lipes. Are one of the unintended consequences of some of the problems we have been raising now and the concerns being raised—are we looking at a decrease in critical collaboration? Are we seeing any impact to that, Mr. Lipes?

Mr. LIPES. Well, one of the requirements we have in our nonprosecution agreement going forward is that we establish a formal comprehensive needs assessment each year that is approved by our compliance officer and approved by our monitor and the U.S. Attorney that lays out exactly what our relationships are going to be with our consulting surgeons, how we are going to use them, and then all payments that will be made will be compared against that needs assessment.

Our needs assessment has just been approved this week. So for the past month and a half, we have had very little activity with

surgeons, as we have waited until that needs assessment is done. I am optimistic that the needs assessment reflects what our business requirements are for input from consulting surgeons, and it will continue to be a very, very productive and fruitful relationship.

Senator COLEMAN. Mr. Phipps.

Mr. PHIPPS. Yes, Mr. Lipes is correct that the annual needs assessment is the key. Again, that came from Zimmer in 2005, so we have been doing that for several years now. But really what we are doing is making sure that when we consult with health care professionals, it is to address one of three things and only one of three things. That is, patient safety, improved outcomes and addressing unmet clinical needs.

So we define that needs assessment at the beginning of the year, and it needs to be very buttoned down, as far as there is little room for adding things throughout the year. So I think those excesses that we talked about before will no longer be an issue. But, as we have gotten up to speed with our monitor these last 4 or 5 months, there has been a big slow down, but I think we are now starting to get to a point where we are going to get into a groove with our monitor and be able to perform services pursuant to that approved needs assessment.

Senator COLEMAN. I think if there were clear codes of ethics, clear understanding compliance with what would hopefully be a Physician Payments Sunshine Act, that you would have more clarity of mind in terms of physicians and others understanding how they can operate without fear of action against them. I think you need to have that in place because clearly it is cloudy today, and clearly there are concerns that are out there. This has not all been—we have not played this out to the final step.

Just one last question. Assuming, then, we enact the Physician Sunshine Payments Act and we gather data, I would be interested in your assessment of how the public would actually use this data when shopping around for health care services? Is there something in place or a sense that in fact it could be usable? Does it have to be in a certain form to be usable? How would folks actually make use of what we are trying to gather here of this greater transparency?

Mr. Lipes.

Mr. LIPES. Well, I think in the last 10 years, we have seen a dramatic shift in the kinds of information that patients bring into their surgeons' offices. Where as before they came in basically because the surgeon had been recommended to them, now they come in on average with stacks of information that they have taken off the Internet. So they do extensive amounts of research in advance before they go in to talk to that surgeon, asking about different types of procedures and technologies. I believe that if this information is available on the Internet, it will be another piece of information that that patient will have at their disposal when they walk in to the surgeon asking for some relief to the pain that they have.

Senator COLEMAN. Mr. Phipps.

Mr. PHIPPS. I think the onus should be on the surgeon and on his institution or practice to make sure that when those patients come in that they are getting that information provided to them and that there is full disclosure between physician and patient so

that the patient can make an informed decision. I think Senator Corker's right, that it is probably not going to change the mind of many patients, but they have a right to know.

Senator COLEMAN. So, White, from an industry perspective?

Mr. WHITE. We have given a great deal of thought to that question, Senator, and I think that it comes down to a few things. One, it is critical that we have preemption. We have one Federal Web site where patients can access this information rather than a series of company-specific or State-specific Web sites. That will only further cloud this question. If we are looking to deliver clear information to patients, it is better to have it on one Federal Web site as I indicated earlier.

Also, it is critical to have context. As we described in our testimony, medical device companies have multiple relationships with physicians, and it is important to provide the context for each of those patients so that there can be no misunderstanding that might diminish collaboration or diminish some of these important relationships. Finally, we think the full range of relevant relationships should be reported on the Web site, including equity investments by physicians and M.D.-owned entities.

Senator COLEMAN. Mr. White, I am a great believer in public-private partnership, and this should be an area where we should be collaborating so we can move the chairman's legislation forward. This is an area where I would welcome the collaboration of the industry and of AdvaMed. We have a good relationship that would be helpful in making sure we do it the right way.

Mr. WHITE. Thank you, we would be happy to help.

Senator COLEMAN. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Coleman. It has been a really good hearing. I think that we have shed light on an issue that is really important in our society. I think we all agree, and apparently we all see a path toward affecting some considerable improvement. It is something that doesn't occur at every hearing around here. So we thank you for being here with us, and thank you for helping us really advance the cause of something that is considered to be very important.

This hearing is closed.

[Whereupon, at 12:16 p.m., the Committee was adjourned.]

APPENDIX

SENATOR CLINTON'S QUESTIONS FOR GREGORY DEMSKE

Question. Of those OIG's inspections of the medical device industry wherein you found industry payments to be kickbacks designed to influence the physicians' medical decision making, how frequently do physicians made payment claims for these devices to private insurance, and how many make claims to the federal government?

Answer. In general, a high proportion of medical device usage and billing is related to Medicare patients. In the New Jersey investigation of 5 manufacturers of hip and knee reconstruction and replacement devices, physicians we interviewed reported that often 80% or more of their patients receiving the devices were Medicare beneficiaries. It is important to note that most medical devices are reimbursed by Medicare (and, for private patients, by their insurers) through payments to hospitals for the procedures in which the devices are implanted. Therefore, the physician is usually not submitting a claim directly for the device. We have found, however, that the hospital almost always uses the device that the physician recommends. Therefore, with respect to Medicare patients, there is a potential kickback violation because of the physician's ability to influence the use of a particular manufacturer's device.

Question. What steps can the government take to address concerns regarding claims made to both public and private insurance?

Answer. With respect to Federal health care programs, OIG addresses concerns about financial relationships between the medical device industry and physicians through enforcement, guidance, and outreach to stakeholders. Working with the Department of Justice, OIG investigates device manufacturers and physicians for possible violations of the Federal anti-kickback statute and False Claims Act. Criminal, civil, and administrative sanctions can provide a meaningful deterrent to illegal conduct. In addition to enforcement, OIG provides guidance to industry and physicians through compliance program guidance, fraud alerts, and widely distributed correspondence relevant to physician-industry financial relationships. Furthermore, OIG has reached out to stakeholders through presentations at conferences sponsored by non-profit groups such as AdvaMed and the American Academy of Orthopedic Surgeons.

The anti-kickback statute, which is the primary basis for government enforcement in this area, only applies to conduct related to Federal health care programs, including Medicare and Medicaid. Therefore, payments intended to induce the referral of privatee insurance business does not violate this statute. Similarly, the False Claims Act, the government's primary civil enforcement tool to combat fraud, only addresses fraud on the Federal Government and is therefore not implicated by improper claims to private insurance companies. Although kickbacks related to private insurance may raise antitrust concerns or potentially violate state laws, OIG does not have jurisdiction to investigate such matters.

SENATOR CLINTON'S QUESTIONS FOR CHARLES ROSEN

*Question.*You recommend that the exact dollar amount of any type of industry compensation from all companies to surgeons, particularly those who are writing papers and running professional organizations, should be available for all to see. Who, in your opinion, should be responsible for obtaining, monitoring and publicizing this information?

Answer. There could be a number of entities responsible for obtaining, monitoring, and publicizing complete financial disclosures of doctors receiving industrial compensation.

The companies themselves should have the legally mandated responsibility to obtain and disclose on their website in a readily available way the information every quarter. There should be significant penalties for non-compliance.

The FDA should require that this information be submitted to them so that it can be in one location on their website and encompass all the companies involved. The non-profit organization of the Association for Ethics in Spine Surgery as a watchdog group could also serve this role since it is the only such organization without industrial ties and is dedicated to full disclosure for the public good. The actions of both the FDA and AESS would go towards both monitoring and publicizing.

Perhaps the appropriate national medical societies could be required to put the information on their website.

Finally, intermittent and random auditing by the OIG should also be part of the monitoring and enforcement process.

Question. How many professional organizations exist that are similar to yours, in requiring that their members do not accept compensation from industry?

Answer. I know of no other professional organizations such as the Association for Ethics in Spine Surgery that requires their members to not have any compensation from industry.

SENATOR CLINTON'S QUESTION FOR EDWARD LIPES

Question. As a condition of your settlement with the federal government, you are participating in 18 months of federal supervision, which you claim helps to "level the playing field" in the medical device industry. Given that voluntary compliance mechanisms were not sufficient in your particular case, how do you suggest that industry improve its ethical standards without federal oversight like that you are currently receiving?

Answer. From the time I became President of Stryker Orthopedics in 1989, we have required our business leaders to follow certain procedures, systems, and controls to guard against abuse. Stryker has paid relatively low per diem rates to its surgeon consultants; had only a small number of royalty relationships; required its consultants to document their interaction with and on behalf of the company; and refused to engage more surgeon consultants than the company needs.

Post-settlement, the majority of our business practices have not changed because we were already complying with the terms of the settlement when actions were voluntary. I expect such practices to continue when the monitor's term ends.

The voluntary guidelines of the AdvaMed Code of Ethics and the terms of the settlement agreements signed by the five major competitors in our industry provide very strong standards that we believe will ensure a level playing field where all companies are working with surgeon consultants in a legal and ethical fashion.

Additionally, we are committed to work to seek reforms to put better controls in place across industry as necessary.

SENATOR CLINTON'S QUESTIONS FOR CHRISTOPHER WHITE

Question. How are you working with physician groups to improve cooperation with your new ethical standards? Why do you think some physician groups have adopted this Code but not others?

Answer. Even prior to our revised Code's effective date of January 1, 2004, AdvaMed engaged in extensive outreach activities, both to individual physicians and to physician specialty societies. We've been able to communicate the importance of the Code through individual letters to physician society executives, articles in medical journals, and presentations to physicians societies, among other outreach activities. We remain committed to working with physicians to foster widespread awareness and adoption of the Code. I speak about the Code regularly at society meetings—including, most recently, at the annual meeting of the American Academy of Orthopedic Surgeons in early March. On March 13, we formally shared, through verbal and written testimony, our perspectives on ethical interactions between industry and physicians with the Institute of Medicine's Committee on Conflicts of Interest in Medical Research, Education, and Practice. While we cannot control whether a particular physician group will officially adopt our Code, we are encouraged by the progress made both in industry and among health care professionals since the Code became effective.

Question. You suggest that any public database that reports payments to physicians should give companies the opportunity to provide context of those payments. Allowing companies to describe the nature of these relationships, however, has the potential to unethically construe and obfuscate the ethical shortcomings. Can you please expand on what type of context you mean, and how you would suggest maintaining consistent standards for payment reporting?

Answer. It is important to ensure that patients receive useful information and do not mistakenly form the opinion that all payments to physicians are suspect. This risk exists when there is no opportunity for a reporting company to give meaningful context to the reason for a reportable "transfer of value." For example, companies should be allowed to specify that payments are made for education and training—that is, to ensure that physicians are able to use medical technology safely and effectively. Simply listing a physician's name next to a payment amount does not give patients the opportunity to make informed decisions about the nature of the payment.

Moreover, to create and maintain consistent reporting standards, the legislation should authorize sufficient appropriations to create and maintain a centralized database and disclosure program, and should only require the disclosure of certain enumerated types of payments. This will standardize both the disclosure of payments by companies and the reporting of date to patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAR 14 2008

The Honorable Herb Kohl
Chairman, Special Committee on Aging
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

I am writing to address an inquiry regarding my written testimony for the Senate Special Committee on Aging hearing held on February 27, 2008, regarding financial relationships between medical device companies and physicians.

Based on a review of information provided to your Committee and the testimony, I have determined that one paragraph of my testimony is inaccurate and I therefore want to correct the record. On page 7 of the testimony, there is a paragraph discussing the conviction of Dr. Patrick Chan. The description of the case should be as follows.

> In January 2008, Dr. Patrick Chan, an Arkansas neurosurgeon, paid a $1.5 million civil settlement to resolve allegations that he accepted kickbacks from medical device manufacturers in violation of the False Claims Act. In a parallel criminal proceeding, Dr. Chan also pled guilty to one count of soliciting and accepting kickbacks from a sales representative selling products on behalf of several medical device companies. The criminal investigation found that Dr. Chan agreed to split the commission with the unnamed sales representative on any products that Dr. Chan utilized during, and after, his surgeries on patients. The government is continuing to investigate device companies that may have paid kickbacks to Dr. Chan and other physicians as part of this scheme.

Thank you for the opportunity to address this matter and correct the record.

Sincerely,

Gregory E. Demske
Assistant Inspector General
for Legal Affairs

cc: The Honorable Gordon Smith
Ranking Member
Special Committee on Aging

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March 11, 2008

Stephen M. Kuperberg
Partner
(202) 637-5768
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The Honorable Herb Kohl
Chairman
Senate Special Committee on Aging
SD-G31 Dirksen Senate Office Building
Washington, DC 20510

Mr. Chairman:

I represent Blackstone Medical, Inc., and I write in reference to the Special Committee on Aging's hearing on February 27, 2008 entitled "Surgeons for Sale? Conflicts and Consultants in the Medical Device Industry." Greg Demske, Assistant Inspector of Legal Affairs in the Office of the Inspector General at the U.S. Department of Health and Human Services, testified at the hearing. I write to request a correction of the record for a factual inaccuracy with his testimony.

On page seven of his written testimony, Mr. Demske submits, "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."

Respectfully, Mr. Demske's testimony is incorrect. On January 3, 2008, Dr. Chan pled guilty to solicitation of and remuneration from an unnamed distributor. Both the government's indictment and Dr. Chan's plea reflect that the unnamed distributor did not distribute Blackstone Medical products. The case against Dr. Chan had nothing to do with Blackstone Medical.

Enclosed please find a copy of both the Indictment against Dr. Chan, filed October 1, 2006, and a copy of the transcript of the Change of Plea proceedings dated January 3, 2008. As you will note, neither document contains any mention of Blackstone Medical.

I am requesting that this letter of correction be submitted for the official hearing record.

Thank you for your time and attention.

Sincerely,

Stephen M. Kuperberg

cc: Cecil Swamidoss
Jack Mitchell
Greg Demske
Gregg Shapiro

Attachments

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v. No. 4:06CR00344-01 SWW

PATRICK CHAN,

Defendant.

January 3, 2008
Little Rock, Arkansas
10:59 a.m.

TRANSCRIPT OF CHANGE OF PLEA PROCEEDINGS
BEFORE THE HONORABLE SUSAN WEBBER WRIGHT,
UNITED STATES DISTRICT JUDGE

APPEARANCES:

On Behalf of the Government:

MS. KAREN D. WHATLEY, Assistant U. S. Attorney
United States Attorney's Office
425 West Capitol Avenue, Suite 500
Post Office Box 1229
Little Rock, Arkansas 72203-1229

On Behalf of the Defendant:

MR. JAMES WINFIELD WYATT, Attorney at Law
Montgomery, Adams & Wyatt, PLC
221 West Second Street, Suite 408
Little Rock, Arkansas 72201

Proceedings reported by machine stenography and displayed in realtime; transcript prepared utilizing computer-aided transcription.

Eugenie M. Power, RMR, CRR, CCR
United States Court Reporter

EXHIBIT A

1 P R O C E E D I N G S

2 THE COURT: Good morning. This is a hearing in United
3 States v. Patrick Chan. Let the record reflect that Dr. Chan is
4 here with his attorney, Mr. James Wyatt, and the government is
5 represented by Ms. Karen Whatley.
6 Ms. Whatley, would you introduce to the Court the people at
7 your table.
8 MS. WHATLEY: Yes, Your Honor. On my far right is
9 Special Agent Jill Hudson. She's with the Federal Bureau of
10 Investigation. Seated next to me is Special Agent Jeffrey
11 Hanna. He is with the Department of Health & Human Services,
12 Office of the Inspector General.
13 THE COURT: I apologize for not remembering them, but
14 I don't remember too well sometimes. It's been a long time.
15 I would like for Dr. Chan to come forward with Mr. Wyatt,
16 and the clerk will swear Dr. Chan.
17 But while they're doing that, I am really warm in here.
18 Are you all just about to roast?
19 MS. WHATLEY: It is kind of hot.
20 THE COURT: Let's ask someone to adjust the
21 temperature in here to make it cooler.
22 COURT SECURITY OFFICER: Yes, ma'am.
23 PATRICK CHAN, DEFENDANT, DULY SWORN
24 THE COURT: Dr. Chan, do you understand that you need
25 to answer my questions truthfully or you could later be

1 prosecuted for perjury or making a false statement, because you
2 are under oath?
3 THE DEFENDANT: Yes.
4 THE COURT: Are you currently under the influence of
5 any drugs or medicine?
6 THE DEFENDANT: No.
7 THE COURT: Mr. Wyatt, do you believe Dr. Chan is
8 competent to proceed?
9 MR. WYATT: I do, Your Honor.
10 THE COURT: He looks competent to me, and I believe he
11 is competent, and I so find, so we will proceed.
12 Dr. Chan, please state your full name.
13 THE DEFENDANT: Patrick D. S. Chan.
14 THE COURT: How old are you?
15 THE DEFENDANT: Forty-three.
16 THE COURT: And tell me about your education. How far
17 did you go in school? I think I know, but tell us for the
18 record.
19 THE DEFENDANT: I got my M.D. degree, medical degree,
20 and I completed specialty training in neurosurgery.
21 THE COURT: All right. Have you received a copy of
22 the indictment that's pending against you?
23 THE DEFENDANT: Yes, Your Honor.
24 THE COURT: And have you fully discussed this matter
25 and the prospect of entering a guilty plea with your lawyers?

1 THE DEFENDANT: Yes, Your Honor.
2 THE COURT: Are you fully satisfied with your
3 attorneys' advice?
4 THE DEFENDANT: Yes.
5 MR. WYATT: Your Honor, if I could just interject.
6 Mr. John Hall is also counsel of record in this matter, but had
7 an emergency hearing in Heber Springs this morning, and that is
8 why he is not present. But he has conferred with us on this as
9 well.
10 THE COURT: That's why I hesitated before I said "Mr.
11 Wyatt," and I just said "your lawyers." I should say that Mr.
12 Hall remains an attorney of record in this case.
13 MR. WYATT: Yes, ma'am.
14 THE COURT: Are you fully satisfied with the advice
15 that your lawyers have given you?
16 THE DEFENDANT: Yes, Your Honor.
17 THE COURT: I know that there has been a plea
18 agreement, and I want Ms. Whatley to describe the terms of the
19 agreement to the Court.
20 Dr. Chan, listen carefully, because I'm going to ask you
21 some questions about it.
22 MS. WHATLEY: Yes, Your Honor.
23 The plea agreement in this case is the basic plea agreement
24 which is normally filed by the U.S. Attorney's Office for the
25 Eastern District of Arkansas. In this plea agreement, Dr. Chan

1 agrees to plead guilty to Count 4 of the pending indictment.
2 Upon his guilty plea and the Court's acceptance of that plea,
3 the United States will move to dismiss Counts 1 through 3 of the
4 indictment.
5 The elements of the crime are listed in paragraph 2, and
6 the defendant has agreed that he's guilty of the offense.
7 The statutory penalties are not more than five years'
8 imprisonment, a fine of not more than $25,000, or both, and not
9 more than three years of supervised release.
10 There's a cooperation agreement, as set forth in the plea
11 agreement, as well as the cooperation during sentencing.
12 The stipulation is set forth as a base offense level of six
13 and that the amount of the loss is $31,000. We have agreed that
14 Dr. Chan should not receive any Chapter 3 adjustments, either
15 aggravating or mitigating, with the exception of the acceptance
16 of responsibility two-level decrease.
17 The rest of the plea agreement just states how the
18 sentencing guidelines work, that we do reserve the right to
19 bring any information to the Court's attention. He understands
20 he has to pay a fine, unless the Court determines he is unable
21 to pay a fine. The special penalty assessment in this case will
22 be $100. There's a cost of investigation of $23,000 that should
23 be returned to the Federal Bureau of Investigation.
24 And those are the main parts of this plea agreement, Your
25 Honor.

1 THE COURT: Dr. Chan, you've heard what Ms. Whatley
2 has said about the terms of the plea agreement. Is what she
3 said substantially correct?
4 THE DEFENDANT: Yes, Your Honor.
5 THE COURT: Has anyone made any other or different
6 promise or assurance to you to get you to plead guilty?
7 THE DEFENDANT: No, Your Honor.
8 THE COURT: Has anyone tried to force you to plead
9 guilty?
10 THE DEFENDANT: No, Your Honor.
11 THE COURT: Do you understand that this offense is a
12 felony?
13 THE DEFENDANT: Yes, Your Honor.
14 THE COURT: And that if the guilty plea is accepted,
15 you will be adjudged guilty, just as if a jury had found you
16 guilty beyond a reasonable doubt?
17 THE DEFENDANT: Yes, Your Honor.
18 THE COURT: And do you understand that this
19 adjudication may deprive you of valuable civil rights, such as
20 the right to vote, the right to hold public office, the right to
21 serve on a jury, and the right to possess any kind of firearm?
22 THE DEFENDANT: Yes, Your Honor.
23 THE COURT: Do you understand that you have a right to
24 plead not guilty, and if you do that, the government must prove
25 beyond a reasonable doubt that you committed the offenses

1 alleged in the indictment?
2 THE DEFENDANT: Yes, Your Honor.
3 THE COURT: And you would have the right to an
4 attorney and to a trial by jury?
5 THE DEFENDANT: Yes, Your Honor.
6 THE COURT: And you would have the right to
7 cross-examine witnesses against you and to call witnesses in
8 your own behalf?
9 THE DEFENDANT: Yes, Your Honor.
10 THE COURT: And you would not be required to testify
11 against yourself?
12 THE DEFENDANT: Yes, Your Honor.
13 THE COURT: Do you understand that by entering a plea
14 of guilty, that if the plea is accepted by the Court, there will
15 be no trial because you will have waived or given up your right
16 to a trial as well as the other rights associated with a trial
17 that I just described?
18 THE DEFENDANT: Yes, Your Honor.
19 THE COURT: Some of this has already been in the plea
20 agreement, but I'm going to review it again. Do you understand
21 that Count 4 charges you with receiving and/or soliciting
22 illegal remuneration, and that the maximum term of imprisonment
23 for this offense is five years?
24 THE DEFENDANT: Yes, Your Honor.
25 THE COURT: And the maximum fine is -- this says

1 $25,000. Is it 250- or is it 25-?
2 MS. WHATLEY: It, actually, is 25,000. I went back
3 and checked a couple of times because it didn't seem right to me
4 either.
5 THE COURT: You understand the maximum fine is $25,000
6 for this offense?
7 THE DEFENDANT: Yes, Your Honor.
8 THE COURT: You understand the Court could both
9 sentence you to a term of imprisonment and fine you?
10 THE DEFENDANT: Yes, Your Honor.
11 THE COURT: Do you also understand that if you're
12 sentenced to prison, your sentence will also include a term of
13 supervised release following imprisonment?
14 THE DEFENDANT: Yes.
15 THE COURT: And if this happens and you violate the
16 terms of your supervised release, the Court could revoke
17 supervised release and sentence you to more time in prison?
18 THE DEFENDANT: Yes, Your Honor.
19 THE COURT: If this is the case, your term of
20 imprisonment either alone or in conjunction with the supervised
21 release could exceed the statutory maximum of five years?
22 THE DEFENDANT: Yes.
23 THE COURT: Do you understand that you must also pay a
24 one-hundred-dollar special assessment?
25 THE DEFENDANT: Yes, Your Honor.

1 THE COURT: And you must also pay -- I believe that we
2 could even call it the restitution, as outlined in the plea
3 agreement -- pay the government for the costs of its
4 investigation?
5 THE DEFENDANT: Yes, Your Honor.
6 THE COURT: And will there be any other restitution
7 that the government asks for with respect to this sentencing?
8 MS. WHATLEY: No, Your Honor.
9 THE COURT: And will there be any forfeitures with
10 respect to this sentencing?
11 MS. WHATLEY: No, Your Honor.
12 THE COURT: Thank you.
13 Do you understand all of the possible consequences of this
14 plea?
15 THE DEFENDANT: Yes, Your Honor.
16 THE COURT: Do you have any questions for me with
17 respect to what I just went over with respect to the possibility
18 of a term of imprisonment, supervised release, a fine, and
19 special assessment, and the restitution?
20 THE DEFENDANT: No, Your Honor.
21 THE COURT: Under the Sentencing Reform Act of 1984,
22 the United States has sentencing guidelines that judges must
23 consider in determining the sentence in a criminal case. Do you
24 understand that the Court will not be able to determine your
25 guideline sentence until after the presentence report has been

1 written?
2 THE DEFENDANT: Yes, Your Honor.
3 THE COURT: Do you understand that I am not a party to
4 the plea agreement that you have with the government?
5 THE DEFENDANT: Can you repeat the question?
6 THE COURT: I am not -- the court and the judge are
7 not parties to this plea agreement that you have signed with the
8 government.
9 THE DEFENDANT: Yes, Your Honor.
10 THE COURT: And I am not bound by what is in that
11 agreement.
12 THE DEFENDANT: Yes, Your Honor.
13 THE COURT: And do you understand that I will have to
14 calculate, through the presentence report, what your guideline
15 sentence is?
16 THE DEFENDANT: Yes, Your Honor.
17 THE COURT: Do you understand that after it has been
18 determined what guideline applies in your case, the judge has
19 authority to impose a sentence that is either more severe or
20 less severe than that called for by the guidelines?
21 THE DEFENDANT: Yes, Your Honor.
22 THE COURT: Do you understand that under some
23 circumstances, you may have the right to appeal the sentence I
24 impose?
25 THE DEFENDANT: Yes, Your Honor.

1 THE COURT: And do you understand the government could
2 also appeal the sentence I impose?
3 THE DEFENDANT: Yes, Your Honor.
4 THE COURT: Do you understand that parole has been
5 abolished, and if you're sentenced to prison, you won't be
6 released on parole?
7 THE DEFENDANT: Yes, Your Honor.
8 THE COURT: Do you understand that if the sentence is
9 more severe than you expect, you will still be bound by the
10 guilty plea and will have no right to withdraw it?
11 THE DEFENDANT: Yes, Your Honor.
12 THE COURT: All right. Ms. Whatley, I want you to
13 state what you would be prepared to prove at trial with respect
14 to Count 4 of the indictment.
15 And, Dr. Chan, please listen carefully.
16 Go on, Ms. Whatley.
17 MS. WHATLEY: Yes, Your Honor.
18 With respect to Count 4 of the indictment, the United
19 States would prove that during the relevant time periods,
20 Dr. Chan was a neurosurgeon who practiced in Searcy, Arkansas.
21 He performed surgeries on a large number of patients, including
22 Medicare and Medicaid patients. These surgeries were performed
23 at Central Arkansas Hospital, as well as White County Medical
24 Center. Sometime in the middle of all this, White County
25 Medical Center bought out Central Arkansas Hospital, so a lot of

1 the records would be from White County.
2 The United States would prove that in July of 2006, a
3 medical sales representative was interviewed by agents of the
4 FBI and HHS/OIG. During that interview, she revealed that she
5 had been paying Dr. Chan part of her commissions for a time
6 period.
7 The agreement had been that she would split any commission
8 with him, less any amount necessary for the payment of taxes, on
9 all products that the defendant utilized during his surgeries
10 and after his surgeries.
11 This representative sold products on behalf of four
12 different companies; Osteotech, Orthofix, Alphatec, and Signus.
13 After she met with the agents, she agreed to cooperate with the
14 investigation and stated that she owed Dr. Chan some money. She
15 then made controlled deliveries, three controlled deliveries of
16 monies, and the monies were provided by the Federal Bureau of
17 Investigation. The dates of the deliveries were July 31, 2006;
18 September 5, 2006; and September 13, 2006. The September 13
19 date is the date which is at issue and the basis for Count 4.
20 The deliveries were videotaped and audiotaped, and Dr. Chan is
21 seen taking the money, putting it in his desk drawer, without
22 any questions.
23 The defendant was arrested after the last delivery on
24 September 13, 2006. A federal search warrant was obtained, his
25 vehicle was searched. The $8,000 that had been given to him

1 that day was located under the driver's seat of his vehicle.
2 The total paid Dr. Chan through the undercover part of the
3 investigation was $31,000, of which the United States has
4 recovered 8,000. Medicare and Medicaid are federal healthcare
5 benefit programs.
6 THE COURT: Dr. Chan, you've heard what Ms. Whatley
7 states she could prove at trial. She's described your conduct.
8 Is what she stated substantially correct?
9 (Mr. Wyatt confers with defendant.)
10 THE DEFENDANT: Yes, Your Honor.
11 THE COURT: How do you plead to Count 4, guilty or not
12 guilty?
13 THE DEFENDANT: Guilty.
14 THE COURT: I accept your guilty plea because I find
15 that you actually committed this offense as charged in the
16 indictment. I further find that you're entering your guilty
17 plea voluntarily with full knowledge of the consequences.
18 And now, Ms. Whatley, I'll permit you to ask the Court to
19 dismiss the other three counts against Dr. Chan.
20 MS. WHATLEY: The United States so moves, Your Honor.
21 THE COURT: Counts 1, 2, and 3 are hereby dismissed in
22 accordance with the rules of criminal procedure.
23 Now I'll refer Dr. Chan to the Probation Office for the
24 presentence interview. You have the right to have your lawyer,
25 Mr. Wyatt, or Mr. Hall, with you during that interview. I don't

1 know whether you're going to have an interview immediately after
2 this hearing or not, but you may, if that is what you all agree
3 to. Keep in mind again, you have the right to counsel during
4 the presentence interview.
5 I will not set a sentencing date at this time. I will wait
6 until after the presentence report has been completed and both
7 Dr. Chan and the government have had an opportunity to work out
8 any differences or disputes they might have before we come
9 together for the formal sentencing hearing, at which time I can
10 work out -- I mean, I will make findings with respect to any
11 other disputes.
12 I know that Dr. Chan is on bond right now, and I want to
13 ask Ms. Whatley what is her position with respect to his bond.
14 MS. WHATLEY: We request that he remain on the same
15 conditions as previously set by Judge Ray.
16 THE COURT: All right. We will do that, if that's
17 suitable. He has, I believe, performed well.
18 MR. WYATT: Yes, Your Honor.
19 THE COURT: Dr. Chan, I'm making no changes to your
20 bond. The conditions that were previously set will remain in
21 place. We will notify your lawyers of the sentencing date.
22 What will happen is the clerk will telephone them and they'll
23 try to agree. I mean, we'll all agree on a good date. It will
24 probably be sometime after 45 days from today. In other words,
25 it won't be in the next month. It will be, typically, 45 to 60

1 days after today.
2 MR. WYATT: I've explained to Dr. Chan the typical
3 situation with that, and he understands that.
4 THE COURT: Sure. And, of course, both of your
5 lawyers are very experienced lawyers and they can answer your
6 questions about that. But do you have any questions for the
7 Court at this time?
8 THE DEFENDANT: No, Your Honor.
9 THE COURT: Anything more, Mr. Wyatt?
10 MR. WYATT: Not this morning, Your Honor.
11 THE COURT: Anything more, Ms. Whatley?
12 MS. WHATLEY: No, Your Honor.
13 THE COURT: Thank you very much. You're excused.
14 MR. WYATT: Thank you, Your Honor.
15 (Whereupon, the hearing concluded at 11:15 a.m.)
16 C E R T I F I C A T E
17 I, Eugenie M. Power, Official Court Reporter, do hereby
18 certify that the foregoing is a true and correct transcript of
19 proceedings in the above-entitled case.
20
21
22
23 _____ Date: January 5, 2008
Eugenie M. Power, RMR, CRR, CCR
24 United States Court Reporter
25

FILED
U.S. DISTRICT COURT
EASTERN DISTRICT ARKANSAS
OCT 04 2006
JAMES W. McCORMACK, CLERK
By: DEP CLERK

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS

UNITED STATES OF AMERICA

v.

PATRICK CHAN

4:06CR00344 SWW

42 U.S.C. § 1320a-7b

INDICTMENT

THE GRAND JURY CHARGES:

COUNT ONE

A. At all times material to this Indictment:

1. PATRICK CHAN was a neurosurgeon licensed to practice in the State of Arkansas whose office was located at 1120 South Main Street, Searcy, Arkansas.

2. Osteotech, Orthofix, Alphatec, and Signus were medical supply companies that produced and sold medical equipment used during and after neurosurgery. The companies utilized a distributor known to the Grand Jury who sold the products for use during and after PATRICK CHAN's surgeries. The distributor received a commission for each product sold.

3. The Medicare Program (Medicare) is a federal program that provides free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. Medicare is administered by the Centers for Medicare and Medicaid Services, an agency of the United States Department of Health and Human Services. Medicare is a Federal health care program within the meaning of 42 U.S.C. § 1320a-7b(f).

4. The Arkansas Medicaid Program (Medicaid) is a joint federal and state program that provides necessary medical services to eligible persons who are not able to pay for such services. Medicaid is administered by the Centers for Medicare and Medicaid Services, an agency of the United States Department of Health and Human Services. The federal government funds 75% of the Medicaid money and the state funds 25%. The Arkansas Medicaid Program is a Federal health care program within the meaning of 42 U.S.C. § 1320a-7b(f).

5. PATRICK CHAN was a Medicare and Medicaid provider who performed surgeries on Medicare and Medicaid patients.

6. In or about late 2002 or early 2003, the exact date being unknown to the Grand Jury, PATRICK CHAN began using Orthofix products and requested that he receive part of the commission. The distributor initially advised that this was not an option.

7. In or about late 2003 or early 2004, the exact date being unknown to the Grand Jury, PATRICK CHAN again asked about the possibility of receiving payment in exchange for using the products. PATRICK CHAN stated that he wanted to receive cash. At that time, the distributor and PATRICK CHAN agreed that PATRICK CHAN would receive 50% of all commissions the distributor earned from sales generated due to PATRICK CHAN's surgeries less any amount necessary for tax purposes.

8. In or about January 2004, the exact date being unknown to the Grand Jury, the first payment of $3,000 cash was made to PATRICK CHAN.

9. From in or about January 2004 until on or about June 28, 2006, PATRICK CHAN continued to receive a portion of the distributor's commissions. Most payments were approximately $7,000 or $8,000 per month, although the amount would vary depending on the number of products used or prescribed by PATRICK CHAN.

B. From in or about January 2004 through on or about June 28, 2006 in the Eastern District of Arkansas,

PATRICK CHAN

knowingly and willfully solicited and received any remuneration, including any kickback and bribe directly and indirectly, overtly and covertly, in cash and in kind in return for purchasing, leasing, ordering and arranging for and recommending purchasing, leasing, and ordering any good, facility, service, and item for which payment may be made in whole and in part under a Federal health care program.

All in violation of Title 42, United States Code, Section 1320a-7b(b)(1)(B).

COUNT TWO

A. The Grand Jury re-alleges and incorporates by reference paragraphs A1 - A9 of Count One of this Indictment.

B. On or about July 31, 2006, in the Eastern District of Arkansas,

PATRICK CHAN

knowingly and willfully solicited and received any remuneration, including any kickback and bribe directly and indirectly, overtly and covertly, in cash and in kind in return for purchasing, leasing, ordering and arranging for and recommending purchasing, leasing, and ordering any good, facility, service, and item for which payment may be made in whole and in part under a Federal health care program.

All in violation of Title 42, United States Code, Section 1320a-7b(b)(1)(B).

COUNT THREE

A. The Grand Jury re-alleges and incorporates by reference paragraphs A1 - A9 of Count One of this Indictment.

B. On or about September 5, 2006, in the Eastern District of Arkansas,

PATRICK CHAN

knowingly and willfully solicited and received any remuneration, including any kickback and bribe directly and indirectly, overtly and covertly, in cash and in kind in return for purchasing, leasing, ordering and arranging for and recommending purchasing, leasing, and ordering any good, facility, service, and item for which payment may be made in whole and in part under a Federal

health care program.

All in violation of Title 42, United States Code, Section 1320a-7b(b)(1)(B).

COUNT FOUR

A. The Grand Jury re-alleges and incorporates by reference paragraphs A1 - A9 of Count One of this Indictment.

B. On or about September 13, 2006, in the Eastern District of Arkansas,

PATRICK CHAN

knowingly and willfully solicited and received any remuneration, including any kickback and bribe directly and indirectly, overtly and covertly, in cash and in kind in return for purchasing, leasing, ordering and arranging for and recommending purchasing, leasing, and ordering any good, facility, service, and item for which payment may be made in whole and in part under a Federal health care program.

All in violation of Title 42, United States Code, Section 1320a-7b(b)(1)(B).

(END OF TEXT. SIGNATURE PAGE ATTACHED.)

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March 11, 2008

The Honorable Herb Kohl
Chairman, United States Senate Special Committee on Aging
Washington, DC 20510-6400
(202)224.5364

Re: **North American Spine Society** (NASS) Response to February 27, 2008 Hearing, *"Surgeons for Sale? Conflicts and Consultant Payments in the Medical Device Industry."*

Dear Senator Kohl,

First, I would like to thank you for the leadership you have shown in further bringing to light the issue of financial conflicts of interest in the medical device industry. NASS appreciates being given the opportunity to comment on the record in relation to the hearing held on February 27. I hope that sharing NASS' experience in dealing with these issues will be helpful to the Committee in your continuing efforts.

We first adopted our "Acceptance of Appointment and Covenant to Disclose" document, requiring all those in leadership or committee positions to disclose all conflicts before serving, in 1996. Promoting the highest ethical standards for spine physicians in every aspect of the society has been something of a passion among NASS leadership since 2001, when Stanley A. Herring, MD chose Ethics as the centerpiece of his NASS presidential efforts. From the creation of the Professional Conduct and Ethics Committee in 2002, to the implementation of a comprehensive disclosure policy in March 2006, to the current effort to expand and strengthen all of our existing policies, we have a legacy of providing spine professionals with strong, clear guidance on ethical practices.

We take this issue very seriously: NASS has implemented some of the most stringent obligations for disclosure among professional medical organizations. Participants in any NASS activity (educator, principle investigator, author, committee member, member of the Board of Directors or Executive Committee) are obligated to identify the entities with whom they have relationships and to specifically categorize remuneration, both by type and a designation of either "major" or "minor" (above or below $10,000). This policy was adopted in March 2006 by an ad hoc Task Force specifically appointed by the Board, involving months of research into not only the nature of consulting relationships but the science of bias and the study of policies of other organizations such as the Mayo Clinic. It has more recently become apparent that more specific documentation of these relationships is needed, and the Professional Conduct & Ethics Committee is in the process of preparing specific recommendations regarding policy modifications for the Board of Directors, including more specificity in regard to remuneration amounts. We anticipate that our policy will continue to evolve over time as NASS, governmental agencies and commercial entities work collaboratively towards the common goal of transparency and accountability for the common good of patients, healthcare entities and society.

During the Aging Committee's hearing, Gregory E. Demske, Assistant Inspector general for Legal Affairs at the Office of the Inspector General of the Department of Health and Human Services, said, "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." Mr. Demske's statement echoes the research presented by NASS member Sohail Mirza, MD at the 2007 NASS Annual Meeting in Austin, during the Ethics Symposium. We would be happy to provide you with a link and member password to access the video of this presentation—as well as the rest of the 2007 Ethics Symposium—on our website if you would like to view it in its entirety.

The future of medical innovation—including cures for diseases and conditions from which many of our patients suffer—is contingent upon collaboration between physicians and industry. The scarcity of medical research funding by government requires that funding arise from other sources. Products are developed specifically to improve patient outcomes, and physicians have a moral responsibility to ensure that products in development are thoroughly researched and tested. A recent study in the journal *Spine* evaluates the views of 245 patients given a one-page, eight-question survey in the waiting room of an orthopedic surgery clinic: "An overwhelming majority (94.3%) believed that the surgeon-industry relationship is beneficial to patients, and a majority (66.5%) of patients thought physicians should be compensated for this role."[1] In his analysis of this study, reviewer Paul M. Arnold MD, FACS observes, "It is also evident that there are 'extremes' in doctor-manufacturer relationships, and it is these abuses that seem to tarnish the vast majority of legitimate consulting deals. If surgeon-driven innovation is to continue, then open, honest, and transparent industry-physician relationships will be the only way for this to occur."

In addition to continuing to revise and strengthen NASS' current Conflict of Interest Disclosure policy, we are also currently undertaking two projects related to ethics and industry relationships. The first is a Roundtable on Ethics in Spine Industry Relations, which will bring together leaders from device manufacturers of all sizes with NASS physician leadership and ethicists to collaborate on the creation of a new Code of Ethics for Industry that addresses such issues. Such a Code would apply to companies both large and small, as well as physicians (supplementing the existing Code of Ethics for members). Second, our Socioeconomic Affairs Council is hosting a forum for industry leaders and physicians, to discuss the socioeconomic issues and forces shaping spine care today. Part of the proposed curriculum for this forum will educate industry on how to participate in collaboration in numerous arenas—including coding, reimbursement issues, research, etc—while maintaining the highest degree of professionalism and ethics for both the manufacturers and the physicians involved. What we strive to do, instead, is to provide clear direction to both our members and to industry for how to collaborate with the highest degree of ethical behavior and professionalism.

The education of both physicians and industry is foremost in our strategy to encourage proper relationships. To that end, we have conducted General Session Ethics Symposia at our Annual Meeting for the past three years to educate our members on the proper way to collaborate with industry. In 2006, the symposia included an overview of the NY Times articles referenced in your hearing, and educated NASS members on the issues involved, including case studies and commentary from a professional ethicist, Wilton Bunch, MD. In 2007, the symposium provided an in-depth look at the moral, ethical and legal implications of relationships with the device industry, including research on the science of bias presented by Dr. Mirza; and a "pop quiz" using an audience response system, whereby audience members in this general session symposium were presented with scenarios for industry interaction and asked to judge whether the interaction was legal and—a higher bar—ethical. There was considerable confusion among a portion of the audience about where to draw the line to

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[1] Khan MH, Lee JY, Rihn JA, et al. "The Surgeon as a Consultant for Medical Device Manufacturers: What Do our Patients Think?" *Spine*. 2007;32(23):2616-2618.

maintain a completely ethical relationship. After responses were tabulated, Peter Winn, Assistant U.S. Attorney, Western District of Washington, gave his perspective on each case study. After Mr. Winn spoke, the audience voted again on whether they thought that each case was legal and ethical. Results clearly showed that audience members brought away from the symposium a measurable improvement in their acuity in judging the appropriateness of physician/industry relationships. This reveals that education is continually needed in this arena. At the end of the symposium, individual members clamored to ask questions of the panel about specific consulting arrangements that they had either seen or been approached to enter into: our members are hungry for guidance on how to conduct themselves, yet most medical schools, fellowships and residency programs omit education on this subject. This is a key role for professional societies.

While certainly the larger device manufacturers have been the subject of much of the recent attention, we feel it would be both unfair and unwise to require disclosure of relationships *only* from companies with revenues of over $100 million. Start-ups should be held to just as high a standard as the larger, more established companies. If such disclosures are required from the start, as a company grows, it is more likely that good ethical practices will become part of the culture of that organization. It is a global culture of ethical behavior, industry-wide, that should be the ultimate goal.

We applaud the Senate Special Committee on Aging for inquiring into this important matter. We look forward to working with the Committee as you continue to examine this issue and would appreciate the opportunity to provide testimony at any future hearings on physician disclosure. Please do not hesitate to let us know if there is anything further we can do to assist you in your efforts.

Sincerely,

Thomas Faciszewski, MD
President, North American Spine Society

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